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Intervening on spontaneous physical activity to prevent weight regain in older adults: Design of a randomized, clinical trial

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Abstract

There is a need to identify evidenced-based obesity treatments that are effective in maintaining lost weight. Weight loss results in reductions in energy expenditure, including spontaneous physical activity (SPA) which is defined as energy expenditure resulting primarily from unstructured mobility-related activities that occur during daily life. To date, there is little research, especially randomized, controlled trials, testing strategies that can be adopted and sustained to prevent declines in SPA that occur with weight loss. Self-monitoring is a successful behavioral strategy to facilitate behavior change, so a provocative question is whether monitoring SPA-related energy expenditure would override these reductions in SPA, and slow weight regain. This study is a randomized trial in older, obese men and women designed to test the hypothesis that adding a self-regulatory intervention (SRI), focused around self-monitoring of SPA, to a weight loss intervention will result in less weight and fat mass regain following weight loss than a comparable intervention that lacks this self-regulatory behavioral strategy. Participants (n=72) are randomized to a 5-month weight loss intervention with or without the addition of a behavioral component that includes an innovative approach to promoting increased SPA. Both groups then transition to self-selected diet and exercise behavior for a 5-month follow-up. Throughout the 10-month period, the SRI group is provided with an intervention designed to promote a SPA level that is equal to or greater than each individual's baseline SPA level, allowing us to isolate the effects of the SPA self-regulatory intervention component on weight and fat mass regain.

Keywords

Obesity; Weight loss maintenance; Self-monitoring; Self-regulation; Physical activity

1. Introduction/background

The prevalence of obesity and its detrimental health effects is increasing rapidly among all age groups, including the elderly [1]. In addition to the higher chronic disease risk attributable to obesity, there is also strong evidence that excess adipose tissue, independent of muscle mass, is associated with declines in physical function, the main predictor of disability, hospitalization, and mortality among the elderly [2,3]. Because of its increasing prevalence, and the economic, societal, and individual health consequences of obesity in this population, there is a need for research designed to identify treatments that are effective, evidenced-based, and perhaps age-specific.

Presently, clinical treatment guidelines for obesity are not age-specific and state that caloric restriction combined with moderate-intensity aerobic exercise for 30 min/day most days of the week, increasing to 60 min/day, is the primary therapy for achieving weight loss [4-6]. Although this recommendation is often efficacious for reducing weight in the short term, long-term maintenance of a lower weight is difficult [7,8]. This difficulty stems, in part, from the 'energy gap' caused by weight loss itself [9], resulting in compensatory decreases in energy expenditure thought to ensue from the propensity to defend one's initial level of adiposity during periods of energy imbalance. Thus, weight loss results in reductions in both resting energy expenditure [10-14] and non-resting energy expenditure, including spontaneous physical activity (SPA), defined as energy expenditure resulting primarily from mobility-related activities that occur during daily life, excluding planned, structured exercise [15-20].

The decline in SPA with induction of negative energy balance through structured exercise may be more pronounced in older [17,18,21-24], compared to young/middle-aged, persons [13,23,25,26]. We recently found that, in older women, there is an overall decrease in SPA in response to an energy deficit induced by a caloric restriction and structured exercise intervention [27]. Importantly, the magnitude of the reduction in SPA predicted the rate of weight regain. To date, there is very little research, especially randomized, controlled trials, testing strategies that can be adopted and sustained to prevent declines in SPA that occur with weight loss. Because it is well recognized that self-regulation and, in particular, self-monitoring, is a powerful behavioral strategy to facilitate behavior change during weight loss [28], a provocative, unanswered question is whether a novel approach to monitoring SPA-related caloric expenditure would override these reductions observed in SPA and retard or prevent weight regain in obese older adults. This paper describes the design of a study whose aim is to begin to answer this question. Our hypothesis is that adding a self-regulatory intervention (SRI), focused around self-monitoring of SPA, to a standard weight loss intervention will result in less body weight and fat mass regain following weight loss than a comparable intervention that lacks this self-regulatory behavioral strategy.

2. Study design/methods

2.1. Overview

The proposed study is a 2-arm, 10-month randomized, clinical trial in older, obese men and women. Participants are randomized to a 5-month standardized weight loss intervention

involving a hypocaloric diet and aerobic exercise (DIET+EX) or to the same weight loss intervention with the addition of a self-regulatory intervention (SRI) for promoting SPA (SRI+DIET+EX). They are then followed for another 5 months following weight loss. Both groups undergo a controlled, hypocaloric diet provided by our metabolic kitchen and a 4-day/week aerobic exercise training program for a period of 5 months as described below. Following postweight loss research assessments, both groups transition to a self-selected program of diet and exercise behavior during a 5-month follow-up period. Throughout the total 10-month period, the SRI+DIET+EX group is provided with an intervention component designed to promote/maintain a SPA level that is equal to or greater than each individual's baseline (before weight loss intervention) SPA level (described below). Research data are collected at baseline, after the 5-month weight loss phase, and after the 5-month follow-up phase.

2.2. Participants

We plan to recruit 72 obese, older women and men ($n=36$ each) with no contra-indications to weight loss or aerobic exercise training. This sample size is based on power calculations (see below) showing we would have 80% statistical power to detect a difference of 2.1 kg in weight regain. Study participants are: 1) age 65–79 yrs and postmenopausal for women (defined as absences of menses for >1yr), 2) sedentary (<2 x/wk of structured exercise), 3) BMI=30–36.9 kg/m², 4) weight-stable ($\pm 5\%$) within the past year, 5) non-smoking for the past year, and 6) not currently taking medications known to affect body weight.

2.3. Screening visits

All respondents to our recruitment strategies are screened via telephone. Potential participants who pass the phone screen are invited to an initial screening visit (Screening Visit 1) to undergo a medical history and physical exam, the Mini-mental State Exam (MMSE) [29] to insure participants have normal cognitive function (MMSE >25), the Center for Epidemiologic Studies Depression Scale (CES-D) [30] to exclude those with depression (CES-D<16), and a Seven Day Physical Activity Recall Questionnaire [31] to insure a sedentary status (exercise<20 min, 2x/wk). The medical history and physical exam excludes people with history of coronary heart disease, cancer, liver or renal disease, chronic pulmonary disease, physical impairment that would prevent treadmill walking, blindness or retinopathy, uncontrolled hypertension, or any contraindications to exercise per ECG results. The physical exam includes a fasting blood profile to exclude those with overt diabetes [32], anemia (Hct<37%), liver, renal, or hematological dysfunction. If the above criteria are met, participants undergo a Bruce treadmill test to exclude exercise-induced ischemia (Screening Visit 2). All participants are free of any contraindications for participation in an exercise program. After screening, those who are eligible and willing to participate in the study are randomized into one of the two intervention groups.

2.4. Interventions

This study is designed to begin to examine whether self-monitoring of SPA via the use of an accelerometer within a SRI will help prevent weight regain following weight loss in older adults. Thus, all participants take part in a weight loss intervention that incorporates hypocaloric diets and aerobic exercise training (4 d/wk) for a period of 5 months. Daily

hypocaloric intake levels are assigned for each person (within 50 kcals/day) and provide for an absolute daily caloric deficit consistent with each person's weight loss goal of 10%. The individual calorie level is derived from subtracting a participant's required energy deficit from his/her estimated daily energy needs for weight maintenance. Weight maintenance energy needs are calculated from the direct measurement of RMR, applying an activity factor based on daily activities (typically 1.2 for sedentary). Individual calorie levels are adjusted during the study if necessary to achieve the desired weight loss.

Participants are provided with 2 meals (lunch and supper) per day prepared by our Clinical Research Unit (CRU) metabolic kitchen. All meals are prepared individually after participants choose from a hypocaloric menu designed by the RD to provide a balanced, healthy diet. No woman is provided with less than 1100 kcal/d and no man with less than 1300 kcal/d. The diet contains less than 30% calories from fat and at least 0.8 g of protein per kg of ideal body weight per day. In addition, all participants are provided with a daily calcium (1200 mg/d) and vitamin D (800 IU/d) supplement. They are educated by the CRU RDs and provided menus to guide their food purchasing and preparation of daily breakfast meals and snacks that are consistent with the prescribed calorie level. They are asked to consume only the food that is given to them or that is approved from the breakfast/snack menu. All participants pick up their food 3 times/wk and are asked to keep a log of everything they eat and drink. These logs are reviewed weekly by the RD to verify compliance to the diet. In addition, body weight is measured weekly to insure that participants are losing weight at a rate approximating their prescribed energy deficit. If it is evident, either through diet records or inadequate body weight loss, that participants are not compliant with the diet, weekly individual counseling sessions with the RD are held to improve motivation and compliance to the intervention.

The exercise component of the weight loss intervention involves aerobic training in accordance with the American Heart Association and American College of Sports Medicine physical activity recommendations for older adults [33]. All exercise sessions take place 4 days/week in our research exercise facility under the direction of a Master's level exercise physiologist. Blood pressure and heart rate (HR) are measured before each exercise session and participants warm-up by walking for 3–5 min at a slow pace and then walk at an intensity of 65–70% of heart rate reserve (HRR, assessed during the VO₂max test). The duration of exercise progresses from 15–20 min at 50% HRR the 1st week to 30 min at 65–70% HRR by the end of the 6th week and thereafter. Each walking session ends with a 3–5 min cool-down followed by 5 min of large muscle flexibility exercise. At least two HR readings (measured by Polar heart rate monitors) are taken during each walking session and recorded in a log book to monitor compliance to the prescribed exercise intensity. Treadmill speed and grade are adjusted individually to insure that participants exercise at their prescribed exercise intensity (as monitored by HR). Treadmill speed, grade, exercise duration, and the amount of energy expended are recorded for each exercise session.

All participants undergo the weight loss intervention; but those assigned to the SRI+DIET +EX group undergo an additional intervention aimed at promoting SPA through self-monitoring. Each participant in this group is provided with an accelerometer (described below) and individual cognitive-behavioral counseling sessions (detailed below) to prevent

the decline in SPA expected from the hypocaloric diet and structured exercise program. Substantial research and theory [28,34] suggests that goal setting and other self-regulatory skills, particularly self-monitoring, are critical for successful behavior change.

The SPA SRI is designed to maintain minutes of SPA at a level that is equal to or greater than each participant's baseline activity. Specifically, in consultation with the interventionist, participants are given personal SPA goals that are calculated to be at least 10% greater than baseline levels. Individuals whose baseline SPA is less than 10 min are counseled to increase to at least 10 min. This energy may be expended in a variety of ways and it is expected that an individual's SPA minutes will result from a combination of several daily activities and will depend on individual habits and preferences.

During the first week of intervention, participants in the SRI intervention are given a Lifecorder Plus® tri-axial accelerometer (Suzuken, Co., LTD; <http://www.new-lifestyles.com/>) with instructions for wear and documentation of usage. They are asked to wear the accelerometers daily for the length of the 5-month intervention and for the length of the 5-month follow-up (see below). The units are small, pedometer-like devices that are worn on the hip. With this model, participants cannot be blinded to the accelerometer output and, thus, are able to instantaneously view their SPA minutes throughout the day and to compare it to their daily SPA goal. Participants record SPA minutes (calculated from the accelerometer) in a daily log so that they become more aware of the metabolic costs of different daily activities, and, if necessary, to devise ways to increase SPA. Daily documentation includes participants' personal SPA goal, actual accumulated daily minutes, adherence information (e.g., wearing the monitor, meeting the goal, etc.), and identifying daily barriers if the participant does not meet the SPA goal. The accelerometers are removed during the on-site, structured exercise sessions.

Participants in the SRI+DIET+EX group meet weekly for the first 6-weeks with an interventionist to review progress. During these 10–15 min sessions, accelerometers are downloaded, the SPA self-reported logs are collected, and participants receive feedback based on a self-management model developed by Rejeski and colleagues [34]. In brief, this model assumes that the motive to change behavior is driven by the desire for specific outcomes along with both facilitative and inhibitory processes. The SRI intervention facilitates SPA behavior by clarifying the intended outcomes of increasing SPA and by providing clear, specific, moderately challenging goals that can be evaluated frequently across the day using the accelerometer. During brief counseling sessions that are collaborative by design, feedback is provided and factors that may be inhibiting successful self-management are addressed using Perri and colleagues approach to social problem solving [35]. If, during the first six-weeks of treatment, participants' level of SPA activity drops below established goals, additional counseling sessions are arranged. After the first 6 weeks, participants meet bi-weekly with the SPA interventionist for the remainder of the 5-month weight loss intervention and then monthly during the 5-month follow-up period.

2.5. Follow-up phase

During the 5-month follow-up phase, all participants follow a self-selected diet and exercise routine (e.g., no dietary counseling, underfeeding, or formal exercise program) and

participants in both groups are asked to complete follow-up visits that occur at 5 week intervals. At these visits, all participants are weighed and those in the SPA SRI group meet briefly with the SPA interventionist to turn in accelerometers to download and change batteries, turn in SPA trackers, and briefly review progress. Additionally, prior to the final weighing visit, participants are contacted by telephone at 3 random time points during the last 2 weeks (conducted by the CRU RD) to obtain a detailed report of their previous day's dietary intake. These records are analyzed to provide an estimate of caloric and macronutrient intake on the self-selected diet over the course of the follow-up phase.

2.6. Assessments

2.6.1. Spontaneous physical activity (blinded accelerometer output)—Outcome measurements of SPA are performed in both groups at baseline, after the 5-month weight loss phase, and after the 5-month follow-up using a Kenz® Lifecorder EX® tri-axial accelerometer (Suzuken, Co., LTD; <http://www.new-lifestyles.com/>). The device provides valid and reliable measures of step counts, total daily energy expenditure, physical activity energy expenditure, and physical activity patterns in free-living conditions [36-38]. Participants in both groups wear the accelerometer for at least 10 h for a period of seven days at each of the assessment time points. Participants are also directed to keep an adherence diary giving details as to when the monitor was worn and taken off during the day. They are instructed to maintain their regular level of physical activity and to wear the monitor at all times during these 7 days, except while bathing and sleeping. Participants are blinded to the results of the data during these assessment periods; thus, they do not receive any performance feedback from the accelerometers or the staff. Data are downloaded from the accelerometer at end of the 7-day period and reported as the average daily physical activity energy expenditure in absolute kcal and kcal per kg body weight.

Resting metabolic rate is assessed to determine the weight-maintaining energy needs of each participant for the purpose of prescribing the 400 kcal/day energy deficit (for the weight loss phase). RMR is measured in the morning after a 10-hour fast by indirect calorimetry using the ventilated hood technique. Upon arrival, participants are asked to lie quietly for 30–45 min before testing. Measurement of oxygen consumption and carbon dioxide production are collected continuously for at least 30 mins and RMR is calculated using the Weir equation [39].

2.6.2. Body composition—Height is measured in centimeters and weight measured in kilograms on the same scale, which is accurate to ± 100 g and calibrated weekly. Percent body fat, lean mass, and adipose tissue mass is measured by dual energy absorptiometry (DXA, Hologic Delphi QDR). The body composition measures will allow us to assess whether changes in SPA are related to changes in body composition during the weight loss and follow-up phases of the study.

2.7. Statistical analyses

We will estimate and compare the magnitude of the amount of weight and fat mass regain during the 5-month follow-up phase between the two intervention groups. We expect that participants in the SPA SRI group (SRI+DIET+EX) will have a smaller weight regain than

those in the DIET+EX group. Data analyses will be performed at the 0.05 significance level using the intent-to-treat approach in which each participant is included in their initial randomization group regardless of adherence. Baseline analyses will include descriptions of the baseline characteristics of the participants. Multivariable regression analyses will be used to investigate relationships between weight regain and SPA including important covariates such as gender, age, and amount of weight lost. The number of factors in these models will be limited due to the sample size of the study. Exploratory models will also be fitted including an interaction term between gender and the interventions to compare weight regain differences by gender. Although statistical power will be insufficient for the interaction test, these models will provide estimates to help plan a larger trial.

2.8. Statistical power

Thirty-six subjects (18 men, 18 women) will be enrolled in each of the two study arms and, based on a conservative drop-out rate of 10%, we expect that at least 32 per group (16 men, 16 women) will complete the study. Data from one of our prior weight loss studies provided estimates of means and standard deviations of weight regain (3.11 ± 2.96 kg) after the weight loss phase. A two-sided, two-sample *t*-test at the 0.05 significance level with 32 in each group will provide 80% statistical power to detect a group difference of at least 2.1 kg in weight regain.

3. Discussion

Our long-term goal is to develop an effective behavioral intervention aimed at the prevention of weight regain following intentional weight loss in older, obese men and women. Presently, there are observational data demonstrating that a high level of physical activity distinguishes the approximately 20% of individuals who are successful at weight loss maintenance [40-42]. For example, those who exercise at least 1 h/day experience less weight regain than those who exercise less than this [43]. However, long-term adherence to this volume of exercise may be particularly difficult for older and obese persons and, as stated earlier, older adults are more likely to compensate for the caloric expenditure of structured exercise by decreasing non-structured exercise, or SPA, resulting in reduced total energy expenditure. Fortunately, evidence suggests that less intense physical activity is also beneficial for weight loss maintenance [44,45]. In fact, a few clinical trials show that less intense and structured exercise may be better for long-term weight loss maintenance than structured, high-volume exercise [46-48]. Thus, we posit that incorporation of more movement into daily activity (e.g., SPA) during and following weight loss may be more beneficial than incorporation of regular, structured exercise in older, obese adults.

The study described here will provide important feasibility and early efficacy data regarding the benefits of using a novel self-monitoring strategy within a broader conceptual model of behavior change to modify the likely reduction in SPA that occurs during periods of negative energy balance among older adults. Our approach focuses on a behavioral strategy to eliminate the compensatory reduction in non-exercise daily activity (SPA) seen in older adults who lose weight with a hypocaloric diet and structured exercise training. These data will inform the design of an efficient and definitive full-scale randomized clinical trial to

examine the effects of a SPA self-regulation intervention compared to structured exercise for the maintenance of weight loss in this population. If our hypothesis is correct, and confirmed in a larger and longer randomized trial, the findings could potentially provide evidence against the current standard of care (i.e., exclusive prescription of structured moderate-intensity exercise) for obesity therapy in seniors, leading to more effective obesity treatment guidelines and/or recommendations for weight loss maintenance.

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