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Weight Management Telehealth Intervention for Overweight and Obese Rural Cardiac Rehabilitation Participants: A Randomized Trial

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Abstract

Aims and Objectives: To determine if a weight management intervention (WMI) plus cardiac rehabilitation (CR) compared to CR alone improves outcomes for overweight and obese cardiac revascularization patients.

Background: Despite participating in cardiac rehabilitation (CR), few cardiac patients lose enough weight to achieve clinically significant cardiovascular disease risk reduction.

Design: A randomized controlled design was used with measurements at baseline, 4 and 6 months; guided by the CONSORT checklist, see Supplementary File 1. Adults who had undergone either coronary artery bypass surgery (CABS) or percutaneous coronary intervention (PCI) and participated in a rural CR programs were recruited. Subjects were randomized to a 12-week telehealth WMI or control group. The primary outcome was weight loss. Secondary outcomes included physical activity, patient activation, perceived self-efficacy and use of weight management behaviors.

Results: 43 subjects participated, with a mean age of 63 (+/- 9.3) years. The WMI group had significantly more weight loss averaged across the 4 and 6 months of 13.8 (+/- 2.8) pounds compared to the control group [Mean = 7.8 (+/- 2.2) pounds]. There were no significant differences in physical activity (activity counts, or daily minutes in moderate or more intense activity). The WMI group had significantly higher levels of patient activation. They also had

significantly higher total scores on the Diet and Exercise Self-Management survey; and subscales that included self-efficacy for specific eating habits and managing diet behavior.

Conclusions: Findings demonstrated the usefulness and feasibility of using telehealth delivery of the WMI for cardiac rehabilitation participants in rural communities to improve weight management outcomes.

Relevance to Practice: Study findings underscore the opportunity to further improve weight loss of overweight and obese cardiac participants using a weight management intervention to augment CR participation.

Keywords

Cardiac Rehabilitation; Cardiac Revascularization; Coronary Artery Bypass Surgery; Percutaneous Coronary Intervention; Weight Loss; Weight Management Overweight and Obese Cardiac Patients; rural communities

INTRODUCTION

Cardiac rehabilitation (CR) is the recommended “gold” standard to reduce cardiovascular disease (CVD) secondary risk factors (Hamm et al., 2011; Smith et al., 2011). However, overweight or obese patients often fail to lose enough weight to significantly reduce their CVD risk by CR participation alone (P. A. Ades, Savage, & Harvey-Berino, 2010; Artinian et al., 2010; Gallagher et al., 2012). This is a critical problem since overweight and obese patients comprise 80% and 40% of CR participants respectively (P. A. Ades et al., 2010). Few CR participants have significant weight changes, most have only small weight changes (Gomadam et al., 2016; Manzoni et al., 2011; McKee, Kerins, Fitzgerald, Spain, & Morrison, 2013) and some gain weight during CR (Gomadam et al., 2016). Rural dwelling cardiac patients are at further risk, given the higher propensity of obesity of rural residents (Befort, Nazir, & Perri, 2012; Trivedi, Liu, Probst, & Martin, 2013).

This study was conducted to determine if a telehealth weight management intervention (WMI) plus CR compared to CR alone improves outcomes for overweight and obese cardiac revascularization patients [coronary artery bypass surgery (CABS) and percutaneous coronary intervention (PCI)] in rural communities.

BACKGROUND

National evidence-based guidelines (Hamm et al., 2011; Smith et al., 2011), from the American Heart Association, American College of Cardiology and Association of Cardiovascular and Pulmonary Rehabilitation recommend weight loss counseling and education for overweight or obese cardiac patients as a part of comprehensive CR. A weight loss of 5–10% weight loss is necessary to achieve clinically significant CVD risk reduction (P. A. Ades et al., 2010; Manzoni et al., 2011; Wing et al., 2011). However, typically weight loss interventions are not included in CR (P. A. Ades et al., 2010; P. A. Ades & Savage, 2017). Although CR participants receive standard nutritional consultations, they are not specific to behavioral weight loss intervention. Typically, CR participants only lose 2% of

their body weight (P. A. Ades & Savage, 2017). These small weight losses are not usually sustained after CR (Magalhaes et al., 2013).

Few studies have examined weight loss interventions used in conjunction with standard CR. Overweight participants (n=27) in a nurse-led intervention focused on daily caloric goals, exercise and behavioral modification had significantly ($<.001$) greater weight loss than CR only participants (n=55); mean weight loss was 4.3 ± 2.8 kg compared to 1.7 ± 2.6 kg (P. D. Savage, Lee, Harvey-Berino, Brochu, & Ades, 2002). Overweight CR participants (n=49) who participated in behavioral weight loss sessions, lost significantly ($p<.001$) more weight (8.1 ± 4.4 vs. 3.6 ± 4.4 kg) (P. D. Savage, Lakoski, & Ades, 2013). Similarly, in a 12-week behavioral weight loss program following CR completion (Aggarwal et al., 2012), overweight and obese participants (N=44) had significant weight losses.

Other researchers focused on use of intense exercise to promote weight loss. When CR participants engaged in a 4-week intensive CR that included exercise 3 hours per day for 5.5 days/week, they had statistically significant weight losses of 3% (Duarte Freitas et al., 2011). Overweight cardiac patients (N=74) in a high caloric expenditure exercise program had twice the weight loss compared to the CR only group (P. A. Ades et al., 2009).

Only a limited number of weight management interventions for CR participants have been delivered by telehealth. Participants in a CVD risk reduction program (INTERxVent®), delivered by either telephone- or internet, had significantly more weight loss than the CR only group (average of 4.5 ± 8.4 vs 2.3 ± 5.1 pounds) (Gordon et al., 2001). In a web-based program for CAD patients, that included CR participants, participants had a significantly ($p<.003$) greater weight loss (average of 3.7 vs. 0.47 pounds) (Southard, Southard, & Nuckolls, 2003). Overweight cardiac patients in CR randomized to a pedometer-based telephone coaching program had greater weight loss than the physical activity only group (Sangster et al., 2015). Although these studies demonstrated effectiveness, weight losses achieved by participants were not sustained and/or did not reach weight loss of clinical significance.

This study addresses a critical gap between current cardiac rehabilitation programs and evidence-based recommendations to promote weight management as a secondary CVD risk factor. The purpose of this study was to test a weight management intervention (WMI) to augment weight outcomes of overweight and obese CR participants. Specific aims of this study were to:

1. Determine whether overweight and obese CR participants in the telehealth WMI group differed from a control group (CR only) on weight outcomes (weight loss and physical activity behaviors) over time at 4 and 6 months after cardiac revascularization.
2. Examine the differences in weight management perceptions (patient activation, self-efficacy and use of weight loss strategies) of overweight and obese CR participants in the WMI and control groups at 4 months after cardiac revascularization.

3. Examine feasibility of implementing a WMI for CR participants (treatment delivery, treatment receipt and treatment enactment).

METHODS

Design

This clinical trial used a repeated measures experimental design to examine the impact of a 12-week telehealth WMI on weight loss outcomes (weight loss and physical activity) and weight management perceptions (patient activation, self-efficacy and weight management behaviors) were examined. This study was guided by the CONSORT checklist (Schulz, Altman, & Moher, 2010), see Supplementary File 1. This study specifically targeted cardiac patients residing in rural settings given their higher CVD risk and propensity of obesity (Befort et al., 2012; Trivedi et al., 2013). Both the control and WMI groups participated in a CR program in a rural community following PCI or CABS at a tertiary medical center. All CR programs, including CR programs in this study, provide care based on national standards set forth by the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) (R. J. Thomas et al., 2010; R. J. Thomas et al., 2018). The 12-week WMI was initiated within 2-weeks after cardiac revascularization. Outcomes for weight loss and physical activity were measured at 4-months and 6-months after cardiac revascularization. At 4-months after cardiac revascularization, perceptions of patient activation, self-efficacy for diet modification and the activity, and diet modification behaviors were measured.

The sample size for this study was based on recommended pilot study sampling (Hertzog, 2008). Estimates with a sample of 25 per group would provide precision of ± 0.03 to ± 0.07 at a 68% level of confidence. Forty-three participants completed this study, 22 in the WMI group and 21 in the control group; a final sample well within the 20–40 range considered to be adequate (Kieser & Wassmer, 1996).

Subjects were recruited from two Midwestern tertiary hospitals. Overweight (BMI > 25 to < 30 kg/m²) or obese (BMI > 30 kg/m² and <50 kg/m²) CABS or PCI subjects were screened by the research nurse; only four potential subjects declined participation in the study. Refer to Figure 1 for recruitment and retention. Additional inclusion criteria included the ability to speak and read English, available land-line telephone service at home to accommodate use of the Viterion® telehealth device to deliver the telehealth WMI, no cognitive impairment (score of ≥ 8 on the Short-Portable Mental Status Questionnaire) and referral to a CR program in a rural community.

Weight Outcome Measures

Weight loss was measured by BMI and weight change. CR nurses used standardized protocols to obtain weight each data collection time. Weight measures were obtained by CR nurse on calibrated scale at subjects' CR site. Standardized waist measurements obtained based on placement of tape measure using anatomical placement.

Physical activity behavior was measured by using a triaxial accelerometer, the Actigraph® (model GT3X), with documented reliability and validity for activity measurement (Matthews, 2005). Average daily activity counts based on vector magnitude from all three

axes and average daily minutes spent in moderate or higher intensity activity were analyzed. The latter was estimated using the cutpoints recommended by Freedson, Melanson, & Sirard (Freedson, Melanson, & Sirard, 1998). Subjects were instructed on device use related to physical activity and asked to wear the device 24 hours a day for a 7-day time period at 4 and 6 months after PCI or CABS. Data were analyzed only if a participant wore the device for a minimum of 3 days, 10 hours per day during a given collection period.

Managing Weight Loss

Subjects' perceptions of managing weight loss were collected at 4 months after PCI or CABS when subjects had completed both outpatient CR and the WMI. Perceptions of self-efficacy and patient activation were important to examine usefulness of the underlying mechanisms of the WMI (Bandura, 2004; Bandura, 2005).

Patient activation was measured using the patient activation measure (PAM), with 13-items measuring knowledge, skill and confidence for self-management of health or chronic conditions (Hibbard, Stockard, Mahoney, & Tusler, 2004; Hibbard, Mahoney, Stockard, & Tusler, 2005). The PAM has been used in a variety of cardiac and other populations and has reported reliability and validity (Hibbard et al., 2005; Shively et al., 2005). Cronbach's alpha for the PAM score in this study was .88.

Self-efficacy for diet behavior modification was measured with the Heart Healthy Eating Self-Efficacy (HHESE) scale, with 43 items using a 1- to 6-point scale; higher scores indicate higher perceived confidence in diet modification. HHESE subscales included self-efficacy for heart-healthy eating habits, situations that may influence eating behaviors and positive outcomes that may result from heart healthy eating (Gaughan, 2003). The HHESE has satisfactory internal consistency and test-retest reliability (Gaughan, 2003). Cronbach's alphas for the HHESE subscales in this study were .96, .87 and .82 respectively.

Self-Efficacy for exercise was measured using the Cardiac Exercise Self-Efficacy instrument (CESEI), with 16 items using a 5-point response scale measuring perceived exercise behavior confidence. Higher scores indicate greater self-efficacy. The tool has documented internal consistency and reliability; with established predictive and factorial validity (Hickey, Owen, & Froman, 1992). The CESI total score Cronbach's alpha was .85 in this study.

Use of weight management strategies by participants was measured using the Diet and Exercise Self-Management tool, with documented validity and reliability (Nothwehr & Peterson, 2005; Nothwehr, Dennis, & Haotong Wu, 2007). A 1 to 4--response scale is used for each item, with higher scores indicating use of an increased number of weight management strategies for: diet self-monitoring, food planning, food preparation, portion control, diet management in social interactions, cognitive strategies for diet behaviors, activity self-monitoring, social interaction activity and cognitive strategies for activity behaviors. Cronbach's alphas for the total scale in this study was .94; and the nine subscales ranged from .46 – .89.

Data Collection

After institutional review board approval, hospital staff screened cardiac revascularization patients for inclusion criteria. All subjects were enrolled prior to hospital discharge by the research nurse and gave written informed consent prior to randomization to WMI or control groups. Demographic and clinical questionnaires were completed. Within a 2-week period prior to start of study, all subjects wore an Actigraph® for 7 days between hospital discharge and start of CR. All subjects had their baseline and subsequent 4- and 6-month weight obtained by the CR nurse using a standardized measurement protocol. At 4 and 6 months, subjects wore the Actigraph® for a 7-day period. At 4 months, subjects completed the PAM, HHESE, CESEI, and the Diet and Exercise Self-Management tools.

Subjects received the usual care for post-cardiac revascularization that included participation in a comprehensive CR program. Overweight and obese CR participants received usual education and counseling to manage elevated BMI as a secondary CAD risk factor.

Subjects in the treatment group received the WMI plus CR. The WMI was based on Social Cognitive Theory (SCT)(Bandura, 2004) concepts that posit behavioral change is supported if patients perceived self-efficacy for behavioral change is high. Self-efficacy enhancing interventions for weight management are related to improved modification and maintenance of diet behavior changes (Burke, Dunbar-Jacob, Sereika, & Ewart, 2003). The WMI focused on self-care self-efficacy (judgment regarding capabilities to implement action for weight management) and self-care consequences (benefits and barriers) for weight loss.

WMI Education component.—The WMI was implemented within 2 weeks after PCI or CABS. The research nurse provided the subject with a WMI packet at time of enrollment. The WMI education component included written target caloric goals [recommended total kcal/day for weight loss] and diet portion guidelines. Total daily caloric goals (recommended total kcal/day or caloric reduction for weight loss of each subject) was determined by estimating the daily calories needed to maintain the subject's baseline weight and subtracting 500–1000 calories/day to achieve a 1 to 2-pound weight loss per week. The WMI also received a handbook for use of portion control guidelines. When the WMI was initiated, the research nurse had a scheduled telephone meeting to review the protocol and review the specifics of the subject's target caloric goal and use of portion control strategy.

WMI Skill component.—This included a 6-week telehealth component delivered by the Viterion® device, that included 6 modules with 36 telehealth sessions (daily sessions for 3 weeks and 5 sessions per week for the remaining 3 weeks) modeled after the Diabetes Prevention Program (DDP) (DPP Res Grp, 2002). The DDP has previously been successfully adapted for weight loss management (Ma et al., 2013).

WMI Telephone Coaching component.—Telephone coaching sessions were delivered by the research nurse at week 9 and 12. Coaching sessions corresponded with completion of CR, or when subjects completed the majority of the outpatient CR sessions. Coaching sessions(Barrone, Maddux, & Synder, 1997) focused on self-monitoring, self-evaluation and self-regulation for weight reduction behaviors.

Analysis

Repeated measures analysis of covariance (RM-ANCOVA) was used to examine weight management outcomes for weight loss with the corresponding baseline measurement used as a covariate. Physical activity outcomes at 4 and 6 months were analyzed using repeated measures analysis of variance (RM-ANOVA). In addition, to evaluate the components of the intervention, group means in perception of managing weight loss (patient activation, self-efficacy for exercise and diet, and use of weight loss strategies) at 4 months after PCI or CABS were compared using one-way ANOVAs. In all analyses, effect sizes were estimated using η^2 (ANOVA) or partial η^2 (RM-ANOVA or RM-ANCOVA). Values of .01, .06, and .14 were interpreted as small, medium, or large effects (Cohen, 1988).

Descriptive statistics and open-ended subject responses were summarized to examine the WMI feasibility for treatment delivery, treatment receipt and treatment enactment.

As this study was designed to be a pilot study, we did not expect statistical tests to be significant at conventional alpha levels. We will report p-values and highlight those which are significant at $\alpha=.05$, but patterns of means and effect sizes also will be discussed.

RESULTS

Participants in the study (N=43) ranged in age from 47–81 years, with a mean age of 63 ± 9.3 years. There were 30 males (70%) and 13 females (30%); 33 had undergone a PCI procedure and 10 had CABS. Most subjects were married (86%, n=37) and had an average of 12.9 ± 1.8 years of formal education; 56% (n=24) of the subjects worked outside of the home and 35% were retired. Subjects' mean body mass index (BMI) was $35.1 (\pm 5.5)$, ranging from 26.1–54.7. Subjects participated in CR programs in rural communities. All subjects completed outpatient CR; they attended an average of $22 (\pm 3.4)$ phase 2 CR sessions. There were no significant differences in baseline demographic or clinical characteristics by group, using chi-square and Fisher's exact test, refer to Table 1. Data collection occurred over an 18-month period to accommodate study follow-up periods (4- and 6-months) as well as feasibility follow-up to subject at 9- and 12-months after cardiac revascularization.

Weight Management Outcomes

Descriptive statistics by group and results of statistical tests of group differences are presented, see Table 2 and 3. For analyses of weight loss outcomes, the only effect significant at the .05 level was the group comparison of weight change from baseline. For the WMI group, the weight loss averaged across 4 and 6 months (the marginal group mean, adjusted for baseline weight) was 13.7 pounds. This was significantly greater than the 8 pounds average weight loss of the control group. This weight change differences represents a medium-to-large effect (partial $\eta^2=.09$). Expressed as percentage of baseline weight, the WMI group had an average loss of 5.9%, while the control group, on average, lost 3.6% of their baseline weight. Although the pattern of means favored the WMI group on BMI, group effects on these outcomes were small (partial η^2 of .02 - .05) and non-significant.

All participants were asked to wear the Actigraph® for 24 hours per day for 7 days at month 4 and month 6. Of the 16 participants with data at both times, the number of days worn at each time ranged from 3–6 (mean=3.7) in the WMI group (n=22) and from 3–7 (mean=4.8) in the control group (n=21). There were no significant effects in the RM-ANOVA on either activity counts (vector magnitude) or daily minutes of moderate or more intense activity. Descriptively, the WMI group was more active at both 4 and 6 months. At 6 months, the WMI group, on average, spent almost twice the average minutes per day in moderate or more intense levels of activity compared to the control group (24.0 minutes compared to 14.2 minutes, respectively). Group effects were in the moderate range ($\eta^2 = .04 - .07$).

Weight Management Perceptions

Descriptive statistics and results of the ANOVAs for comparing the WMI and control groups at 4 months on the tools measuring perceptions of managing weight loss management are summarized on Table 4. Perceptions of subjects' patient activation for managing their own healthcare, as measured by the PAM at 4 months, demonstrated a significant group difference ($F(1,38)=5.3, p=.02$). The WMI group had higher activation scores than control subjects (64.7 ± 9.0 vs. 58.4 ± 8.3); and a medium-to-large effect size of $\eta^2=.12$.

There were also significant differences between the groups on two of three self-efficacy health heart eating subscales. Participants in WMI had significantly higher perceived self-efficacy for specific eating habits [$F(1,36)=12.6, p=.001$] and managing diet behavior in different situations [$F(1,36)=8.6, p=.006$]; both had large effect sizes (η^2 ranging from .19 –.26).

The CESI measured self-efficacy for exercise, or the perceptions of confidence to engage in exercise behaviors as recommended for cardiac patient. There was no significant differences between groups, although the estimated effect size was in the moderate range ($\eta^2=.06$).

Use of weight management strategies demonstrated the WMI group had a statistically significantly higher overall total mean score [$F(1,38)=10.7, p=.002$], with a large effect size ($\eta^2=.22$). Five weight management strategy use subscales of monitoring diet, planning diet, preparing and buying food and portion control were significantly higher among WMI group. Analysis of the remaining four subscales were not significantly different by group, although moderate effect sizes were estimated for group differences in cognitive strategies used related to diet ($\eta^2=.06$) and cognitive ($\eta^2=.08$) and social interaction strategies related to activity ($\eta^2=.06$).

Feasibility

All WMI participants (100%) received one-to-one education on the target caloric goals [recommended total kcal/day for weight loss for each individual participant] and written copy of diet portion guidelines. Treatment delivered was measured by the number of intervention sessions delivered by the Viterion® and treatment receipt was the number of WMI sessions accessed by the participants. Four of the 22 WMI subjects (18%) completed < 5 sessions (e.g., less than one week) of the telehealth component. Of the remaining subjects, 8 subjects (36%) completed all 36 sessions; and 10 of (46%) completed from 30–36 sessions. Telephone coaching for the WMI subjects was delivered, with the 2 telephone

coaching sessions delivered during week 9 and week 12 of the intervention. All subjects (100%) received and participated in the coaching sessions of the intervention, average telephone coaching sessions were from 10–15 minutes.

Treatment enactment or the reported perception of usefulness of the strategies and participant satisfaction with intervention (satisfaction with the mode of delivery, satisfaction with content of intervention, satisfaction with helpfulness of sessions—both telehealth sessions and virtual coaching) was evaluated at 9- and 12-months after their cardiac event. At 9 months after their cardiac event, 11 subjects in the WMI group were able to be contacted by telephone and provided a self-report of their weight. Of these subjects, comparing their reported weight to their 6-month weight, six had further weight loss; while four had maintained their weight and one had gained weight. In the control group, 10 subjects were contacted and reported their weight. In comparison to their 6-month weight, two subjects had lost weight; while five subjects weighed the same and three subjects gained weight.

At 12 months after their cardiac event, 21 subjects in the WMI group were able to be contacted and provided a self-report of their weight. Comparing their reported weight to their 6-month weight, 10 had further weight loss; while nine had maintained their weight and two had gained weight. In the control group, 13 subjects were contacted and provided their weight. Subjects' reported weights were compared to their 6-month weight. Three had lost weight; while eight subjects weighed the same and two had gained weight.

Subjects in the WMI group were queried about their satisfaction at 9-months; WMI subjects (n=11) had a mean satisfaction score of 6.19 ± 1.8 on a 0–10 scale (a higher score indicates higher satisfaction) for the weight management intervention. At 12-months, WMI participants (n=21) had a mean satisfaction score of 6.3 ± 1.9 .

Participants were also asked about their perceptions regarding the length of the WMI. At 9-months (n=11), 4 subjects indicated the intervention was “too long”, 1 subject thought it was “too short” and 6 subjects thought it was “just about right” in length. At 12-months (n=21), 14 subjects thought the intervention was “too long”, one subject reported the intervention to be “too short” and six subjects reported their perception as length of intervention being “just right”. During the 9- and 12-month follow-up session of subjects in the pilot study, open ended questions were used to elicit feedback on perceived strategies being used to manage weight. The feedback indicated that the most frequently cited strategies were: use of portion control with dietary intake, mindfulness of what one is eating, making diet intake focus a priority daily, engaging in activity that is more physical and/or exercise.

DISCUSSION

Findings from this study further inform cardiac rehabilitation research examining interventions to augment cardiac patients' weight loss outcomes as recommended by experts (P. A. Ades et al., 2010). This concept is not unlike providing a formal program for smoking cessation (p.2679) as a core component of CR programs (Balady et al., 2007). Delivering a WMI in conjunction with CR for cardiac patients in this study was found to be both feasible

to deliver and implement; and useful for the rural WMI participants. Use of the telehealth WMI standardized the intervention implementation and did not rely on delivery of the WMI by the CR staff. Nor did the intervention require additional travel to the CR program site to participate in this WMI program.

The increased weight loss by the WMI group is consistent with other studies that reported greater weight loss when interventions were implemented in conjunction with CR (P. A. Ades et al., 2009; Duarte Freitas et al., 2011; Jiang, Sit, & Wong, 2007; Magalhaes et al., 2013). However, like other WMI studies, the weight losses were modest. Furthermore, sustained weight loss associated with the WMI used in this study is unknown given the limited follow-up of subjects in this pilot study.

Subjects in the study had significantly higher patient activation, self-efficacy for diet behaviors and use of weight management strategies by the WMI group, with large effect sizes. These findings support the importance of patient engagement to activate behavior change (Dietz et al., 2015) and improve self-efficacy for self-management that may be useful in future studies to modify the intervention for greater effect size.

Study limitations constrain the generalizability to the larger population of overweight and obese patients in CR, as the sample size was small (N=43), with subjects recruited from two Midwestern, tertiary hospitals. In this pilot study, the perceptions of managing weight loss (patient activation, self-efficacy for diet and physical activity and uses of cognitive behavioral strategies for weight management) were measured only one-time coinciding with completion of the telehealth intervention. Furthermore, the study sample was not ethnically or economically diverse. Physical activity, measured by the Actigraph®, and the measurement of weight were the only objectively measured outcome variables; all other measures were based on participants' self-report.

CONCLUSIONS

In summary, the implementation of a telehealth WMI intervention in conjunction with CR provided a simple, effective approach to augment weight loss. This study demonstrated the feasibility of implementing a specific WMI program component for CR participants that could be implemented in conjunction with standard CR in response to the national guidelines to use behavioral interventions to promote adherence and self-management skills in weight management (P. A. Ades et al., 2010; Hamm et al., 2011). Furthermore, the use of telehealth delivery of the WMI provides access to the intervention by CR participants regardless of location in urban or rural communities. Further study is warranted, using a fully powered study to evaluate the efficacy of using a WMI integrated in CR programs. Efficacious weight management programs should be disseminated and implemented into CR as a standard approach to improve weight loss outcomes for overweight and obese cardiac patients.

RELEVANCE TO CLINICAL PRACTICE

Given the paucity of research evidence on managing weight as a modifiable cardiac risk factor for CR participants, this study demonstrates the feasibility of integrating a WMI for

overweight and obese cardiac patients participating in CR. Use of telehealth strategies may be useful to deliver weight management interventions for cardiac patients in rural communities.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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What does this paper contribute to the wider global clinical community?

- Overweight and obese cardiac patients often fail to lose enough weight in cardiac rehabilitation to clinically reduce their cardiac risk.
- Strategies to support weight loss, beyond standard cardiac rehabilitation components are needed to attain clinically significant weight loss.
- The WMI used in this study is an exemplar of types of interventions that may be useful with further study to augment weight loss outcomes of overweight and obese cardiac rehabilitation participants.

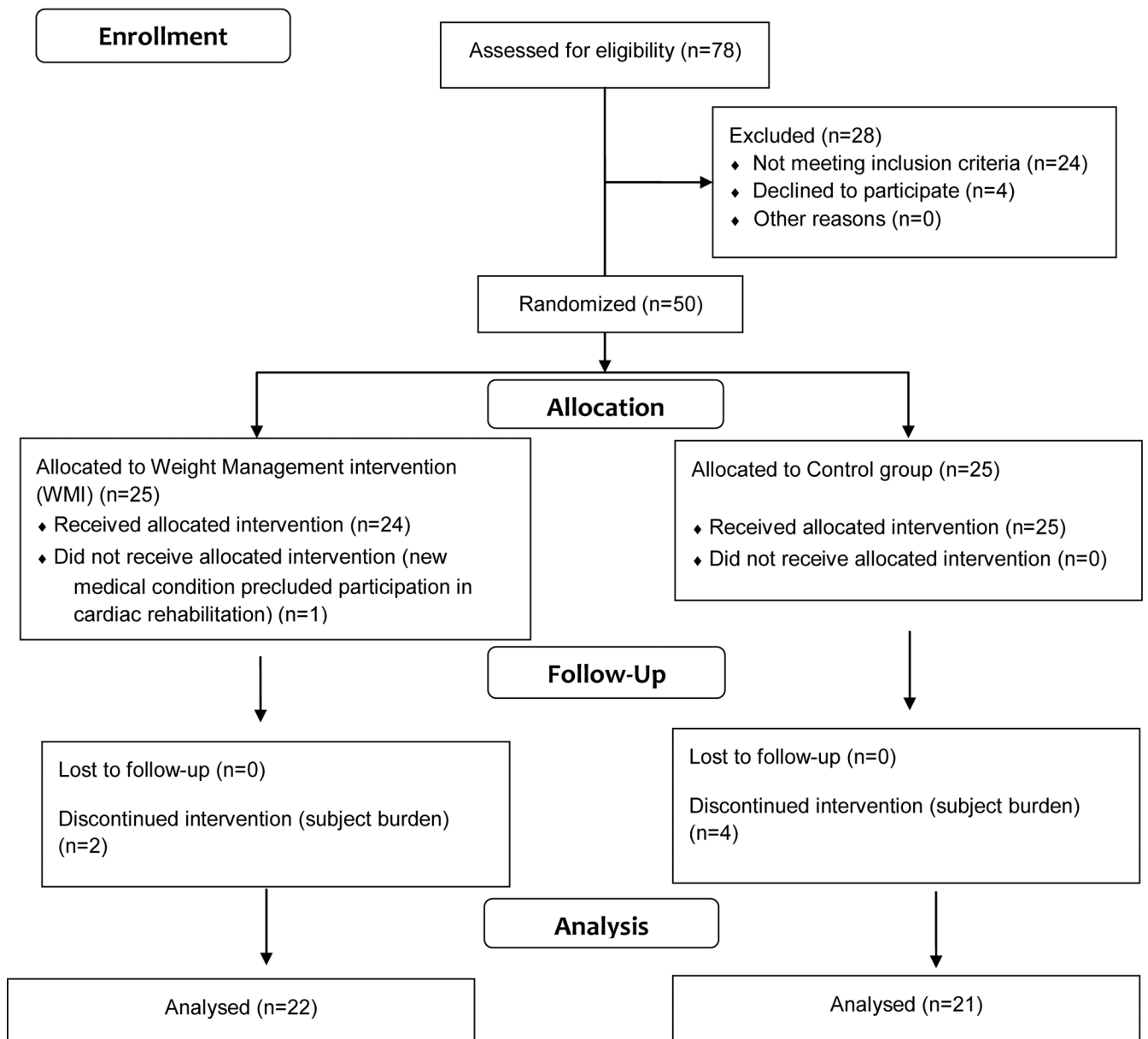


Figure 1.
Subject Recruitment and Randomization

Table 1.

Demographic and Clinical Characteristics of Study Sample (N = 43)

Variable	Total Sample N=43 (%)	Weight Management Intervention (WMI) Group n (%)	Control Group n (%)	Sig
Gender				
Male	30 (70)	17 (77)	13 (62)	
Female	13 (30)	5 (23)	8 (38)	$\chi^2 = .273$
Marital Status				
Married	37 (86)	20 (91)	17 (81)	
Not Married (single, widowed, or divorced)	6 (14)	2 (9)	4 (19)	Fisher Exact test $p = .412$
Employment Status				
Currently working	24 (56)	14 (64)	10 (48)	
Not currently working or retired	19 (44)	8 (36)	11 (52)	$\chi^2 = .290$
Cardiac Revascularization				
PCI	33 (77)	16 (73)	17 (81)	
CABS	10 (23)	6 (27)	4 (19)	$\chi^2 = .721$

Table 2.

Mean Scores for Weight Management Outcomes

Group	Sample n	Means (SD) Baseline	Means (SD) 4-month	Means (SD) 6-Months
Body Mass Index (BMI) (Mean BMI)				
WMI	20	37.6 (6.0)	35.8 (6.0)	35.2 (6.0)
Control	21	32.8 (4.0)	31.8 (3.9)	31.3 (4.1)
Weight Change (# of Pounds)				
WMI	20	242.8 (38.0) ^a	-11.9 (7.0)	-15.8 (9.7)
Control	21	217.7 (35.9) ^a	-6.2 (7.9)	-9.3 (11.4)
Physical Activity (Actigraph®): Vector Magnitude (Mean # counts/day)				
WMI	6	-----	432703 (206537)	513696 (217882)
Control	10	-----	395739 (96960)	387911 (164664)
Physical Activity (Actigraph®): Moderate or More Intense Level of Activity (Mean # minutes/day)				
WMI	6	-----	14.4 (16.1)	24.0 (34.1)
Control	10	-----	11.0 (7.9)	14.2 (19.4)

^aBaseline weight in pounds was used as a covariate in analysis of weight change outcome.

Table 3.

Weight Management Outcomes over Time

ANCOVA with Repeated Measures for Weight Management Outcomes: BMI, Waist Measurement, Weight Change, and Diet Behavior with Baseline Measures as Covariates									
Variable	Group			Time			Group * Time		
	F (df)	p	η_p^2	F (df)	p	η_p^2	F (df)	p	η_p^2
BMI	1.9 (1,38)	.18	.05	.06 (1,38)	.81	<.01	.00 (1,38)	.99	<.01
Weight Change from baseline to 4 months and baseline to 6 months	4.0 (1,38)	.05*	.09	.45 (1,38)	.51	.01	.19 (1,38)	.67	<.01
ANOVA with Repeated Measures for Weight Management Outcomes: Physical Activity									
Variable	Group			Time			Group * Time		
	F (df)	p	η_p^2	F (df)	p	η_p^2	F (df)	p	η_p^2
Physical Activity Behavior (Actigraph®): Mean Vector Magnitude Counts	1.1 (1,14)	.32	.07	1.2 (1,14)	.29	.08	1.8 (1,14)	.21	.11
Physical Activity Behavior (Actigraph®): Mean Levels of Moderate Activity	.56 (1,14)	.47	.04	1.5 (1,14)	.25	.10	.37 (1,14)	.56	.03

Note: η_p^2 = partial eta squared

* p .05

Table 4.

Perceptions of Managing Weight Loss: Descriptive and ANOVA Analyses for PAM, HHESE scale, CESEI, and Diet and Exercise Self-Management Survey at 4-months after Cardiac Revascularization

Patient Activation Measure (PAM)					
	n	WMI Group M (SD) Control M (SD)	F (df)	p	η^2
PAM	19 21	64.7 (9.0) 58.4 (8.3)	5.3 (1,38)	.027*	.12
Heart Healthy Eating Self-Efficacy Scale (HHESE)					
Self-efficacy beliefs for specific eating habits	19 19	5.3 (.26) 4.7 (.71)	12.6 (1,36)	.001*	.26
Self-Efficacy for Situational/Environmental diet management behaviors	19 19	5.2 (.27) 4.9 (.37)	8.6 (1,36)	.006*	.19
Self-efficacy for diet management outcome expectations	19 19	4.9 (.48) 4.7 (.45)	2.1 (1,36)	.15	.06
Cardiac Exercise Self-Efficacy Index (CESEI)					
Total Mean Score	19 20	4.6 (.38) 4.4 (.29)	2.4 (1,38)	.13	.06
Diet and Exercise Self-Management Survey					
Total Mean Score	21 19	2.4 (.32) 2.1 (.28)	10.7 (1,38)	.002*	.22
Monitoring strategies: diet	21 19	2.6 (.62) 1.9 (.51)	11.3 (1,38)	.002*	.23
Planning strategies	21 19	2.4 (.37) 2.0 (.41)	9.7 (1,38)	.003*	.20
Preparation/buying food strategies	21 19	3.8 (.32) 3.3 (.45)	12.2 (1,38)	.001*	.24
Portion control strategies	21 19	3.0 (.38) 2.7 (.36)	7.8 (1,38)	.008*	.17
Social interaction strategies: diet	21 19	2.4 (.62) 2.2 (.46)	1.1 (1,38)	.30	.03
Cognitive strategies: diet	21 19	1.9 (.45) 1.7 (.46)	2.5 (1,38)	.12	.06
Monitoring strategies: activity	21 19	2.2 (.42) 2.0 (.33)	4.5 (1,38)	.04*	.11
Social interaction strategies: activity	21 19	1.8 (.43) 1.6 (.33)	2.4 (1,38)	.13	.06
Cognitive strategies: activity	21 19	1.9 (.38) 1.7 (.37)	3.2 (1,38)	.08	.08

Note: η^2 = eta squared

*
p .05