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ORIGINAL ARTICLE

Recruitment and Retention for a Weight Loss Maintenance Trial Involving Weight Loss Prior to Randomization

C. I. Voils[1,2], J. M. Grubber[1], M. A. McVay[1,3], M. K. Olsen[1,4], J. Bolton[1], J. M. Gierisch[1,2], S. S. Taylor[1], M. L. Maciejewski[1,2] and W. S. Yancy Jr.[1,2]

[1]Center for Health Services Research in Primary Care, Durham Veterans Affairs Medical Center, Durham, NC, USA; [2]Department of Medicine, Duke University Medical Center, Durham, NC, USA; [3]Department of Psychiatry, Duke University Medical Center, Durham, NC, USA; [4]Department of Biostatistics and Bioinformatics, Duke University Medical Center, Durham, NC, USA

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Address for correspondence: Corrine I. Voils, Center for Health Services Research in Primary Care, Veterans Affairs Medical Center (152), 508 Fulton St., Durham, NC 27705, USA. E-mail: corrine.voils@duke.edu

Abstract

Objective

A weight loss maintenance trial involving weight loss prior to randomization is challenging to implement due to the potential for dropout and insufficient weight loss. We examined rates and correlates of non-initiation, dropout, and insufficient weight loss during a weight loss maintenance trial.

Methods

The MAINTAIN trial involved a 16-week weight loss program followed by randomization among participants losing at least 4 kg. Psychosocial measures were administered during a screening visit. Weight was obtained at the first group session and 16 weeks later to determine eligibility for randomization.

Results

Of 573 patients who screened as eligible, 69 failed to initiate the weight loss program. In adjusted analyses, failure to initiate was associated with lower age, lack of a support person, and less encouragement for making dietary changes. Among participants who initiated, 200 dropped out, 82 lost insufficient weight, and 222 lost sufficient weight for randomization. Compared to losing sufficient weight, dropping out was associated with younger age and tobacco use, whereas losing insufficient weight was associated with non-White race and controlled motivation for physical activity.

Conclusions

Studies should be conducted to evaluate strategies to maximize recruitment and retention of subgroups that are less likely to initiate and be retained in weight loss maintenance trials.

Keywords: clinical trials, retention, recruitment, weight loss maintenance.

Introduction

Behavioral weight loss programs targeting modifications to diet and physical activity produce clinically significant weight losses.(1,2) The long-term benefits of such interventions are limited, however, as more than half of individuals return to their baseline weight in three to five years.(3–5) Accordingly, there has been an emphasis on testing weight loss maintenance interventions.(6–9)

Trial registration: ClinicalTrials.gov NCT01357551 http://clinicaltrials.gov/show/NCT01357551

To test the efficacy of weight loss maintenance interventions, at least three trial designs may be employed.(9) These designs differ in recency of initial weight loss and timing of randomization. In the first design, individuals with recent weight loss are recruited and randomized to maintenance intervention versus comparator/control. For example, Wing(8) and Sherwood(10) each recruited people who had lost at least 10% of their body weight in the past 1-2 years and randomized them at study entry. Thus, participants who receive the maintenance intervention vary in recency

and method of weight loss and education and skills training.

Some of these limitations are addressed in a second design, in which participants are recruited and randomized to receive weight loss intervention followed by maintenance intervention versus weight loss intervention followed by no further intervention, as in a study by Pekkarinen.(11) In this design, participants who expect to receive the maintenance intervention may experience the weight loss intervention differently (e.g., engage more) than those who do not expect the maintenance intervention.

These limitations are addressed in a third design, in which individuals receive a weight loss intervention and, if they lose sufficient weight, are randomized to maintenance intervention versus comparator/control. For example, in Svetkey,(6) people who lost at least 4 kg in a 6-month weight loss program were randomized. In this design, participants who receive maintenance intervention should be similar to those in comparator/control arm(s) in recency of weight loss, education, and skills.

All of these designs pose recruitment and retention challenges, including non-initiation among eligible patients and dropout subsequent to initiation. The third design may be associated with increased non-initiation and dropout if, for example, patients believe that they will not achieve the weight loss requirement. Additionally, some people will lose insufficient weight to be eligible for randomization. To allocate sufficient resources to recruitment and retention when employing this third design, it would be helpful to know where in the process dropout might occur, the extent of dropout at each step, and which individuals might be more likely to drop out. Many analyses have been conducted on rates and correlates of retention in weight loss programs,(12–14) with limited data available on factors associated with initiating an intervention. In this paper, we report on rates and correlates of non-initiation, dropout, and insufficient weight loss during the Maintenance After Initiation of Nutrition TrAINing (MAINTAIN) trial.

Methods

Setting

Participants were enrolled from the Durham Veterans Affairs Medical Center (VAMC) and associated community-based outpatient clinics. The study protocol was approved by the Durham VAMC Institutional Review Board (IRB) and Research and Development Committee and the Duke University Medical Center IRB.

Design

This report includes secondary analyses of data obtained during enrollment and the weight loss initiation phase of the MAINTAIN study, which involved a 16-week weight loss program focusing on calorie and fat restriction for all participants who met initial eligibility criteria.(15) Participants who lost at least 4 kg during the 16 weeks were eligible for randomization to the maintenance arm (42 weeks followed by 14 weeks of no intervention) or usual care arm (56 weeks).

The study was conducted in six cohorts. Each cohort was recruited over a 6 to 8-week period. Recruitment involved telephone screening followed by in-person screening. For ease of describing the study time points, we refer to in-person screening as week -17, the first group weight loss session as -16, and the time of randomization as week 0.

Screening and Recruitment

Eligibility was determined in a three-step protocol. Eligibility criteria are detailed in our protocol paper.(15) Briefly, an electronic medical record (EMR) data pull was conducted to obtain names and contact information of patients who had a body mass index (BMI) $\geq$30 kg/m^2, an assigned primary care provider, and were aged 18-75. Patients were excluded if they had unstable health (kidney or liver disease, type I diabetes, elevated blood pressure, severe psychiatric illness) or were currently enrolled in a lifestyle program.

Individuals meeting these criteria were randomly chosen to receive a recruitment letter. Patients could also self-refer in response to flyers or be referred by health care personnel via a consult option in the EMR. Interested patients called study staff for further eligibility screening. Inclusion criteria determined by telephone included BMI $\geq$30 kg/m^2; desire to lose weight; agreeing to attend visits per protocol; and access to telephone and reliable transportation. Exclusion criteria included unstable health; severe psychiatric illness; pregnancy, breastfeeding, or lack of birth control if premenopausal; previous weight loss surgery; current use of weight loss medication or appetite suppressants; weight loss of at least 10 pounds in the previous 3 months; and enrollment in lifestyle program. Eligible patients were scheduled for a screening appointment.

At the screening appointment, written informed consent was obtained. Patients completed a screening medical history to confirm BMI $\geq$30 kg/m^2. Exclusion criteria that were rechecked given the potential to change over short time periods included pregnancy, breastfeeding, or lack of birth control; enrollment in a lifestyle program;

unstable health; and weight loss ≥10 pounds in the previous 3 months. Eligible patients chose one of six meeting times for the group-based weight loss program.

To be eligible for randomization, participants had to provide a weight at week -16 (at the first group session or within one week before or after that session) and a weight at week 0, and the difference between these weights must have been ≥ 4 kg. This requirement is consistent with a recent systematic review of non-surgical maintenance interventions.(16) Based on our previous study,(17) we assumed that all eligible patients would initiate weight loss intervention and that 30% of patients who entered the weight loss initiation phase would be ineligible to be randomized into the maintenance phase. As our goal was to randomize 230 participants to maintenance intervention versus usual care, we estimated that we would need to enroll 330 patients in the weight loss initiation phase.

Procedures and Measures

During the screening telephone call, potential participants were informed that they would undergo a 16-week weight loss program that involved eight group-based visits every two weeks. They were also told that, if they successfully lost ≥4 kg during 16 weeks, they would be eligible to be randomized to the maintenance intervention or usual care for 56 weeks additional weeks. Thus, the potential involvement of each participant could be as few as 16 weeks or as many as 72 weeks. Details of the intervention have been reported.(15)

Several self-report measures were administered during the week -17 in-person screening appointments. These constructs were informed by our conceptual model that distinguishes weight loss initiation versus weight loss maintenance.(18)

Favorable expectations

Favorable expectations about future weight loss were assessed in the domains of enjoyment of food, health, physical attractiveness, fit of clothes, physical fitness, ability to complete tasks requiring physical exertion, social life, and positive feedback about weight loss.(19)

Self-efficacy

Items to assess self-efficacy to initiate behavior change (action self-efficacy) were created for dietary behavior and for physical activity following Schwarzer.(20) The 11 dietary self-efficacy items began with the stem, "I am sure I can start a low-fat diet even if…" and included endings such as "my weight doesn't improve immediately." The nine physical activity self-efficacy items began with the stem, "I am sure I can start getting regular physical activity" and included endings such as "I have to start all over again several times until I succeed."

Behavioral intentions

Intentions to change one's diet and to engage in more physical activity were assessed separately with five semantic differential items ranging from 1 to 7 (*unlikely* to *likely*; *impossible* to *possible*; *definitely would not* to *definitely would*; *no chance* to *certain*; and *probably not* to *probably*) following the methods of Azjen.(21)

Motivation to change diet and increase physical activity

The 15-item Treatment Self-Regulation for Diet questionnaire assessed the extent to which motivation for dieting is autonomous (6 items), controlled (6 items), or lacking (amotivation; 3 items).(22) The 15-item Treatment Self-Regulation for Exercise questionnaire similarly assessed source of motivation for physical activity. In the current study, the amotivation subscale from each measure was unreliable (alpha = 0.37 for the dietary measure and alpha = 0.31 for the exercise measure) so was excluded from analyses.

Social support for diet and physical activity

In a previous weight loss study involving veterans, some participants indicated that they could not complete the social support measures because they lacked a support person.(23) Accordingly, we created a gateway item to assess whether participants have a social support person ("*Do you have a friend, spouse, partner, acquaintance, coworker or other person whom you confide in regularly*?"). Participants responding affirmatively completed the 10-item Social Support and Eating Habits Survey and the 13-item Social Support for Exercise Habits Survey.(24) For each measure, participants were asked to rate items for their social network (i.e., friends and family combined). The eating habits scale has *encouragement* and *discouragement* subscales.(24) The physical activity measure has *participation and involvement* and *rewards and punishment* subscales. In this study as well as our previous, (25) the *rewards and punishment* subscale was unreliable (current alpha = 0.37) so was excluded from analyses.

Demographic and clinical measures

During the in-person screening visit at week -17, self-reported current tobacco use, race, sex, and whether

the participant has engaged in a previous weight loss attempt were assessed. Weight obtained at week -16 (time of the first group session) served as the study entry weight. Weight obtained at week 0 served as the final weight for the initiation phase and the initial weight for the maintenance phase. Weight was assessed on a calibrated digital scale in light clothing and with shoes removed. Height was assessed with a stadiometer. Weight and height were double-entered into an electronic case report form; if the two entries were discrepant, a third entry was prompted and used in analyses. Participants received $20 for the week 0 visit.

Efforts to Promote Retention

Several strategies were utilized to promote retention. To remind participants of their in-person screening appointments or outcome assessment visits, we mailed a letter one week prior and placed a reminder telephone call the night before. To remind them of their group sessions, we placed telephone calls the night before. We called and offered make-up sessions within the same week to participants who missed a group session and within the outcome window (2 weeks prior to and following the target date) to participants who missed an outcome assessment visit. Participants who withdrew (i.e., made contact with study team to indicate they would like to drop out) were asked to provide reason(s). Participants who were lost to follow-up (i.e., did not contact the team to indicate their intentions to drop out) received up to three telephone calls to re-establish contact. After three failed call attempts, we mailed a letter asking for a return call.

Analyses

To characterize the sample, means and standard deviations were calculated for continuous variables, and frequencies (N, %) were calculated for categorical variables. The outcome of failure to initiate a weight loss program was a dichotomous variable (failure to initiate vs. initiate). Unadjusted (bivariate) relationships between failure to initiate and clinical, demographic, and psychological variables were characterized with logistic regression. Variables significant ($p \leq 0.05$) in unadjusted analyses were entered simultaneously into a logistic regression model to estimate adjusted relationships. These analyses were conducted with all people who screened as eligible. When the variable representing presence of a support person was significant, the same analyses were conducted on the subset of participants who reported presence of a social support person with *encouragement* and *sabotage* for diet and *participation and involvement* in physical activity subscales entered (and the indicator for presence of social support person removed) so that the effects of social support for diet and physical activity could be assessed among those individuals.

The outcome of treatment completion and success was a three-level variable: completed and lost sufficient weight (at least 4 kg; reference group); dropped out (did not return for final outcome assessment); and completed but lost insufficient weight (<4 kg). Multinomial logistic regression was used to examine relationships between this three-level outcome and clinical, demographic, and psychological variables. As before, unadjusted analyses were conducted initially, with significant variables entered simultaneously into an adjusted model.

Results

Participants

As shown in Fig. 1, 1130 patients called in response to recruitment letters, flyers, or consults from their provider. Of those, 267 patients were ineligible, 143 refused, five asked to be held for the next cohort, and 32 were unable to be contacted after three attempts. Three ineligibility reasons accounted for the majority of patients found to be ineligible at the time of phone screen: BMI < 30 kg/m^2 (37%); enrollment in competing study (14%); and inability to attend group session (14%). The most common reason for refusal at phone screen was lack of interest (85%); other reasons included lack of time, resources or transportation; distance; and health. In-person screening appointments were scheduled for 685 patients. Of those, 573 patients were eligible and scheduled for a weight loss group meeting time. Of the 573, 69 did not initiate (i.e., provide a weight at study entry), whereas 504 did. These represent the sample sizes for analyses comparing patients who failed to initiate versus initiated. Of the 504 who initiated, 222 attended the program and lost sufficient weight to be randomized; 82 attended the program but lost insufficient weight; and 200 never returned for outcome assessments (i.e., dropped out). These represent the sample sizes for analyses comparing participants who dropped out or who lost insufficient weight to participants who lost sufficient weight.

Failure to initiate weight loss program

Table 1 displays descriptive statistics for the 573 participants who were scheduled for a weight loss group, overall (column 2) and by initiation status (columns 3 and 4). The average age was 59; there were equal numbers of

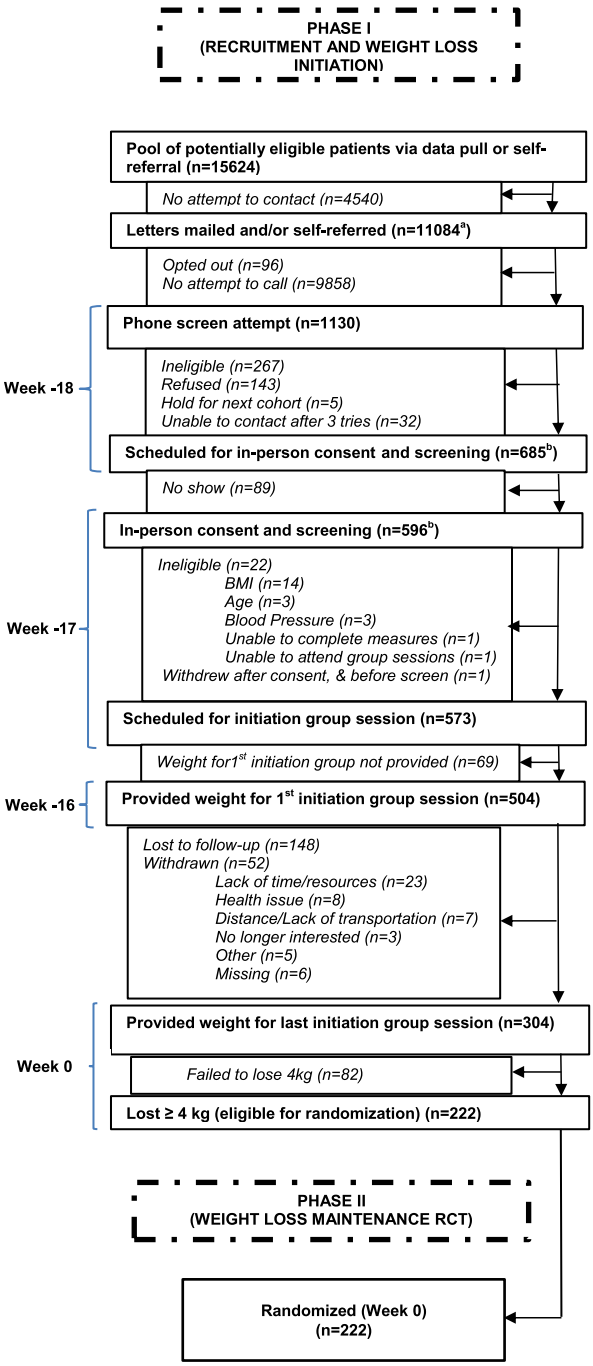

Figure 1 CONSORT Flow Diagram for Phase I of MAINTAIN Trial. Note: [a]N = 10,807 were mailed letters; n = 38 were mailed letters as well as being self-referred; n = 239 were self-referred with no letter sent [b]N = 2 of the n = 267 ineligibles at phone screen (1 due to BMI $< 30\ kg/m^2$, and 1 due to age) are included in both the "Scheduled for in-person consent and screening" and "In-person consent and screening" boxes. One was ineligible at phone screen due to BMI $< 30\ kg/m^2$, but then was erroneously re-screened in-person and excluded at that point for the same reason. The second was listed as excluded due to age > 75 at both phone and in-person screen. Both exclusions were erroneous as the patient was 75 at both time points; however, the patient was not included in study after the in-person screen.

White and Black participants; nearly one-quarter were female; nearly all had at least a high school education; and 10% were current tobacco users. Four-fifths had attempted weight loss previously, and 85% identified a support person. The mean weight at week -17 was 109 kg, mean BMI was $36\ kg/m^2$, and 45% had a BMI $\geq 35\ kg/m^2$ (i.e., class II or III obesity). Table 2 shows descriptive statistics for the psychosocial measures.

Table 1 Characteristics of Eligible Participants, Overall and by Initiation Status and Retention and Weight Loss Success at Week -17

		Initiation status		Retention and Weight Loss Success		
Characteristic	Overall (n = 573)	Did not initiate (n = 69)	Initiated (n = 504)	Dropped Out (n = 200)	Lost <4 kg (n = 82)	Lost ≥4 kg (n = 222)
Age, M(SD)	58.5 (10.3)	55.1 (11.0)	58.9 (10.1)	55.6 (11.6)	59.3 (8.3)	61.8 (8.3)
White, N(%)	273 (47.6)	28 (40.6)	245 (48.6)	84 (42.0)	32 (39.0)	129 (58.1)
Black, N(%)	273 (47.6)	36 (52.2)	237 (47.0)	107 (53.5)	47 (57.3)	83 (37.4)
Multiracial/Other, N(%)	18 (3.1)	3 (4.3)	15 (3.0)	6 (3.0)	3 (3.7)	6 (2.7)
Female, N(%)	130 (22.7)	25 (36.2)	105 (20.8)	47 (23.5)	24 (29.3)	34 (15.3)
High school graduate, N(%)	560 (97.7)	66 (95.7)	494 (98.0)	197 (98.5)	80 (97.6)	217 (97.7)
Current tobacco user, N(%)	57 (9.9)	10 (14.5)	47 (9.3)	27 (13.5)	6 (7.3)	14 (6.3)
Attempted weight loss previously, N(%)	460 (80.3)	54 (78.3)	406 (80.6)	157 (78.5)	66 (80.5)	183 (82.4)
Identify a support person, N(%)	489 (85.3)	50 (72.5)	439 (87.1)	167 (83.5)	73 (89.0)	199 (89.6)
Weight, kg, M(SD)	108.6 (19.9)	108.4 (21.1)	108.6 (19.8)	107.2 (19.5)	106.2 (18.5)	110.8 (20.3)
Body mass index, M(SD)	36.0 (5.5)	36.5 (5.2)	35.9 (5.6)	35.8 (5.4)	35.3 (5.0)	36.3 (5.9)
Body mass index ≥ 35 kg/m^2, N(%)	256 (44.7)	35 (50.7)	221 (43.8)	86 (43.0)	31 (37.8)	104 (46.8)

Abbreviations: DNI = did not initiate; DO = dropped out; L < 4 kg = lost < 4 kg; L > 4 kg = lost > 4 kg. Missing values: Race: DNI(2); DO(3); L > 4 kg(4); Sex, current tobacco use, and attempted weight loss previously: DNI(1); DO(1); L < 4 kg(1); L > 4 kg(1); high school graduate: DNI (1); L > 4 kg(1); identified a social support person: DNI(1).

Table 2 Descriptive Statistics for Psychosocial Measures at Week -17 (n = 573[a])

Measure	Possible range	Mean (Standard Deviation)	Cronbach's alpha
Favorable expectations about weight loss[b]	-4 - +4	2.5 (1.0)	.86
Self-efficacy to initiate diet	0-3	2.1 (0.4)	.90
Intentions to change diet	1-7	6.2 (0.9)	.95
Autonomous motivation for eating healthy	1-7	6.5 (0.7)	.85
Controlled motivation for eating healthy	1-7	3.6 (1.5)	.84
Encouragement for diet[c]	5-25	15.8 (5.5)	.86
Discouragement for diet[c]	5-25	11.0 (4.2)	.78
Self-efficacy to initiate physical activity	0-3	2.1 (0.5)	.93
Intentions to engage in physical activity	1-7	6.2 (1.2)	.98
Autonomous motivation for physical activity	1-7	6.5 (0.8)	.91
Controlled motivation for physical activity	1-7	3.7 (1.6)	.87
Participation in physical activity[c]	5-60	32.2 (11.9)	.93

[a]Missing values were present for 1 to 2 of the n = 573 eligible patients for each psychosocial measure in this table, unless noted otherwise.
[b]Negative numbers indicate unfavorable expectations (e.g., -4 = health *will worsen a great deal*); positive numbers indicate favorable expectations (e.g., +4 = health *will improve a great deal*).
[c]These measures were administered only to the subset of n = 489 participants who responded that they had a support person. There were no missing values for the encouragement or discouragement for diet measures, and n = 1 missing value for the participation in physical activity measure.

In unadjusted analyses (Table 3), the odds of failing to initiate decreased as age increased (OR (10-unit increase) 0.71, 95% CI: 0.57, 0.90), were greater among females than males (OR 2.19, CI: 1.28, 3.75), and were higher among participants reporting lack of a support person (OR 2.43, CI 1.34, 4.42). After adjustment, the associations remained significant for age (OR (10-unit increase) 0.74, CI: 0.57, 0.96) and lack of support person (OR 2.37, CI: 1.28, 4.38), whereas the association with female sex was no longer significant (OR 1.65, CI: 0.91, 2.98).

Among the subset of participants reporting a support person (n = 489), the odds of failing to initiate decreased with age (OR (10-unit increase) 0.65, CI 0.50, 0.84), were greater among females (2.84, CI: 1.53, 5.24), and decreased as encouragement for making dietary changes increased (OR: 0.94, CI: 0.89, 0.99). After adjustment, the associations remained significant for age (OR (10-unit increase) 0.73, CI: 0.54, 0.99), female sex (OR 2.19, CI: 1.10, 4.39), and encouragement for making dietary changes (OR 0.94, CI: 0.89, 1.00).

Table 3 Unadjusted and Adjusted Odds of Failure to Initiate a Weight Loss Program by Demographic, Clinical, and Psychosocial Factors, Overall and within Subset Having a Support Person

	All participants (n = 573)		Subset of participants with support person (n = 489)	
Characteristic	Unadjusted Odds Ratio (95% Confidence Interval)	Adjusted Odds Ratio (95% Confidence Interval)[a]	Unadjusted Odds Ratio (95% Confidence Interval)	Adjusted Odds Ratio (95% Confidence Interval)[a]
Age (10-unit increase)	**0.71 (0.57, 0.90)**	**0.74 (0.57, 0.96)**	**0.65 (0.50, 0.84)**	**0.73 (0.54, 0.99)**
Weight (kg) at in-person screen (Week -17)	1.00 (0.99, 1.01)		1.00 (0.99, 1.02)	
Non-white vs. White	1.35 (0.81, 2.27)		1.09 (0.60, 1.96)	
Female	**2.19 (1.28, 3.75)**	1.65 (0.91, 2.98)	**2.84 (1.53, 5.24)**	**2.19 (1.10, 4.39)**
< High School Graduate vs High School Graduate	1.66 (0.35, 7.87)		1.99 (0.42, 9.46)	
Current tobacco user	0.60 (0.29, 1.25)		0.62 (0.26, 1.47)	
Past weight loss attempted	1.11 (0.59, 2.08)		0.70 (0.31, 1.62)	
Lack of support person	**2.43 (1.34, 4.42)**	**2.37 (1.28, 4.38)**	n/a	n/a
Favorable expectations about weight loss	1.05 (0.81, 1.36)		0.97 (0.72, 1.31)	
Self-efficacy to initiate diet	0.94 (0.51, 1.75)		1.10 (0.54, 2.24)	
Intentions to change diet	0.87 (0.66, 1.15)		0.87 (0.62, 1.20)	
Autonomous motivation for eating healthy	0.88 (0.61, 1.27)		0.82 (0.55, 1.23)	
Controlled motivation for eating healthy	0.91 (0.77, 1.08)		0.87 (0.72, 1.05)	
Encouragement for making dietary changes[b]	n/a		**0.94 (0.89, 0.99)**	**0.94 (0.89, 1.00)**
Discouragement for making dietary changes[b]	n/a		1.02 (0.95, 1.09)	
Self-efficacy to initiate physical activity	1.10 (0.65, 1.87)		1.18(0.64, 2.18)	
Intentions to engage in physical activity	0.92 (0.76, 1.13)		0.93 (0.74, 1.18)	
Autonomous motivation for physical activity	1.06 (0.76, 1.48)		1.07 (0.73, 1.56)	
Controlled motivation for physical activity	0.92 (0.79, 1.13)		0.87 (0.72, 1.05)	
Participation in physical activity[b]	n/a		1.00 (0.97, 1.02)	

[a]Adjusted model included only those characteristics significant at the $\alpha = 0.05$ level of significance in unadjusted analyses.
[b]These measures were assessed only among the subset of n = 489 participants who responded that they had a support person.

Dropping out and losing insufficient weight

The last three columns of Table 1 show descriptive statistics for the 504 participants who initiated the intervention (i.e., provided a week -16 weight) by retention and weight loss success; they are nearly identical to 573 patients who screened as eligible.

Table 4 shows the unadjusted and adjusted odds of dropping out and losing insufficient weight by demographic, clinical, and psychological factors. In unadjusted analyses, the odds of dropping out compared to losing sufficient weight decreased as age increased (OR (10-unit increase) 0.52, CI: 0.42, 0.65) and were greater among participants of non-White race (OR 1.95, CI: 1.32, 2.88), females (OR 1.70, CI: 1.04, 2.78), and current tobacco users (OR 2.32, CI: 1.18, 4.57). In adjusted analyses, the relationships remained significant with age (OR (10-unit increase) 0.56, CI: 0.44, 0.72) and tobacco use (OR 2.29, CI: 1.14, 4.60) but were no longer significant for race (OR 1.48, 0.97, 2.26) and sex (OR 1.04, CI: 0.59, 1.81).

In unadjusted analyses, the odds of losing insufficient weight decreased with age (OR (10-unit increase) 0.74, CI: 0.56, 0.98) and with controlled motivation for physical activity (OR 0.81, CI: 0.69, 0.96) but were greater among participants of non-White race (OR 2.26, CI: 1.35, 3.81) and females (OR 2.32, CI: 1.27, 4.23). In adjusted analyses, the odds remained significant for non-White race (OR 1.95, CI: 1.12, 3.39) and controlled

Table 4 Unadjusted and Adjusted Odds of Dropping Out of a Weight Loss Program or Losing Insufficient Weight, by Demographic, Clinical, and Psychosocial Factors

	Dropping Out of Weight Loss Program(n = 200)		Losing Insufficient Weight(n = 82)	
Characteristic	Unadjusted Odds Ratio (95% Confidence Interval)	Adjusted Odds Ratio (95% Confidence Interval)[a]	Unadjusted Odds Ratio (95% Confidence Interval)	Adjusted Odds Ratio(95% Confidence Interval)[a]
Age (10-unit increase)	**0.52 (0.42, 0.65)**	**0.56 (0.44, 0.72)**	**0.74 (0.56, 0.98)**	0.95 (0.69, 1.31)
Weight (kg) at 1st Group Session (Week -16)	0.99 (0.98, 1.00)		0.99 (0.98, 1.00)	
Non-white vs. White race	**1.95 (1.32, 2.88)**	1.48 (0.97, 2.26)	**2.26 (1.35, 3.81)**	**1.95 (1.12, 3.39)**
Female	**1.70 (1.04, 2.78)**	1.04 (0.59, 1.81)	**2.32 (1.27, 4.23)**	1.88 (0.95, 3.69)
< High School Graduate vs High School Graduate	0.83 (0.18, 3.74)		1.36 (0.24, 7.55)	
Current tobacco user	**2.32 (1.18, 4.57)**	**2.29 (1.14, 4.60)**	1.18 (0.44, 3.19)	1.15 (0.42, 3.16)
Past weight loss attempted	1.29 (0.79, 2.10)		1.09 (0.57, 2.12)	
Lack of support person	1.71 (0.97, 3.03)		1.07 (0.47, 2.41)	
Favorable expectations about weight loss	1.15 (0.95, 1.40)		1.12 (0.86, 1.45)	
Self-efficacy to initiate diet	0.80 (0.50, 1.28)		1.14 (0.62, 2.08)	
Intentions to change diet	0.89 (0.71, 1.11)		0.80 (0.60, 1.07)	
Autonomous motivation for eating healthy	0.93 (0.70, 1.25)		0.94 (0.64, 1.39)	
Controlled motivation for eating healthy	0.88, (0.78, 1.00)		0.85 (0.72, 1.01)	
Self-efficacy to initiate physical activity	1.11 (0.75, 1.65)		0.66 (0.39, 1.12)	
Intentions to engage in physical activity	1.16 (0.98, 1.38)		1.09 (0.87, 1.35)	
Autonomous motivation for physical activity	1.16 (0.90, 1.50)		0.85 (0.65, 1.12)	
Controlled motivation for physical activity	0.91 (0.81, 1.03)	0.96 (0.84, 1.09)	**0.81 (0.69, 0.96)**	**0.84 (0.71, 0.99)**

[a]Adjusted model includes only those characteristics statistically significant at the $\alpha = 0.05$ level of significance in unadjusted analyses.

motivation (OR 0.84, 0.71, 0.99) but were no longer significant for age (OR 0.95, CI: 0.69, 1.31) or sex (OR 1.88, 0.95, 3.69).

Discussion

Weight loss maintenance trials that involve an initial intervention for all eligible patients followed by randomization of participants who meet some threshold of success pose unique design and logistical challenges. Understanding these challenges can lead to more accurate sample size calculations, timelines, and budgets as well as provide information on generalizability of study findings. Understanding characteristics of individuals who show initial interest but dropout prior to or after the first treatment session may also improve our ability to improve initiation and retention in weight loss programs in research and community settings where programs are generally underutilized, such as the VA's MOVE! program.(26,27)

In our trial, 12% (69 of 573) individuals who screened as eligible for the weight loss program failed to initiate it. The association of failure to initiate with younger age may reflect that younger people have less flexible schedules. Most of our group-based weight loss sessions occurred on weekdays during business hours. Younger individuals may also have responsibilities (e.g., employment, care for children or parents) that make them less likely to focus on self-care. That younger adults were less likely to initiate the program is concerning given that younger adults experience more rapid weight gain than older adults, and weight gain during early adulthood is associated with greater coronary artery calcification and mortality risk than weight gain during later years.(28,29) Moreover, younger adults are less likely to enroll in lifestyle trials and have, in many studies, been more likely to drop out.(14,30) This may be because, in younger compared to older adults, appearance is a strong motivator for weight loss, and downstream obesity-related outcomes are less salient.(31) Indeed, the need for effective

weight loss strategies in younger adults was the impetus behind the National Heart Lung, and Blood Institute's Early Adult Reduction of Weight through Lifestyle Intervention trials, which sought to promote weight loss and/or prevent weight gain among adults aged 18-35.

Failure to initiate was also more prevalent among females, which may seem surprising given that males tend to be underrepresented in weight loss interventions in many settings.(10) Users of the Veterans Affairs healthcare system are predominantly male.(32) As weight is tied to self-esteem and sexuality, particularly in severely obese individuals,(33) the issue may not be one of women versus men being more motivated to enter weight loss programs, but, rather, that both sexes prefer more homogenous groups. Female veterans may prefer all-female groups given their shared experiences and high prevalence of psychological comorbidities.(34)

The odds of failing to initiate the weight loss program were also higher among people who lacked a social support person and, among enrollees with a support person, failure to initiate was associated with less encouragement for making dietary changes. Eating behaviors are influenced by the immediate social context, and lack of support can sabotage dietary change.(35) Conversely, social support is an oft-cited benefit of group-based interventions.(36) In future studies, strategies should be identified to enhance support, such as emphasizing the support that can be gained from participating in an intervention with similar others. It is interesting that support was not associated with attrition. Support received in the intervention setting (i.e., from the interventionist or other group members) may have been enough to overcome lack of support from family members, friends, or acquaintances.

Among participants who initiated the weight loss intervention, only 40% (222 of 504) lost sufficient weight to be eligible for randomization in the maintenance phase. This rate is lower than the 60% rate observed in Svetkey, which had an identical design, and may be explained by differences in the populations and shorter duration of our weight loss program (four versus six months).(6) Just as younger age increased the odds of failing to initiate our weight loss program, younger age increased the odds of dropping out and of losing insufficient weight. Recruitment and retention efforts might be enhanced by offering group sessions in the evenings or weekends to accommodate individuals with typical work schedules and offering childcare to participants with childcare responsibilities. We were only able offer two evening sessions during this trial and observed high attendance at those sessions.

The odds of dropping out and losing insufficient weight were also greater among participants of non-white race (primarily Black). This finding is consistent with Svetkey's trial, in which Blacks lost less weight on average during phase I (initiation) and a lower percentage of Blacks lost sufficient weight to qualify for phase II (maintenance).(6) Yet, among those who went on to Phase II in WLM, weight loss maintenance was similar across racial subgroups.(37) These findings have implications for designing weight loss maintenance trials that require a minimal amount of weight loss to qualify for randomization. For example, the duration of initial weight loss interventions could be extended; the weight loss criterion could be reduced for the whole cohort or specific subgroups; or participants could transition to maintenance when they reach their own weight loss nadir.

The odds of dropping out of the initial weight loss program were also greater among current tobacco users. In the above described review of predictors of attrition from weight loss programs, smokers were more likely to drop out than non-smokers in three of the five studies in which it was examined.(14) In a recent trial, females who smoked were more likely to drop out early. Yet, among those who were retained in the trial, weight loss did not differ among smokers and non-smokers even though smoking is widely known to be associated with lower weight.(38)Smoking status likely did not impact weight loss because weight change is likely related more closely to initiation or cessation, not continuation, of smoking.

Finally, we found that the odds of losing insufficient weight decreased as controlled motivation increased. Previous studies have tended to measure autonomous motivation rather than controlled motivation and have found that autonomous motivation is positively associated with weight loss.(39) In a recent weight loss study involving only males, autonomous but not controlled motivation mediated the intervention effect.(40) Participants in our study, military veterans, have shared experiences that may make them more responsive to extrinsic sources of control. Anecdotally, we often find that veteran patients prefer more prescriptive behavior change plans. Although veterans may experience greater initial weight loss to the extent that they are extrinsically motivated, a question for future research is whether motivation will become more intrinsically motivated and whether habits formed during the initiation period will persist beyond the study period.

This study has some limitations. Psychosocial constructs such as motivation and self-efficacy are not static; thus, our associations with baseline variables thus may not reflect the complexity of associations. Another limitation is that we did not select constructs based on empirical or theoretical reasoning that they would be associated with retention (e.g., socioeconomic status, depression)(14); instead, we selected constructs that

were based on their theoretical association with behavior change and clinical outcomes.(18) Nonetheless, we reasoned that many of the variables that would be associated with weight loss would also be associated with initiation and retention. Finally, the study was conducted in a single VAMC may not generalize to other settings.

In sum, the design employed in our trial is strong for testing the efficacy of a weight loss maintenance intervention but poses challenges for execution. As indicated by our experience, calculations and budgets need to consider dropout among initially eligible patients and those who start the program in addition to those who lose insufficient weight. Future trials should embed studies to evaluate recruitment and retention strategies that target difficult-to-reach populations.

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Disclosure

Dr. Maciejewski reports a conflict of interest due to his spouse's employment at Amgen.

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