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The Midwest Exercise Trial for the Prevention of Weight Regain: MET POWeR

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Abstract

Weight reduction in overweight and obese individual's results in physiological and behavioral changes that make the prevention of weight regain more difficult than either initial weight loss or the prevention of weight gain. Exercise is recommended for the prevention of weight regain by both governmental agencies and professional organizations. To date, the effectiveness of exercise recommendations for the prevention of weight regain has not been evaluated in a properly designed, adequately powered trial. Therefore, we will conduct a randomized trial to evaluate the effectiveness of 3 levels of exercise on the prevention of weight regain, in initially overweight and obese sedentary men and women. Participants will complete a 3 month weight loss intervention of decreased energy intake (EI) and increased exercise (100 minutes/week). Participants achieving clinically significant weight loss (≥ 5% of initial weight), will then be randomly assigned to 12 months of verified exercise at 3 levels (150, 225 or 300 minutes/week). This study will evaluate: 1) the effectiveness of 3 levels of exercise on the prevention of weight regain over 12 months subsequent to clinically significant weight loss (≥ 5%); 2) gender differences in weight regain in response to 3 levels of exercise; and 3) potential compensatory changes in daily physical activity (PA) and EI on weight regain in response to 3 levels of exercise. Results of this investigation will provide information to develop evidenced based recommendations for the level of exercise associated with the prevention of weight regain.

Keywords

aerobic exercise; weight management; weight regain; obesity; gender; energy expenditure

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1. Introduction

Numerous combinations of restricted energy intake (EI) and increased exercise energy expenditure (EEEx) have shown moderate short-term (< 6 mos.) success in producing clinically significant (≥5%) [1-6] reductions in body weight [7-10]. However, the prevalence of overweight and obesity among US adults continues at approximately 69% [11], due in part to the inability of individuals who lose weight to maintain weight loss [8, 12-16]. The prevention of weight regain differs from both initial weight loss and from maintenance of normal weight. Weight loss increases the propensity for weight regain through decreases in sympathetic tone, leptin, insulin, and bioactive thyroid hormones, an increase in ghrelin and changes in substrate utilization which result in altered energy balance by impacting EI and energy expenditure [resting metabolic rate (RMR) and physical activity (PA)] [17-23].

Exercise has been recommended for the prevention of weight regain by both governmental agencies and professional organizations including the International Association for the Study of Obesity (IASO) [24], the Institute of Medicine (IOM) [25], and the American College of Sports Medicine (ACSM))[26]. The US Department of Health and Human Services (HHS) 2008 report entitled “Physical Activity Guidelines for Americans” recommends 30 min/d of moderate PA to elicit health benefits [27]. The HHS guidelines, although not specific to weight management have been interpreted to be sufficient for that purpose. Support for these recommendations is tenuous and is derived from studies with important limitations including: 1) cross-sectional, non-randomized observational designs [2, 15, 28-33], randomization prior to weight loss: secondary analyses of exercise groups formed at study completion [34-36], self-reported levels of exercise [28] [36, 37] [38]; and 5) failure to supervise exercise and verify level of EEEx [36-38].

Three organizations offering exercise recommendations for the prevention of weight regain (HHS, IOM, ACSM) have highlighted the need to conduct adequately powered studies of sufficient duration, with randomization to different levels of exercise following completion of weight loss to address the issue of the amount of exercise required to minimize weight regain. Therefore, we will conduct a randomized trial to evaluate the effectiveness of 3 levels of exercise on the prevention of weight regain in a sample of initially overweight and obese sedentary men and women. Participants will complete a 3 month weight loss intervention consisting of decreased EI and increased PA (100 min/week). Participants achieving clinically significant weight loss (≥ 5% of initial weight), will then be randomly assigned to 12 months of exercise at either 150, 225 or 300 min/week. This study will evaluate: 1) the effectiveness of 3 levels of exercise on the prevention of weight regain over 12 months subsequent to clinically significant weight loss (≥5%); 2) gender differences in weight regain in response to 3 levels of exercise; and 3) potential compensatory changes in daily PA and EI on weight regain in response to 3 levels of exercise.

2. Materials and methods

2.1. Participants

We will recruit 287 overweight or obese adults from Lawrence and the Kansas City, Kansas metropolitan area who will be compensated for their participation. The sample will include at least 50% women and 20% minorities. Primary care physician (PCP) clearance will be required for participation. The following inclusion/exclusion criteria will be used: **Inclusion.** 1) Age 21 to 55 years. We have restricted our sample to this age range because we believe that behavioral interventions for weight loss may be different for individuals who are younger or older than this proposed age range. Additionally, individuals above age 55 are likely to have a greater numbers of medical problems and medication use that could significantly impact the exercise protocol and outcomes. 2) BMI of ≥ 25.0 to 45.0 kg/m^2.

We have restricted our sample to this BMI range because individuals with a BMI less than 25 kg/m^2 are not classified as overweight and individuals with a BMI >45.0 kg/m^2 may require more aggressive weight loss/prevention of weight regain interventions than we have proposed (e.g., surgery, medication, etc.). 3) Clearance for participation from their PCP. This will be obtained via a letter to the PCP that explains the research program and is returned to the investigators. **Exclusion.** 1) Participation in a research project involving weight loss or exercise in the previous 6 months, as these proximal experiences may impact the results of this study. 2) Participation in a regular exercise program (i.e., > 500 kcal/week. of planned activity as estimated by questionnaire [39]. 3) Not weight stable (±4.5 kg) for 3 months prior to intake as determined from an online initial eligibility questionnaire 4) Unwilling to be randomized to 1 of 3 exercise groups subsequent to weight loss. 5) Pregnant during the previous 6 months, lactating, or planned pregnancy in the following 15 months. 6) Serious medical risk such as type 1 diabetes, cancer or recent cardiac event (i.e., heart attack, angioplasty,etc.). Medical risk will be determined by a health history questionnaire and physician consent form. 7) Eating disorders as determined by a score of 20 or greater on the Eating Attitudes Test [40]. These individuals require counseling which is outside the scope of this study. 8) Current treatment for psychological problems, or taking psychotropic medications. Based on our experience, individuals meeting these criteria typically are problematic due to time conflicts with other treatments and medications which induce weight change. Addressing psychological problems is outside the scope of this study. 9) Taking medications known to significantly affect weight (gain or loss). 10) Adherence to specialized diet regimes, i.e., multiple food allergies, vegetarian, macrobiotic, etc. 11) Do not have access to grocery shopping and meal preparation (i.e. those in military, college with cafeteria plan, etc.). Approval for this study has been obtained from the Human Subjects Committee at the University of Kansas-Lawrence and the University of Kansas Medical Center-Kansas City.

2.2. Randomization

Randomization subsequent to weight loss is the only appropriate study design to adequately address our aims. Thus, only participants who achieve clinically significant weight loss (≥ 5%) from baseline (-3 to 0 months) will be eligible for randomization for prevention of weight regain. Data from our previous weight loss trials indicate that 97%-99% of participants will meet the 5% criteria for weight loss at 3 months and we expect ~70% will achieve ≥10% weight loss over 3 months [41-43], thus providing a range of weight loss typical of many weight loss programs available to the public. A range of weight loss will also allow for for exploratory analyses to evaluate the impact of the amount of weight loss on weight regain in response to the exercise intervention. Participants will be stratified by gender and level of weight loss (i.e., 5 - 9.9%, 10 - 14.9%, ≥ 15%) and will be sequentially randomized in a 1:1:1 allocation to 1 of 3 exercise groups. All randomization procedures will be completed by the project statistician. Those participants who achieve at least 5% weight loss will then be notified on an individual basis regarding of their randomization assignment. Participants will be instructed not to share their randomization assignment with other participants and staff members associated with the study.

2.3. Intervention: Behavioral weight loss clinics

Sixty minute in-person behaviorally based clinics will be conducted weekly during the 3 month weight loss period (-3 to 0 months) and during the first 3 months of the prevention of weight regain intervention. During the final 9 months of weight regain prevention, clinics will be held twice per month using telephone conference calls. All clinics will use behavioral strategies based on Social Cognitive Theory (SCT) to promote change in both diet and exercise [44]. The following components of SCT will be employed: goal setting, self-monitoring, self-efficacy, manipulation of the environment to promote behavioral

change, and reflection on outcome expectations and outcome value. Clinic sessions will begin with a check-in question designed to identify barriers to diet and exercise and to allow the group to work together to identify solutions which promotes group cohesion and social support. Weekly homework assignments are designed to increase self-efficacy for both diet and exercise and to provide practice of behavioral skills. For example, participants will be asked to identify items at the grocery store that meet calorie, fat, or fiber content consistent with a healthy diet. This learning experience improves confidence in the ability to identify food items to promote weight loss and prevent weight regain.

Clinics will be delivered by health educators trained and supervised by a co-investigator who will assure quality control and standardization of materials by conducting weekly staff meetings and reviewing tape recordings of clinic sessions. All clinic participants will receive a comprehensive program notebook which includes general guidelines regarding participation in the program, calendars and timelines for class meetings and data reporting, lessons for each clinic meeting, and detailed instructions for both the weight loss and prevention of weight regain diets, including appropriate recipes, handouts, worksheets, and assignments specific to the topic for each session.

During the last 9 months of the weight regain prevention intervention group phone clinics (conference calls) will be used instead of the traditional face-to-face clinic to reduce the burden of time and expense to participants and to maximize compliance with the intervention. The phone clinic (60 minute group conference call) will provide identical content and utilize the same procedures as the face-to-face clinic, with small differences for logistics associated with the conference call. At each phone or face-to-face clinic meeting, participants will record their consumption of pre-packaged meals (PM's-section 2.4),fruits and vegetables, and minutes of physical activity (both on and off site) and receive feedback, if needed, to improve dietary and physical activity compliance. Data on 295 participants from our recently completed effectiveness trial comparing weight management delivered by group phone conference vs. face-to-face (FTF) clinics suggests that weight change during the weight loss phase (baseline to 6 months) was −13.4 ± 6.7% and −12.3 ± 7.0% for FTF clinic and phone, respectively. Weight change during weight regain prevention (6 to 15 months) was 6.4 ± 7.0% and 6.4 ± 5.2%, for FTF clinic and phone, respectively [45]. Results from this study and an earlier study by our group [43] suggest that phone delivery compared to FTF clinic meetings provides equivalent weight loss as well as maintenance. Therefore we are confident in our ability to deliver effective weight gain prevention clinics by group phone conference call as proposed for this study. An outline of clinic topics is presented in Table 1.

2.4. Intervention: Weight loss diet (−3 to 0 months)

The weight loss and weight regain prevention diets for this study will be based on 25^{+} years of experience with weight management [41-43, 46, 47]. EI will be reduced to ~1,200 to 1,500 kcal/day using a combination of commercially available prepackaged meals (PM's), fruits and vegetables, low calorie shakes, and non-caloric beverages. Participants will consume a daily minimum of 2 entrees (180 to 270 kcals each), at least 5 servings of fruits and/or vegetables, and 3 shakes (~100 kcal each). Non-caloric beverages such as diet soda, coffee, etc. will be allowed ad libitum. When combined with a variety of fruits and vegetables, PM's (entrees + shakes) provide a diet with all necessary nutrients specified by the Dietary Reference Intakes [25].

We have targeted a minimum of 5% weight reduction from baseline to 3 months; an amount of weight loss which is known to produce clinically significant reductions in risk for chronic diseases such as diabetes, heart disease, hypertension, and others [1-4]. In previous investigations by our group using a similar diet, weight loss at 3 months averaged 12.5%

(range (11.1-13.7%) [41, 43, 47]. Participants reaching a BMI of 22 kg/m^2 during weight loss will be transitioned to the prevention of weight regain diet described below; however, in our experience, this is an infrequent occurrence. Individuals achieving < 5% weight loss at 3 months will not be eligible for randomization and will be referred to our ongoing weight management programs or to other community resources for weight management.

2.5. Intervention: Prevention of weight regain diet (0 - 12 months)

We recognize there are numerous approaches to the prescription of EI for the prevention of weight regain. We were influenced by the IOM dietary recommendations for weight regain prevention [25], over 25 years experience with research trials and clinical weight management, and the desire to evaluate a practical and generalizable approach. Therefore, following weight loss we will recommend a daily EI of estimated RMR * 1.2 to account for activities of daily living [48]. This EI recommendation theoretically results in a negative energy balance in all groups when EEEx is considered. However, we anticipate compensatory changes in components of energy balance such as increased EI and/or decreased daily PA (both of which are measured in this trial) as the literature indicates most individuals regain weight subsequent to weight loss [8, 12-16]. Thus, we believe our approach will maximize the potential to prevent weight regain and provides a reasonable compromise between scientific rigor, practicality, and generalizability.

During the weight regain prevention intervention, participants will receive a meal plan with suggested servings of grains, proteins, fruits, vegetables, dairy, and fats, based on their energy requirements and the USDA/HHS Dietary Guidelines for Americans 2010 [34]. Participants will be encouraged (not required) to continue consuming a minimum of 14 PM's (entrees or shakes) and a minimum of 35 servings of fruits and vegetables per week. They will be provided with a list of low calorie PM's and shakes available at local supermarkets or may purchase the PM's and shakes provided during the weight loss phase from the study coordinator.

2.6. Intervention: Exercise during weight loss (-3 to 0 mos.)

During weight loss we will use a verified, progressive exercise protocol that we have used in numerous previous investigations [41-43, 49]. Exercise will progress from 10 minutes/day, 5 days/week, 65% age-predicted maximal heart rate (HR_{max} = 220 - age in years) to the goal of 20 minutes/day, 5/days/week, 70% HR_{max} (100 minutes/week) at week 7 and remain at this level through study week 12. The intensity and duration of both on-site supervised and non-supervised exercise (walking or running) sessions will be verified by a HR monitor.

Participants will be required to complete a minimum of 3 of the 5 sessions under supervision in one of our 3 exercise facilities (2 in Lawrence, 1 in Kansas City). One of the supervised exercise sessions may be completed prior to/following the clinic meeting since the facilities for exercise and clinics are located in the same building. Each facility contains state-of-the-art exercise equipment, televisions and provides an environment similar to a modern commercial exercise center. Treadmill walking will be the primary mode of supervised on-site exercise; however, we will permit alternative modes of aerobic exercise (elliptical, bike, etc.) during 1 exercise session/week. Allowing alternative exercise modes provides relief from the routine for some participants and may help prevent overuse injuries.

2.7. Intervention: Exercise during prevention of weight regain (0 to 12 months)

Subsequent to 3 months of weight loss, participants will be randomized to exercise groups of 150, 225 or 300 min/week. Exercise will be progressed from 100 min/week at 70% HRmax at the end of weight loss (week 12) to the prescribed goals over weeks 13-17 of weight regain prevention and remain at goal for the duration of the trial (weeks 18-60) (Table 2).

Consistent with the protocol for exercise during weight loss (-3 to 0 months) participants will be asked to complete a total of 5 exercise sessions/week and will be required to complete a minimum of 3 sessions under supervision in our exercise facilities. As during weight loss, treadmill walking will be the primary mode of on-site exercise; however, we will permit alternative modes of aerobic exercise (elliptical, bike, etc.) during 1 exercise session/week. We realize that these are demanding exercise protocols; however, they represent national recommendations for the level of exercise associated with the prevention of weight regain. Our group, as well as others, have demonstrated the ability of previously sedentary, overweight and obese individuals to adhere to these levels of exercise (185-300 min/wk) in trials of 10 [50], 12 [38] and 16 mo. [51] duration.

2.8. Assessment of exercise compliance: Heart rate monitoring

The frequency, intensity and duration of both supervised and unsupervised exercise sessions will be documented using downloadable HR monitors (Polar RS 400, Polar Electro Inc., Woodbury, NY) which are capable of collecting and storing 99 hours of HR data collected over 1-minute epochs. A valid exercise session will be defined as an average HR ± 4 beats/min of target HR for the prescribed exercise duration. Participants not completing a valid exercise session will be counseled to meet both the intensity and duration prescriptions.

Each exercise session will be preceded by a brief (5 minutes) warm up. Participants will then be instructed to increase their exercise intensity to reach their prescribed target HR (70% of maximal HR ± 4 beats/minute) prior to starting the HR monitor and to remain at the target intensity for the duration of each exercise session. During all supervised exercise sessions trained research staff will monitor participants exercise HR to insure that it remains at target. Prior to each supervised exercise session (minimum of 3 sessions/week) research staff will download HR data from all unsupervised exercise sessions completed since the last visit to the exercise laboratory using the Polar HR Software. Research staff will review intensity and duration of the unsupervised exercise sessions and provide feedback to the participant.

2.9. Assessment of exercise compliance: Aerobic fitness

As a secondary measure of compliance with the exercise protocol we will assesses aerobic fitness using a sub-maximal treadmill test at −3, 0, 6 and 12 months. The treadmill will be initially set a 3 m.p.h., 0% grade. Speed will remain constant and grade will be increased 1% each minute until the participant reaches either 75% age predicted HR_{max} (participants not on beta blockers) or a rating of perceived exertion (RPE) of 16 on the Borg Scale (REF) (participants taking beta blockers). Heart rate (3-lead electrocardiogram: Marquette Electronics, Milwaukee, WI, USA) and perceived exertion will be assessed during the last 15 seconds of each stage. Aerobic fitness will be defined as the metabolic equivalent (MET) level estimated from treadmill speed and grade achieved during the last stage completed after achieving either the HR or RPE criteria.

2.10. Assessment of EEEx

Variation in body weight results in inter-individual differences in EEEx when performing weight bearing exercise of the same duration [51]. Therefore, to document the actual level of energy expenditure associated with each of the 3 exercise prescriptions (150, 225 and 300 minutes/week) over the course of the weight regain prevention trial we will assess EEEx in all participants at months 2, 7 and 12 to document the level of EEEx associated with each of the 3 exercise prescriptions. EEEx will be assessed by indirect calorimetry (ParvoMedics TrueOne2400, ParvoMedics Inc., Sandy, UT) during treadmill exercise over a 15 minute interval (1-minute epochs) at 75% age-predicted HR_{max} (± 4 beats/minute).The average EEEx (kcal/minute) over the 15 minute interval will be calculated from measured oxygen

consumption and carbon dioxide production using the Weir equation [23]. We have not proposed measures of EEEx during weight loss since the exercise prescription is progressive, and will be confounded by continuous changes in body weight induced by the weight loss protocol. In addition, our primary aim is to evaluate the effect of EEEx on the prevention of weight regain, not on weight loss.

2.9. Behavioral strategies for increasing exercise compliance

We will employ behavioral strategies to increase exercise compliance that are based on well-accepted theoretical models including SCT, Problem Solving Theory, Relapse Prevention and Stages of Motivational Readiness for change, to provide participants the necessary skills to adopt and maintain the targeted exercise behaviors [52-56]. Specific strategies will include, but not be limited to, self-monitoring, goal setting, problem solving, mastery skills, social support, and relapse prevention. In the context of this investigation, goals for the level of exercise will be predetermined by study design, with strategies implemented by exercise facility staff to reinforce the attainment of these prescribed goals.

To facilitate adoption of prescribed doses of exercise the prescription will be progressed slowly (Table 3) to provide mastery experiences and improve self-efficacy as participants move from a sedentary state to 100 and then to, 150, 225 or 300 min/week, during the first 3 to 6 months of the intervention. Participants will also be provided access to an exercise facility that is easily accessible (on-site free parking), temperature controlled, and with state-of-the-art equipment and entertainment packages. In addition, during the first 6 months of the study we will provide the opportunity for participants to complete one of their supervised exercise sessions prior to/following their regular face-to-face clinic meetings which will reduce participant burden and may improve exercise compliance.

2.12. Strategies for participant retention

We will obtain participant contact information to include name, address, telephone numbers, and email, as well as contact information for at least two family members or close friends who will know the location of the participant throughout the duration of the intervention. Participants who miss more than 3 consecutive scheduled on-site exercise sessions will be contacted by study staff by phone, text or email. After a maximum of 3 unsuccessful contact attempts, no further attempts will be made during the intervention period. However, participants as well as family members will be contacted to encourage completion of the end-study outcome assessments. Staff training will focus on relationship building between participants and the intervention team. Weekly project meetings with the principal investigator and the intervention team will problem solve any participant retention issues that may arise. We will also mail birthday cards, holiday cards, and program reminders to all participants. Undeliverable mailings, returned with a forwarding address, will be used to track participants who were potentially lost to follow-up. We will use behavioral contracts at multiple time points during recruitment, assessment, and after randomization to support our retention efforts and to determine the understanding of participants regarding the requirements for study participation. These strategies resulted in a loss to follow-up of 22% in our recently completed trial comparing the effectiveness of phone with face-to-face behavioral clinics for weight management [45]

2.13. Outcome assessments

All outcome assessments will be completed by trained research staff in the Center for Physical Activity and Weight Management, Energy Balance Laboratories (EBL) at either The University of Kansas-Lawrence or the University of Kansas Medical Center, Kansas City, Kansas. Research staff performing outcome assessments will be separate from those

who supervise exercise or conduct behavioral clinics and will be blinded to study condition. The schedule for outcome assessments is presented in Table 3.

2.13.1. Anthropometrics—Body weight, height and waist circumference will be recorded at −3, 0, 3, 6, 9 and 12 months. Weight will be obtained using a digital scale accurate to ± 0.1 kg (Befour Inc. Model #PS6600, Saukville, WI). Participants will report to the EBL between the hours of 6 and 10 AM, after an overnight fast, and be weighted prior to breakfast after attempting to void wearing a standard hospital gown. Height will be measured using a stadiometer (Model PE-WM-60-84, Perspective Enterprises, Portage, MI) and BMI (kg/m^2) will be calculated. Waist circumference will be assessed using procedures described by Lohman et al. [41]. We will obtain 2 measurements per site within 2 cm.

2.13.2. Energy intake—Energy intake will be assessed by 3-day food records (2 week days/1 weekend day) at −3, 0, 3, 6, 9 and 12 months prior to reporting to the laboratory for anthropometric assessments. Participants will be given verbal instructions and provided with written instructions titled “How to complete your food record” to improve record keeping. Food records will be reviewed by a registered dietitian during the laboratory visit to clarify any ambiguities. Data from the 3-day food records will be entered in the Nutrition Data System for Research (NDSR, version 2012, University of Minnesota) for calculation of energy and macronutrient content.

2.13.3 Dietary staff training and quality control—All staff will complete standardized training for 24-hour recalls and NDS-R coding, prior to the beginning of data collection, with refresher sessions every 2 months, thereafter. After initial training, all dietary assessment staff will be required to complete ten 24-hour recalls obtained from non-study subjects and enter this data directly into NDS-R. The recalls will be evaluated according to a published dietary recall documentation checklist [51]. An error rate of less than 5% on this checklist and on NDS-R coding will be required before interviewers will be allowed to collect and process dietary recall data. During the study, all dietary recalls will be evaluated by our study dietician using the recall documentation checklist before entry into the study database. Any recall with greater than 5% error will be eliminated and another recall obtained. Study staff demonstrating an error rate of 5% or greater for either energy intake or macronutrient composition, will be required to obtain further training and repeat assessment of accuracy described previously. Staff not meeting our criteria for accuracy at any time during the study following 3 attempts will not be permitted to collect or process dietary data.

2.13.4. Physical activity by accelerometry—To determine day-to-day and within-day variation in PA (i.e., compare exercise to non-exercise days, exercise time vs. non-exercise time), as well as to estimate the time spent in a range of PA intensity levels (moderate, vigorous), participants will wear an ActiGraph Model GT3+ (ActiGraph, LLC, Pensacola, FL) portable accelerometer for 7 consecutive days at −3, 0, 6, and 12 months on a belt over the non-dominant hip. The data collection interval will be set at one min with a minimum of 12 hours constituting a valid monitored day. We will apply the intensity cut-points used in the National Health and Nutrition Examination Survey as described by Troiano et al [57]; moderate (> 3 METS= >2020 counts/min), vigorous (>6 METS= >5999 counts/min). We have a custom SAS program to complete these analyses.

2.13.5. Process Measures: Diet/exercise—Process data will be collected to assess the fidelity of both the dietary and exercise components of the intervention. Diet: Health educators will track the number of PM’s consumed, fruit and vegetable intake, attendance at clinic meetings, and the number of reported midweek checks completed. Exercise: Staff will

track the number of both supervised and unsupervised sessions completed and the intensity and duration of all completed sessions.

2.13.6. Medical management—Signed clearance from a licensed physician will be required prior to participation. Additionally, all individuals must qualify based on their health history reported at baseline.

2.14. Analysis plan and statistical power

2.14.1. Analysis plan aims 1 and 2—1) To assess the effectiveness of 3 exercise recommendations on the prevention of weight regain over 12 mos. subsequent to clinically significant weight loss (≥ 5%); and 2) To evaluate gender differences in weight regain in response to 3 exercise recommendations. To evaluate the significance of the main effects (treatment and/or gender) on weight change (month 12 - month 0) we will use a 2-factor analysis of variance to compare weight change during the weight regain prevention intervention while including the treatment X gender interaction term in the initial model. If the interaction term is not significant, as expected, it will be excluded and the model will include only main effects for treatment and gender. If Treatment effect is significant ($p<0.05$), we will conduct pairwise comparisons between the 3 treatment groups using a type I error rate of 0.0167 for each pairwise comparison. The test of the main effect of gender involves only one comparison and thus will be evaluated with a type 1 error rate of 0.05. We will then use linear mixed models, assuming an autoregressive correlation structure over time, to model weight at 3, 6, 9 and 12 months post randomization, using weight at time 0 as a covariate. We will include main effects (treatment, gender, time) and also examine potential main effect by time interactions. This analysis will allow us to determine the time course of change, evaluate when treatment differences occur, and determine if treatment differences continue to increase or attenuate over time. We will also determine at what time point gender differences occur and whether or not differences increase or attenuate over time.

We will determine if proportion of participants lost to follow-up differs by treatment and/or gender and compare demographic characteristics between those lost to follow-up and completers. If the proportion lost to follow-up differs across treatment groups, we will examine demographic characteristics (gender, age, amount of weight loss) between lost to follow-up and completers) then determine if there are between group differences in those characteristics. If missing data are related to treatment and/or demographic characteristics, missing data will be imputed with model based multiple imputation methods, if not, traditional multiple imputation will be used. Based upon our previous effectiveness weight management trial, we expect ≤25% of randomized participants will be lost to follow-up [45].

2.14.2. Analysis plan aim 3: To assess potential compensatory changes in daily PA and EI on weight regain in response to 3 exercise recommendations —We will compare change in daily PA and EI in a similar manner as described for aims 1 and 2. We will first conduct 2-factor (treatment/gender) analysis of variance to examine changes in PA and EI over the duration of the prevention of weight regain intervention (0 to 12 months). We will then construct linear mixed models to evaluate the impact of PA and EI on weight regain while controlling for both treatment group and gender.

2.14.3 Potential exploratory analyses—Data collected in this study will provide the opportunity for a number of interesting exploratory analyses which will include by not be limited to: Dose/response: A preliminary assessment of the dose-response association between total EEEx and weight regain will be obtained by calculating the actual EEEx during the weight regain prevention intervention and using this as a covariate in a linear

mixed model assessing weight change while controlling for gender. Efficacy: We will conduct a "per protocol/pseudo-efficacy" analysis for weight regain including only participants who complete the study and are at least 80% compliant with exercise recommendations. This analysis will be performed as described for our primary aims 1 and 2. Amount of weight loss: The amount of weight loss may impact weight regain. We will include the amount of weight loss as a covariate in our longitudinal linear mixed models to examine its impact on weight regain while controlling for treatment, gender and time. Energy intake/diet composition: To determine if energy intake and/or diet composition (% fat, protein, carbohydrate) impact weight regain we will include these variables in a longitudinal model controlling for treatment, gender, time, and initial weight loss, if significant. All statistical analyses will be completed with SAS version 9.2 or higher.

2.14.4. Power and sample size—Table 5 details the hypothesized amount of weight regain in each of the 3 exercise groups (100, 225, 300 minutes/week) by gender during weight regain prevention (0 to 12 months) based on the results from our recently completed trial comparing the effectiveness of weight loss/regain between behavioral clinics delivered face-to-face vs. phone conference call which included unsupervised PA [45]. Using these assumptions we propose to randomize 86 participants who lose ≥5% of initial weight (43 men and 43 women) to each of the 3 groups following our 3 month weight loss intervention. This provides a total sample of 258 participants (129 males; 129 females). To be conservative, we estimate a total attrition during weight loss (drop out + failure to achieve 5% weight loss) of 10%, thus we will enroll a total of 287 participants at baseline (-3 months). Baseline enrollment has not been inflated for potential loss to follow-up as we will use intent-to-treat as our primary analysis using imputed data for those lost to follow-up as described previously (2.14.1). Using a 2-factor analysis of variance on weight regain with a type 1 error rate of 5% the proposed sample size will provide 99% power for overall trend across the 3 treatment groups, 98% power for test of gender and 5% power for interaction, assuming a common standard deviation of 6.0kg for weight regain from baseline to 12 months. Based on the hypothesized gender differences (Table 4) we do not expect a statistically or clinically significant treatment by gender interaction, thus the limited power. If, as expected, the interaction term is not significant, it will be excluded from the model which will then include main effects for treatment and gender. Adjusting the type 1 error rate for 3 pairwise comparisons (0.0167) we will have over 80% power for comparisons of weight regain between the 100 vs. 225 minutes/week and 225 vs. 300 min/week groups, and 99% power for a pairwise comparison of the 100 vs. 300 minute/week groups. Thus, we have adequate statistical power to evaluate each main effect and all potential pairwise comparisons across the 3 treatment groups.

3.0. Discussion

The prevention of weight regain following weight loss is problematic. Approximately 50% of individuals who initially lose weight will regain more than 45-75% of the weight lost within 12 to 30 months from the end of treatment [8, 12-16]. This trial is designed and adequately powered to evaluate the level of exercise associated with the prevention of weight regain subsequent to clinically significant weight loss. Important design features of this study include: randomization subsequent to weight loss to assure equal distribution of physiologic changes associated with weight loss that may impact weight regain across exercise groups; verification of completion of all exercise sessions and the assessment and documentation of EEEx; adequate statistical power to evaluate gender differences in the response to 3 levels of exercise; and a long duration intervention (12 months) with assessment of primary outcomes at 3 month intervals to examine the time course of weight change. The results of this trial will provide a more complete understanding of the weight change response to exercise following weight loss in both men and women and will provide

preliminary information regarding compensatory changes in energy intake and daily PA that may affect this response. This information will be important for the development of evidenced based recommendations for the level of EEEx associated with the prevention of weight regain in men and women.

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Abbreviations

ACSM	American College of Sports Medicine
EBL	Energy Balance Laboratory
EI	Energy intake
EEEx	Energy expenditure of exercise
HR	Heart rate
IOM	Institute of Medicine
NDS-R	Nutrition Data Systems for Research
PA	Physical activity
PCP	Primary care provider
PM's	Pre-packaged meals
RMR	Resting metabolic rate
SCT	Social Cognitive Theory

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Table 1

Clinic Topics

		Lesson Title	Focus
Weight Loss (FTF) Phase	**Intro**	Program Introduction: Intro to diet, meeting format, group members	Diet/Exercise/Behavior
	1	Diet Review and Benefits of Exercise	Diet/Exercise
	2	Goal Setting, Realistic Weight Loss Goals, Personal Reasons for Weight Loss and setting goals for Exercise	Behavior
	3	Increasing Fruits and Vegetables/Benefits of Fiber	Diet
	4	Exercise 101 (clothing, distractions, adverse weather, etc.)	Exercise
	5	Self-Monitoring of diet and exercise behaviors	Diet/Exercise
	6	Know Your Health Numbers (effects of nutrient dense diet and PA on metabolic risk factors)	Diet/Exercise
	7	Reading Food Labels – Your Tool to Healthy Eating	Diet
	8	Warm-up/Cool-down and Injury prevention	Exercise
	9	Making Exercise Part of Your Routine (i.e., planning, adherence, and coping with sore muscles)	Exercise
	10	F.I.T (Frequency, Intensity, and Duration)	Exercise
	11	Healthy cooking and Meal Planning	Diet
	12	Personal Plan (maintenance calories and approved entrees)	Diet
Weight regain prevention Month 0-3 (FTF)	**13**	Review of Program Goals/Objectives Exercise Adherence (importance of attendance and coping with life events)	Behavior/Exercise
	14	Intuitive eating	Diet/Behavior
	15	Grocery Shopping	Diet
	16	Portion distortion	Diet
	17	Maintaining motivation for diet and exercise	Diet/exercise
	18	Exercising on vacation	Exercise
	19	Environmental Control	Behavior
	20	Eating on the Go / Hidden calories	Diet
	21	Resistance Training	Exercise
	22	Emotional Eating	Diet/Behavior
	23	Energy Density	Diet
	24	Circuit Training (With demo)	Exercise
Weight regain prevention Month 3-12 (Phone)	**26**	Doing exercise on your own	Exercise
	28	Social Relationships and Social Situations	Behavior
	30	Benefits of Exercise (i.e., general physiology and diseases)	Exercise
	32	Mental Traps, Cognitive Attributions & Reframing	Behavior

	34	Myth Busters- Exercise	Exercise
	36	Coping with Cravings &Stress Related Eating (Urge surfing)	Diet/Behavior
	38	Increasing Lifestyle Activities and Decreasing Sedentary Time	Exercise
	40	Mindful Eating	Diet
	42	Myth Busters - Diet and fad diets	Diet
	44	Exercise Variety	Exercise
	46	Evidence Based Advice on Eating for Long-term Weight Control	Diet/Behavior
	48	Healthy Breakfast Tips/ Picking Healthy Snacks	Diet
	50	Energy expenditure and metabolism	Exercise
	52	Psychosocial Barriers to Weight Maintenance & Self and Body Image	Behavior
	54	Accountability and Self-Monitoring Revisited - Looking towards the future	Behavior
	56	Meal Planning Revisited	Diet
	58	Successful Weight Management Tips & Strategies/Relapse Prevention Revisited	Diet/Exercise/Behavior
	60	Reflecting and Re-Motivating and Reassessing Goals	Behavior

Table 2

Exercise progression (minutes/week) during the prevention of weight regain (weeks 13-60) for the 3 exercise groups

	Treatment Groups		
Study Week	**150 min/wk.**	**225 min/wk.**	**300 min/wk.**
13	125	125	175
14	130	135	200
15	135	150	225
16	140	175	250
17	145	200	275
18-60	150	225	300

Table 3

Outcome assessment schedule

	Time Points					
Variable	**−3 months**	**0 months**	**3 months**	**6 months**	**9 months**	**12 months**
Anthropometrics Weight Height Waist Circumference	X X X	X X X	X X X	X X X	X X X	X X X
DXA	X	X		X		X
Energy Intake (3-day food records)	X	X	X	X	X	X
Fitness	X	X		X		X
Physical Activity (Accelerometer)	X	X		X		X

Table 4

Weight change (kg) over the weight regain prevention intervention

	Treatment Groups		
	150	**225**	**300**
Overall change (kg)	8.0	5.0	2.0
Female change (kg)	9.6	6.5	3.5
Male change (kg)	6.4	3.5	0.5