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The Cooperative Lifestyle Intervention Program-II (CLIP-II): Design and Methods

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Abstract

A complication of cardiovascular disease (CVD) and the metabolic syndrome (MetS) among older adults is loss of mobility. The American Heart Association has identified weight management as a core component of secondary prevention programs for CVD and is an important risk factor for physical disability. The American Society for Nutrition and the Obesity Society have highlighted the need for long-term randomized clinical trials to evaluate the independent and additive effects of diet-induced weight loss (WL) and physical activity in older persons on outcomes such as mobility, muscle function, and obesity related diseases.

Here we describe the rationale, design, and methods of a translational study, the Cooperative Lifestyle Intervention Program-II (CLIP-II).

CLIP-II will randomize 252 obese, older adults with CVD or MetS to a weight loss only treatment (WL), aerobic exercise training (AT)+WL, or resistance exercise training (RT)+WL for 18 months. The dual primary outcomes are mobility and knee extensor strength. The interventions will be delivered by YMCA community partners with our staff as trainers and advisers. This study will provide the first large scale trial to evaluate the effects of diet-induced WL on mobility in obese, older adults with CVD or MetS as compared to WL combined with two different modes of physical activity (AT and RT). Because uncertainty exists about the best approach for promoting WL in older adults due to concerns with the loss of lean mass, the design also permits a contrast between AT+WL and RT+WL on muscle strength.

Keywords

translational science; exercise; older adults; obesity; weight loss; physical activity

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Introduction

Over 80 million Americans have one or more types of cardiovascular disease (CVD) and the numbers at high risk for this disease such as those with the metabolic syndrome (MetS) are increasing (1). A major complication of CVD among older adults is loss of mobility, i.e., mobility disability, where mobility is defined as the ability to move independently in one's environment. Diseases of the heart and circulatory system are a major cause of mobility disability in adults over the age of 60 years, running a close second only to arthritis (2). This has led Ades (3) to argue that the primary goal of medical care for older adults who have CVD should be to improve physical functioning and to extend disability-free survival.

Although aerobic exercise training (AT) has been the cornerstone of rehabilitation for patients with CVD or MetS, experts agree (4-6) that, with the escalating problem of obesity, prevention programs in this area need to target weight loss (WL) as well. Obesity is a major risk factor for physical disability among older adults (7;8). From a translational perspective, clinical researchers have recommended that effective community partnerships are needed to deliver such programs (9). In response to this call, we have recently completed a translational study, the Cooperative Lifestyle Intervention Program (CLIP) where 288 obese, older adults with CVD or MetS were randomized to a successful aging control treatment (SA), AT, or AT+WL for 18 months. The primary outcome was mobility, operationalized as the time to complete the 400 m Walk Test (400MWT) and our staff co-delivered the interventions with North Carolina Cooperative Extension Centers agents from 3 counties. As previously published, the PA+WL group improved their 400-meter walk time (adjusted mean [SE], 323.3 [3.7] seconds) compared with both PA (336.3 [3.9] seconds; $p=0.02$) and SA (341.3 [3.9] seconds; $p<0.01$). The clinical significance of this effect is discussed in the main outcomes paper (10).

Building on CLIP, we hypothesize that the addition of PA to a WL intervention will lead to greater improvements in mobility compared to WL alone. However, as we detail in the discussion section of the current paper, RT may offer some unique advantages over AT with respect to the preservation of muscle mass and strength as well as bone mass. CLIP-II also increases the translational significance of our interventions by having them delivered by YMCA community partners with our staff as trainers and advisers. CLIP-II will be the first large scale randomized controlled clinical trial to evaluate the effects of diet-induced weight loss (WL) on mobility in obese, older adults with CVD or MetS as compared to WL combined with physical activity. The dual primary outcomes will be the 400MWT and knee extensor muscle strength. Because uncertainty exists about the best approach for promoting WL in older adults due to concerns with the loss of lean mass, the design also permits a contrast between AT+WL and resistance exercise training (RT)+WL on muscle strength. To accomplish our goals, we have created a community partnership with the YMCA of Northwest North Carolina. We are moving this project from Cooperative Extension Centers to the YMCA because the former have neither the equipment nor the personnel necessary to independently train and monitor RT or AT. The primary hypotheses are that (1) physical activity+WL (the average effect of AT+WL and RT+WL) will yield more favorable changes in the 400MWT than WL alone and (2) that RT+WL will provide greater changes in strength at the knee joint as compared to AT+WL.

Methods

Overview

The institutional review board of Wake Forest University has approved the testing protocol. All participants will provide written informed consent. CLIP-II aims to recruit 252 participants across 8 waves and 4 sites.

Eligibility

In order to be included in the CLIP-II Study, participants must be community dwelling men and women aged 60-79 years of age with documented evidence of myocardial infarction (MI), percutaneous coronary transplant intervention (PCTI), chronic stable angina, cardiovascular surgery, or an ATP III diagnosis of metabolic syndrome. Participants must have low levels of structured physical activity (less than 60 minutes of moderate intensity physical activity per week) where structured denotes participation in physical activity for the specific purpose of increasing one or more of the domains of fitness (e.g., cardiorespiratory capacity, strength, balance, and/or flexibility). They must have a body mass index (BMI) of ≥28 and <42 and have self-reported difficulty with their mobility. In order to increase the translational significance of CLIP-II, participants with a variety of comorbidities such as osteoarthritis or peripheral arterial disease are not excluded. In advance of any study testing, each participant's primary care physician is provided with a description of the study weight loss and physical activity program, and study inclusion/exclusion criteria and asked to approve or disapprove his/her patient for participation in the study. Inclusion and exclusion criteria are detailed in Table 1.

Recruitment and Screening

Participants will be identified from the greater Winston-Salem, NC area using direct mailings to community-dwelling men and women 60-79 years of age. The goal for minority recruitment is 30% of the sample as specified by the funding agency. Potential participants will be initially screened for eligibility by telephone. After the phone screen, interested and eligible participants will be invited to attend an initial screening/baseline visit at Wake Forest Baptist Medical Center's Clinical Research Unit where the following assessments will be performed: informed consent; medical history; cognitive function assessed with the Montreal Cognitive Assessment (MoCA)(11); fasting blood draw to determine CVD or MetS eligibility; body mass, height, waist circumference, and resting blood pressure measured, and BMI calculated; Short Physical Performance Battery (SPPB); and 400 m walk test. Following the first baseline visit, eligible participants will be asked to return for a second baseline visit at Wake Forest University Health and Exercise Science Department labs where the remaining measures will be made.

Study Assessments

Study assessments will be conducted at baseline, 6 months, and 18 months and are described in detail below. They include assessments of strength and physical function (self-reported and performance-based), body composition, depressive symptoms, health related quality of life, diet/nutrition, physical activity, autonomic function, and gait characteristics. Also, a fasting blood draw, body mass, height, waist circumference, and resting blood pressure will be collected again at 6 and 18 months. Technicians who conduct the study assessments are blinded to treatment condition.

Primary Outcome Measures

400mWalk Test (400MWT)—Performance on the 400MWT is an important prognostic indicator for total mortality, cardiovascular disease, and mobility disability in older adults (12). The 400MWT represents a realistic task that this population encounters on a regular basis, and has been used in numerous studies investigating mobility (10;13;14). Participants will be asked to walk 400 m (10 laps of a 20 m course between 2 cones) as quickly as possible and the time for completion will be recorded. Standard encouragement will be given and participants will be reminded of the number of laps completed and number remaining. The reliability and validity of the 400MWT are excellent (15).

Knee extensor muscle strength—Concentric knee extensor strength for the dominant limb will be assessed on a HUMAC dynamometer using a protocol modeled on previous studies of older adults and our own experience (16-19). The participant will be seated with the hips at 95 deg. and knees flexed at 90 deg. All testing will be performed on the dominant limb unless contraindicated. In this case the non-dominant limb will be tested. To stabilize the hip joint and the trunk, subjects will be restrained with straps at the chest, hip and thigh. Seat height and depth, and lever length, will be recorded for each participant to be used in follow-up testing. The lever arm pad will be positioned 2 cm proximal to the anterior ankle crease. The knee joint center (lateral femoral condyle) will be aligned with the axis of rotation of the dynamometer. Start (Towards) and stop (Away) angles will be set at 90 deg and 30 deg, respectively. Gravity effect torque will be calculated based on the weight of the subject's leg at a 45 deg angle. Subjects will complete a warm-up of 6-8 trials with a low to moderate effort at 120 degrees per second (deg/s) to familiarize themselves with the movement. We also use Ratings of Perceived Exertion (RPE) (20) during these submaximal efforts to assist the participant in understanding what is required in a maximal effort. For maximal effort trials, an angular velocity of 60 deg/s will be used through a joint range of motion from 90 to 30 deg (0 deg = full extension). The first and last 10 deg of movement will be deleted to account for the acceleration and deceleration of the dynamometer at the ends of the range of motion (21). Two trials of 4 maximal efforts will be conducted with the 2 highest efforts being averaged. Standardized instructions and verbal encouragement will be given during each trial. A rest period of 90 s will be provided between each trial. Typically 6-9 trials elicit two comparable maximal efforts. The test-retest reliability of this protocol in our laboratory is excellent (Intra-class Correlation Coefficient > 0.9). Muscle strength will be assessed by peak torque (Nm). Participants experiencing pain, or those that have had knee replacement on their dominant limb, will have their non-dominant limb assessed.

We use knee extensor strength as it is representative of the strength of the lower extremity and the focus of CLIP-II is on lower extremity mobility. The RT intervention incorporates three important lower extremity exercises (knee extension, knee flexion, leg press) and the quadriceps muscle group is an important contributor to these exercises. We have found the knee extension and flexion movement to be easy for participants to master. We believe this is important to identifying an individual's the maximal voluntary strength.

Secondary Outcome Measures

Stair Climb Task (SCT)—Raising the body mass has particular relevance in the context of weight loss and strength for older adults. The SCT involves ascending and descending a flight of 5 stairs as quickly as possible. Performance will be measured as the time to complete the task. The SCT also has excellent reliability and validity (22).

Body composition and Bone Mineral Density—Whole body and bone mineral density dual-energy x-ray absorptiometry (DXA) scans will be obtained using a Lunar iDXA (GE Medical Systems, Madison, WI). Fat-free mass (FFM) will be calculated as the sum of muscle mass and bone mineral content. Percent body fat will be calculated as (Fat Mass/Body Mass) × 100. Appendicular skeletal muscle (ASM) and total muscle mass will be estimated using established methods (23). Loss in body fat is commonly associated with a subsequent decrease in lean muscle mass. The body composition and bone density analyses are important to determine the effects of diet-induced weight loss alone on muscle mass and bone density while permitting a contrast between AT+WL and RT+WL on muscle strength and bone density status.

CVD risk factors—The following risk factors will be assessed to ensure that participants meet the criteria required to participate in the study (CVD, MetS) and as secondary outcomes for the trial.

- Lipid panel. An analysis of total cholesterol, triglycerides, low density lipoproteins, and high density lipoproteins will be performed after an overnight fast.
- Blood assays for glucose will be collected by venipuncture after an overnight fast.
- Resting blood pressure. Blood pressure will be assessed following a 5-minute rest period and while in a seated position from the brachial artery via auscultation following a standardized protocol (24).

Health Related Quality of Life (HRQL)—HRQL will be assessed using the SF-12, a generic measure of HRQL that consists of two norm-based composite T-scales, mental health and physical function. There has been extensive data published in support of the psychometric properties of this instrument (25).

Depressive symptoms—We will use the Center for Epidemiologic Studies Depression scale, the CES-D(26) to assess depressive symptoms.

Self-reported physical function—Self-reported disability will be assessed using a validated 19-item questionnaire, the Pepper Assessment Tool-Disability (PAT-D) (27). The questionnaire asks about perceived difficulties in general activities of daily living during the last month and has three sub-scales: mobility, activities of daily living (ADLs), and instrumental activities of daily living (IADLs).

Process/Adherence Measures

BMI, body mass, waist circumference—Height without shoes will be measured to the nearest 0.25 cm using a stadiometer and body mass measured to the nearest 0.05 kg using a calibrated and certified digital scale. Height and body mass will be used to calculate BMI. Waist circumference will be measured to the nearest 1 mm with a Gulick II spring-retractable fiberglass tape, using the technique described by Pollock and Wilmore (28).

Assessment of energy, macronutrient and micronutrient intake—The Vioscreen electronic food frequency questionnaire requires participants to estimate consumption of a wide variety of foods. Scoring yields estimates of macro- and micro-nutrient intake, as well as intake by specific food groups for both group and individual analysis. The measurement properties of this questionnaire have been previously described (29). In addition, in order to monitor macronutrient consumption during the course of the trial, every participant will complete a daily food diary. The diary will be regularly monitored by a registered dietitian (RD) to assess adherence.

Accelerometry—Accelerometry will be used to objectively assess the relative impact of interventions on physical activity over time. The NL-2000 accelerometer is a small hip mounted device that stores activity “counts” for 2 minute epochs (30). Accelerometers are worn for 7 days with a minimum of 5 days and 10 hours per day wear time required to be considered valid. Previous investigations have found that the Lifecorder accelerometer is valid and reliable in a research setting (31;32), that the intensity of physical activity assessed with the Lifecorder is closely correlated with directly measured oxygen uptake (33), and that the Lifecorder detects time spent in specific physical activity intensity levels comparable to the Actigraph (34).

Tracking exercise adherence and volume—The Fitlinxx exercise system, a computer based exercise prescription and tracking program will be used to track adherence to the exercise interventions, as well as the volume of work done and the intensity. It is available at YMCAs nationwide which means that it has translational relevance. The YMCA intervention staff will create an individualized program for each participant and enter it into the Fitlinxx system. Participants in the AT+WL group will record the duration, distance, and intensity of the exercise session and input that information via the Fitlinxx system. Participants in the RT+WL group will login via a small touch screen on each RT machine and are then prompted on the weight to be lifted and the number of sets and repetitions based on the program established by the interventionist. This individualized RT program is based on a participant's initial one repetition maximum (1RM) on each of the 16 resistance machines. The 1RM is defined as the maximum amount of weight that a person can lift through a full range of motion with good lifting form. Each piece of RT equipment is instrumented to automatically track sets, repetitions, weight, range of motion, and speed of concentric and eccentric phases of the movement. The system prompts the user to complete the full range of motion for each exercise at the designated movement speed. Reports can be generated by the intervention staff using the Fitlinxx system to track adherence, volume of work, duration, and exercise intensity so that personalized feedback is communicated to each participant.

Exploratory Measures

There are a number of other measures that are not primary or secondary outcomes but that are important in enhancing our assessment of physical activity, lower extremity function, and parasympathetic activity. These measures include: the Mobility Assessment Tool-Physical Activity (MAT-PA): a computer animated self-report physical activity questionnaire designed to provide additional insight into participant's physical activity and sedentary behavior; the Mobility Assessment Tool-short form (MAT-sf): a computer animated questionnaire assessing self-reported lower extremity function and mobility (35;36); the Short Performance Physical Battery (SPPB): a widely utilized method of assessing lower extremity function that includes standing balance tasks, usual gait speed over 4 meters, and a repeated (five) sit to stand task (37); and Respiratory Sinus Arrhythmia (RSA): an assessment of parasympathetic nervous system activity measured using an Actiwave Cardio unit (38). Gait spatiotemporal characteristics, (e.g., stride length, stride time, stride width, single/double support time), during usual and fast pace walking will be assessed using a GAITRite instrumented mat (39).

Randomization

Eligible participants will be randomized to one of the three treatment arms at the end of baseline testing using a stratified (by wave) block randomization scheme. Participants will be asked to return for follow-up (FU) visits at the end of 6 (FU6) and 18 months (FU18).

YMCA Staff Training

The overarching goal of this training is to provide the YMCA staff with a skill set that will allow them to become independent of the CLIP-II study staff. The ongoing involvement of the CLIP-II staff after the first 6 months of the intervention is a necessary component of the study to ensure intervention fidelity consistent with the research goals of the study.

The YMCA staff training will occur in 3 stages. Initially, YMCA staff will receive 12 hours of instruction and practice sessions over a six-day period. Training includes: introduction to the study investigators and staff, CLIP-II study design and protocol; an overview of the nutrition philosophy and approach to weight loss and information resources; group education and facilitation tools, techniques and strategies; walking and strength training

theory, goals, and progression, and safety monitoring and event management; and instruction on data management duties and participant retention strategies. The training will be delivered by the study's behavioral specialist, RD, and the two principal investigators (APM, WJR). Because the YMCA prefers shorter, multiple day trainings vs. full day trainings, the training format will be delivered in six 1-2.5 hour sessions. To ensure all key personnel involved in research with human participants understand ethical principles and guidelines for protection of human research subjects, YMCA staff will be required to complete and submit the basic Collaborative IRB Training Initiative (CITI) program certification to the project manager prior to the start of intervention. All YMCA staff leaders are certified in Cardiopulmonary Resuscitation (CPR).

The second phase of training will involve the weekly WL content and performance monitoring. CLIP-II staff trainers (RD or Behavioral specialist) will be present at each WL group meeting during the first 8 weeks to monitor content delivery. The YMCA staff will meet weekly for 1 hr with the behavioral specialist and the RD for the first 6 months of the study. This time will be spent reviewing participants' data (e.g., adherence issues, percent WL, AT and RT progressions) and potential or known barriers (e.g., caregiving, traveling, illness or injury, etc.) towards WL and/or physical activity. YMCA staff will be trained on session content, methods to facilitate group dynamics, and interpersonal skill development. YMCA staff receive both the session handouts and an outline that highlights what to focus on with suggestions in ways to facilitate topics of discussion. Flip charts will be used as a medium to deliver key points of session content.

The weekly one-hour training or "briefing" meetings between YMCA staff and CLIP-II training staff will prepare YMCA staff for upcoming session content and delivery, allow CLIP-II staff to collect data documents and files for data entry, and review and problem-solve any safety, program compliance, and retention issues. This routine continues until all 36 program content sessions have been covered. In addition, the CLIP-II staff RD, Behavioral Specialist and principal investigators will be available on an as needed basis to address study protocol, safety, or retention issues that require immediate attention.

In CLIP-II, group leader skills will be evaluated primarily as a means to 1) provide feedback to YMCA intervention staff; 2) provide on-going training and development; and 3) ensure reliability and consistency in session presentation across all waves of the study. For the first six-months, group leaders will receive a minimum of three evaluations. Thereafter, a minimum of two evaluations will occur during the second six-months of the study, and at least one during the last six-months. The CLIP-II Behavioral Specialist and RD are the team members primarily responsible for monitoring and providing this feedback.

YMCA Staff Evaluation

YMCA staff will be evaluated on ten key skills that should be applied to every group weight loss session. The ten skills, rated on a 5-point Likert scale (5 = excellent, 4 = very good, 3 = good, 2 = fair, 1 = poor), are defined below:

1. Performance during the checking-in process (e.g., weigh-in, reaction towards participants' weight progress, and use of appropriate feedback).
2. How well they engage participants in session discussion (use of linking skills, engaging questions or comments).
3. Use of active listening to generate the most appropriate responses and questions (observance of body language and word choice).
4. Use of open-ended questions instead of always using closed-ended questions that cause participants to give one-word answers.

5. Allowing adequate time for discussion or problem-solving (ideally, the group will be in discussion or reflection for 80-90% of the time).
6. Creating an emotionally and physically safe environment that invites discussion and prevents accident or injury in the classroom.
7. The ability to accept participants' responses without judgment. This includes being aware of physical and emotional reactions during active discussion.
8. How well staff keep the group focused on the topic of the day (e.g., the ability to get the group back on task; keeping the session information and interactions flowing in the right direction).
9. Allowing time for thinking and reflection after a question is asked and avoiding use of the staff members' personal experiences in their responses.
10. The quality of summarizing; that is, ensuring that participants understood the key points of the session and their goals for the upcoming week. Also, did staff members allow sufficient time for participants to write down their reflections and goals?

Study Interventions

Weight Loss—All three treatment arms will receive the same weight loss intervention. This 18 month weight loss intervention is divided into three 6-month phases: intensive (months 1-6), transition (months 7-12), and maintenance (months 13-18). During the intensive phase participants will meet at the YMCA for 3 group sessions and 1 individual session per month. Group sessions taper off to 2 and then 1 per month for the subsequent phases with individual sessions scheduled as needed. All sessions have a scheduled duration of 60 minutes. The approaches to weight loss and nutrition are based on recommendations provided by The 2010 Dietary Guidelines for Americans by the U.S. Department of Health and Human Services, and the National Cholesterol Education Program Therapeutic Lifestyle Changes (TLC) Diet for High Cholesterol from the National Institutes of Health. Weight loss program content was modeled after previous successful WL interventions (LookAHEAD (40), CLIP (10)) that focus on self-regulation. The primary treatment objectives of the WL intervention are to decrease caloric intake in a nutritionally sound manner to elicit a 0.3 kg/week weight loss in the intensive phase and a total weight loss of 7-10% body mass. The aims of the transition phase depend on the individual whilst the focus moves towards weight maintenance for the maintenance phase (12-18 months). For the three study arms, no specific physical activity goals are provided except for the AT and RT programs described below. However, participants are encouraged to seek ways to increase spontaneous physical activity such as taking the stairs instead of the elevator, parking farther away from destinations, standing, washing dishes, and other household chores. We provide additional details on the WL intervention below.

Calorie goal: The calorie goal for individuals with a starting weight of <250 lbs is 1200-1500 kcal/day and for those >250 lbs it is 1500-1800 kcal/day with < 30% calories from fat for all individuals. These recommendations are consistent with recommendations from the Academy of Nutrition and Dietetics and the American Diabetes Association. During the first 6 months of the study, participants focus on how to control food portions and count calories within their assigned "budgets" while practicing various behavioral tools, techniques and strategies for weight control. During months 7-18, the emphasis is placed on portion control for weight loss or maintenance with the gradual addition of information on how to improve the quality of food choices.

Self-monitoring: For self-monitoring, participants will be asked to track calories and fat grams daily to ensure that they are within their assigned budgets. They will be provided tracking books that include space for documenting foods or beverages consumed, amount consumed, and the calories and fat from each. Participants will be encouraged to weigh themselves at home periodically in addition to the regular weigh-ins obtained by staff at weekly, bimonthly or monthly group meetings. Both the dietary tracking and exercise monitoring reports are reviewed by the YMCA study staff. These reports are reviewed more critically by the study RD and Exercise Physiologist/Behavioral Specialist on a weekly basis mainly as a check of intervention fidelity and safety (e.g., protein intake).

Protein: Due to body compositional changes associated with aging including loss of skeletal muscle and bone, we felt it prudent to reinforce the importance of minimum protein nutrition in our study population. The current U.S. Recommended Daily Allowance for protein for adults is 0.8 g/kg. In fact, as suggested by Chernoff (41) and Layman (42), the drop in rate of whole body protein turnover to 20% or less by age 70, warrants an even higher protein/kg body weight of exogenous protein of approximately 1.0 gram or more. Therefore, in CLIP-II we set the study goal at a minimum of 0.8 g/kg with the aim to counsel to a goal of 1.0 g/kg. We acknowledge that the higher number is a better minimum standard; however, it has been our observation that the behavioral challenges associated with free living older adults attempting to incorporate protein at this level on a weight reduction diet are difficult. In our dietary counseling, 0.8 g/kg is simply our recommended starting point. Participants who begin showing trends of not meeting the minimum protein intake (< 0.8 g/kg), as assessed by weekly tracking, are encouraged to track their protein intake more closely. This evaluation and intervention is made and subsequently monitored by the study RD (BAN).

Behavioral Strategies: The CLIP-II weight loss intervention is grounded in Social Cognitive Theory and the group dynamics literature; it uses self-regulation for portion control and eating mindfully rather than habitually. To do this, participants will record their daily food and fluid intake throughout the 18-month intervention. They will be shown how to accurately calculate food intake by measuring, weighing, and approximating using measuring cups, spoons, food scale, or other items such as a tennis ball or deck of cards. At the end of each week, participants will reflect on their past eating behaviors by averaging their weekly calorie and fat gram intake. In addition, they will answer a question regarding their satisfaction with their eating behaviors from that particular week on a 4-point Likert scale (0 = not satisfied; 3 = very satisfied). Although participants are provided with a calorie range based on their baseline weight (less than 250 lbs = 1200-1500 kcals; ≥250 lbs = 1500-1800 kcals), participants gain insight by averaging their weekly caloric and fat gram intake to a more specific caloric range that will allow them to lose about 1-2 lbs per week. YMCA group leaders will facilitate discussions focused on ways to meet their long-term weight goal of 10% and short-term goal of 1-2 lbs each week in both a larger group setting or in private when a participant weighs-in at the start of the group WL sessions. If a participant consistently loses more than 1-2 lbs per week, the YMCA staff will consult with the study's dietitian to modify intake. If a participant is not losing 1-2 lbs a week or is struggling to reach their 10% goal by 6-months, the YMCA staff will consult with the behavioral specialist to determine how to overcome weight loss barriers (e.g., motivation/ prioritizing, health, caregiving, accuracy of food/drink intake, etc.). The YMCA staff use the study's RD and Behavioral Specialist less as they gain efficacy with their knowledge and facilitation skills.

Aside from monitoring food and fluid intake, participants will also monitor their weight, thoughts and emotions, and support systems towards their weight loss and physical activity efforts. Although participants weigh in during all 36 group weight loss sessions, they will be encouraged to weigh themselves at least once a week, particularly when the frequency of

weight loss sessions with the YMCA staff decrease from once a week, to every other week, and finally to once a month. Participants will record their weekly weight and compare it to their average caloric intake for that particular week. This approach helps to create awareness of what caloric intake range it will take to not only lose, but also maintain weight. In addition, participants become aware of their thoughts and feelings that influence their weight loss efforts. Such behaviors might include: reaching for comfort foods while feeling anxious, eating when not hungry due to boredom or habit, etc. This awareness allows participants to slow down the process of making a decision (i.e., to give in to craving or postpone it) instead of reacting to their thoughts and feelings. Furthermore, participants will identify their support systems to help keep them motivated to lose the weight and meet their physical activity goals. These support systems range from YMCA staff, group members, RD, Behavioral Specialist, family/friends, physicians, and other healthcare professionals.

In addition to self-monitoring weight, participants will be asked to come up with other ways to find successes (e.g., recognizing reductions from waist line, smaller sizes in clothing, emotional or physical changes, mobility improvements, etc.). The YMCA staff will facilitate these discussions as participants talk about what works and what does not work for them. Other topics that group weight loss sessions will highlight are motivation, discretionary calories, accountability, managing cravings, addressing weight loss and activity barriers, portion control, food quality (MyPyramid/MyPlate), and ways to self-monitor thoughts, emotions, and behaviors related to weight loss and physical activity behaviors. All of this is will be done in a systematic manner and facilitated through group-mediated discussions by the YMCA staff. Below is an outline of what a typical weight loss session entails. The intervention manuals will be made available on-line at the completion of the study.

Session Outline

1. Sharing of progress (10-15 minutes)—the group leader welcomes the participants and begins by asking them to share thoughts about their progress over the past week or month. Thoughts may include their progress with goals, barriers and how they overcame them, or praise (something positive that they have noticed such as an increase in energy).
2. Presentation of topic (1-2 minutes)—the facilitator wraps up/summarizes the key thoughts and transitions into the topic of the day. Facilitators are encouraged to present the topic of the day in a unique and interesting way.
3. Facilitated group discussions (25-30 minutes)—The group leader guides the participants in an interactive discussion of the topic or behavioral strategy for that session. Participants are asked to participate in several ways: helping the group define and relate to the topic, giving examples related to the topic, problem solving, and actively listening and responding to ideas/thoughts of other group members. The use of flipcharts and participant session handouts help to guide discussions.
4. Summary/Take-aways (5 minutes)—The group leader summarizes the key points of the session with the assistance of the participants and answers any questions.
5. Mindfulness Reflections (5 minutes)—After each group session, participants reflect upon the key points of the session using the Mindfulness Reflections handout located as the last page of each session. Participants are encouraged to sign each other’s goal section of the Mindfulness Reflection page as a way to hold one another accountable to the week’s upcoming weight loss goals.

Aerobic Training + Weight Loss

Aerobic training will be individualized by YMCA intervention staff following American College of Sports Medicine (ACSM) recommendations and occurs 4 days/week. The primary mode of aerobic training is walking on an indoor cushioned track at the YMCA. All sessions will be supervised by YMCA staff and monitored using the Fitlinxx software described above. The stimulus component of the sessions shape towards a goal of 45 minutes/session with a walking intensity of 12-14 on the Borg RPE Scale (20). We will use RPE to measure exercise intensity in both exercise groups. Although heart rate is a well-known objective measurement of intensity level, it does not serve this population well. First, arrhythmias and atrial fibrillation are common in older adults. Also, certain medications may affect heart rate creating bradycardia or tachycardia. This population is at higher risk for such conditions compared to an active, normal weight population of their age, making it challenging to prescribe a heart-rate intensity goal. We have found that some overweight/obese participants find it challenging and frustrating to find their pulse. RPE provides a subjective measure that can be taught to the participant so that, with some practice, they can determine the difference among the intensity levels (i.e., light, moderate, hard). Participants will be carefully instructed on how to judge their level of intensity through an initial experiential exposure to the RPE scale. During this orientation, participants will be asked to describe how their body is reacting to different intensity levels as they perform their specific exercise (e.g., Can you feel how hard your heart is beating, how hard you are breathing, and how your muscles feel right now? Could you talk comfortably while walking at this pace? Could you hum/sing while walking at this pace?). In the AT group, participants will be told to increase or decrease their walking speed to adjust their RPE to a moderate intensity. The YMCA staff will assist in monitoring participants' RPE by walking with participants, educating them on RPE, and showing them the RPE scale during their walk to determine the level of intensity. As participants show improvements in cardiovascular fitness, staff will continue to challenge participants to maintain an RPE of moderate intensity.

Resistance Training + Weight Loss

Participants randomized to the resistance training intervention will also train 4 days per week to ensure the time devoted to RT and AT are comparable. The stimulus component of the sessions will be shaped towards a duration of 45 minutes, including both the weight lifting and rest periods between sets or exercises. We will use Cybex resistance machines with weight stacks that are instrumented with the Fitlinxx hardware. Individual orientations will be performed and all sessions will be supervised by YMCA staff and monitored using the Fitlinxx software. Participants will complete 8 exercise machines within this time frame. For the RT sessions the goal for intensity level is an RPE of 15-18. Starting resistance for the machines is determined from the 1RM testing at the initial orientation session. The RT program will progress gradually to allow time for the musculoskeletal system to adapt to this new activity and for the participant to learn the new exercises. Intensity will increase progressively from 40-50% of 1RM with 1 set of 10-12 repetitions in week 1, to 50-60% of 1 RM with 2 sets of 10-12 repetitions in week 2, and 70% of 1RM with 3 sets of 10-12 repetitions in weeks 3-12. From week 13 onwards, the intensity will increase to 75% of 1RM. To avoid the need for regular 1RM testing and mimic a real-world application of the program, from week 13 onwards, participants will perform 2 sets of 10-12 repetitions, followed by a third set in which the goal is to complete as many repetitions of the exercise as possible. Once the participant completes >12 repetitions in the third set for two consecutive training days the resistance will be increased to ensure that there is progressive overload of the musculoskeletal system. We will use RPE in a manner similar to that of the AT group, except the RT group intensity goal is hard, not moderate (RPE 15-18). As described above, the weight lifted is progressively increased with the expectation that the participant will be at this RPE goal.

To assist with recovery time, participants follow a Day 1 and Day 2 schedule. Day 1 consists of the following RT machines: leg press, hip adduction, hip abduction, calf extension, seated-row, pec fly, shoulder press, rotary torso. Day 2 consists of: leg extension, leg curl, lateral pull down, seated chest press, lateral raise, arm curl, triceps extension, and abdominal crunch. Participants are instructed to perform the full range of motion for the concentric movement in 0.5 seconds and then 2.0 seconds for the eccentric phase.

Participants' physical activity progress will be measured in several different ways. The RT group will receive feedback from their YMCA staff interventionist in the form of verbal encouragement, checking proper form, and RT progression. The FitLinx system provides participants in the RT group with immediate feedback on their effort for each machine they use, including completing the prescribed number of sets, repetitions, and weight as well as completing the full range of motion. Participants in the AT will receive direct feedback in the form of encouragement from their YMCA staff interventionist. While on the track, staff will provide verbal support, monitoring of RPE, and assistance with walking progression and goal-setting. Setting walking goals and having participants meet their minute goal is motivating and rewarding. At various intervals throughout the training, the FitLinxx system will provide congratulatory feedback when the participant reaches a training milestone, e.g., lifting 100,000 lbs, reaching a walking distance milestone. Therefore, both exercise groups will receive regular feedback during the study.

Web-Site Data Management System

The CLIP-II Study will use an intervention web-site and a web-based intervention tracking system that provides access to data and information central to the integrity and conduct of the intervention. This system is based on an interactive web-user interface built with Adobe® Cold Fusion®, Version 10 (Adobe Systems, San Jose, CA, USA) with a Microsoft SQL Server 2008 (Microsoft Corporation, Redmond, WA, USA) database. SAS 9.3 and SAS/IntrNet® (SAS Institute Inc., Cary, NC, USA) are used for dynamic reports. The web-site and tracking system have two broad goals: to create a platform for monitoring treatment fidelity and to provide study staff with a tool to assist in the delivery and management of the intervention with participants. The system will enable study staff to dynamically monitor attendance and training progression. Reports provide both the mean (± 90% CI) and medians (Q1 and Q3) for each variable and generate results by individual clinic site and aggregated across sites. Other valuable reporting features of the tracking system are the capability to generate attendance and study status reports, e.g., medical leave, withdrawn from study. The FitLinxx system training data will be uploaded on a monthly basis facilitating tracking and reducing staff burden related to data entry. The tracking system can generate tabular and graphical displays of individual participants' physical activity behavior over time so that the CLIP-II staff can monitor study progress. Group level reports can also be generated for weekly staff meetings. An additional feature of the website is that it provides on-line access to participants' baseline medical and functional profiles to enhance staff/participant interactions and to allow for the tailoring of the AT and RT interventions.

Statistical Analysis

The primary comparisons will be between physical activity + WL (the average effect of AT + WL and RT + WL) and WL alone (as a one degree-of-freedom contrast) for 400MWT (seconds) and between AT + WL and RT + WL on knee extensor muscle strength (Newton meters). In these analyses, the alpha will be set at 0.025 to maintain an experimentwise error rate of 0.05. Secondary outcomes include measures of physical function, body composition, CVD risk factors, health-related quality of life, and self-reported mobility. For these analyses, we will make a Bonferroni adjustment for the pairwise comparisons. In exploratory analyses, we will test for interactions between the treatment and factors such as

race, gender, and time (6-, 18-month follow-up). Between-group comparisons will be made by mixed-model repeated measures analysis of covariance with a subject random effect to account for the fact that multiple measurements within a participant over time are not independent. Covariates used in the analysis of end points will include gender (as a fixed effect), YMCA site and wave within each site (as random effects), and the baseline (pre-randomization) value of the end point being analyzed. All tests of hypotheses and reported P values will be two-sided. In the primary analyses, all randomized subjects will be included in their original study group regardless of the final mode of intervention or the extent of compliance with the study protocol; that is, the primary analysis will be an “intent to treat” analysis. Because differences in attrition rates among the study arms may complicate the analysis of the primary outcome measures, attrition rates across the study arms will be compared. If a particular arm has a markedly higher dropout rate, we will attempt to identify baseline covariates that predict attrition in secondary analyses. If such covariates can be identified, the analyses of outcome measures may need to be stratified on these covariates to decrease bias in secondary analyses. We will use multiple imputation techniques as sensitivity analyses to account for missing data.

Power Calculations

We have used data from CLIP for the 400MWT and the OPTIMA study for muscle strength to estimate standard deviations and correlations within subjects. These result in assumed standard deviations of 36 seconds for the 400 MWT and 26.3 Nm for maximum strength. The effect of 20 seconds for 400MWT was proposed by Kwon and colleagues (43). The 20% effect (of 80 Nm = 16 Nm) on muscle strength as assessed by knee extensor torque is based on our judgment. An average knee strength of 80 Nm in the target population was assumed based on work from our lab (44) that showed an average knee strength of about 55 Nm for women and 105 Nm for men. Note, however, that in a previous study (45) we observed an 18.5 to 19.5% effect over 12 weeks. We feel confident that we will have at least a 20% effect over 18 months. As we are delivering the intervention in groups rather than to individuals, we have accounted for this in our power calculations. The “design effect” is the ratio of variances comparing a simple randomized design to a cluster design and is 1+ICC(n-1) where n is the size of each group and ICC is the intra-class correlation coefficient (46). The design effect is also the ratio of effective sample sizes for designs where the subjects are randomized independently compared to a group-randomized design (46). Participants will be treated in three successive waves across 4 sites with a total of 84 participants in each wave—21 at each site. Using n=7 and ICC=0.0200 (from CLIP) we calculate that the design effect is 1.12. Therefore, we need a sample size 1.12 times larger due to the effect of clustering. This effect has been incorporated into the sample sizes presented below.

As indicated previously, the two primary outcomes will be tested at α=0.025 (two-sided). Using the above assumptions and with 84 participants in each treatment, we would have 91.0% power to detect a main effect of treatment on the 400MWT and 87.5% power for the strength outcome (maximum knee extensor torque).

Discussion

While prolongation of life is an important public health goal, as important is that the life gained is of high quality with preservation of the capacity to live independently and function well (47). The presence of CVD is a major cause of disability in older adults (2;48). The significance of CVD as a risk factor for morbidity and mobility disability is significant since over 80 million Americans have one or more types of CVD and the number of at-risk older adults is increasing (1). Despite recent improvements in the prevention of CVD-related mortality and morbidity in older adults, coronary heart disease, stroke, and congestive heart

failure remain the conditions that are most frequently associated with morbidity and physical disability (24;49).

There also exists a cluster of metabolic complications collectively called the metabolic syndrome (MetS) (50). Individuals with MetS are at increased risk for both progressive atherosclerosis and heart disease (51). An estimated 43.5% of those 60-69 yrs and 42% of those 70+ yrs of age currently have MetS (52). The significance of MetS is underscored when one considers the prevalence of obesity in the United States (53). Obesity is a significant risk factor for frailty and mobility disability (54;55). The links between MetS, obesity, and mobility disability are strong since added weight compromises ambulation (56) and overall physical function (55;57-59).

Regrettably, there is very limited access to prevention programs that address the threat posed by mobility disability among older adults that have CVD or MetS (9;60). Although structured cardiac rehabilitation fills a niche in the management of these conditions, what is needed are community-based partnerships to discover practical, sustainable, and economically viable approaches to safely implement physical activity and weight loss interventions at the population level (61). Therefore, the focus of the CLIP-II study is the preservation of mobility in older, obese adults with CVD or MetS, since the loss of mobility is a precursor of disability in activities of daily living (62), and the inability to perform mobility related activities marks a serious decline in functional health, conferring increased risk of institutionalization and death (37;63;64). CLIP-II will compare WL alone to AT+WL and RT+WL to elucidate the independent and additive effects of RT or AT with WL on physical function and CVD risk factors.

The rationale for treating obesity in older adults stems from a body of research demonstrating that WL interventions, which usually include both caloric restriction and increased physical activity, can reverse many adverse health outcomes (65). Even modest reductions in body weight produce beneficial effects on hypertension (66), glucose intolerance (67), and hyperlipidemia (68). The Diabetes Prevention Program (DPP) (69) dramatically illustrated the ability of WL, through a combined dietary and physical activity intervention, to prevent disease onset; the lifestyle intervention decreased the incidence of diabetes by 58% as compared with a placebo control group. Two recently completed randomized control trials (10;70) showed that improvements in physical function are superior when WL and exercise are combined. However, in the management of cardiovascular risk factors, WL alone continues to be recommended by clinicians and practiced by people of all ages. Nevertheless, concerns exist that WL may have adverse health effects for older adults. Certainly, unintentional WL frequently portends serious health problems from the array of diseases that can result in muscle wasting or cachexia (71) and WL may have deleterious effects on bone mass (72), an effect linked to the decline in lean body mass that occurs in parallel to a decline in fat mass (73-75). However, physical activity and specifically RT, can have a number of therapeutic effects that may serve to alleviate these concerns.

Sarcopenia, a term that describes the loss in lean body mass with advancing age (76), is closely linked to functional decline and disability in older adults (77-79). This age-related decrease in muscle mass is associated with a decline in strength (80-82). Among older adults, the loss of muscle strength and/or mass has been associated with functional decline and disability (83-85), falls (86), hip fractures (87), and mortality (88). Fortunately, older adults and even the “oldest old”, show positive adaptations to both short-term and long-term RT, including improvements in muscle size and strength (89-91). Importantly, RT appears to be more effective at preserving lean mass than AT (92). Latham and colleagues (91) concluded that progressive RT improves muscle strength and physical function, both of

which have a profound impact on the daily life of older adults. Likewise, Ades and colleagues (93;94) argued strongly for RT among patients in cardiac rehabilitation since most household activities, such as carrying groceries, cooking, cleaning, and climbing stairs, depend more on strength compared to aerobic exercise capacity (94).

One reason that AT is combined with caloric restriction in WL is the energy costs of the activity; however, there may be unique advantages of RT. In a recent review (95), the observation was made that the caloric deficit of RT was comparable to the deficit observed during AT (96). More important, in a concise summary of this literature, Wolfe (97) suggested that even small increases in muscle mass can have a significant effect on daily energy expenditure. It also appears that AT and RT are equally effective at modifying risk factors for CVD and MetS, including improvements in glucose tolerance (98), glucose metabolism (99), and lowering fasting and oral glucose tolerance test insulin values (100), but recent evidence indicates that the benefits of RT may actually be superior to AT for glycemic control and blood lipids (101;102), total body fat mass (103), and blood pressure (104;105). Finally, there is evidence that RT increases or preserves bone mineral density (BMD) and bone mineral content (BMC) in middle-aged and older adults (106-108).

This study will provide the first large scale randomized controlled clinical trial to evaluate the effects of diet-induced WL on mobility in obese, older adults with CVD or MetS as compared to WL combined with physical activity. The dual primary outcomes will be the 400MWT and muscle strength. Because uncertainty exists about the best approach for promoting WL in older adults due to concerns with the loss of lean mass, the design also permits a contrast between AT+WL and RT+WL on muscle strength. Consistent with CLIP, our WL intervention will target a protein intake of 0.8 g/kg body mass/day. Reasons to consider RT+WL for older adults include: 1) the central role of muscle loss and decline in strength in mobility disability (109); 2) the underappreciated role of RT in cardiovascular health (110); 3) the influence of muscle mass on both resting and total energy expenditure as well as fat mass (97;111) and bone health (106); and 5) the potential value of RT for improving mobility on tasks that depend heavily on the vertical movement of the center of mass (e.g., stair climbing) (112;113). In fact, Eves and Plotnikoff (114) have emphasized the importance of RT in older diseased populations and stated that “we need to discover practical, sustainable, and economically viable ways to safely implement RT at the population level.”

There is an urgent need to provide physicians and health care professionals with concrete recommendations on lifestyle interventions to preserve mobility in obese, older adults with CVD and/or MetS, and to develop community infrastructures for the delivery of such services. The CLIP-II study addresses this need and increases the translational significance of our previous work by having the interventions delivered exclusively by community partners with our staff as trainers and advisers for desired behavior change. Our translational partnership is with the YMCA, an organization that has the personnel, equipment, and facilities needed to provide WL, AT, and RT programs for this target population across the country.

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Table 1

Inclusion and Exclusion Criteria

Inclusion
• **Residence:** community dwelling men and women from the county of interest
• **Age:** between 60-79 years
• **Activity Status:** low levels of physical activity (less than 60 minutes of moderate intensity structured physical activity each week and occurs in no less than 10 minute blocks)
• **Adiposity:** BMI ≥28 and <42
• **Medical Criteria:** documented evidence of an MI, PCTI, chronic stable angina, cardiovascular surgery (coronary artery or valvular heart disease) or an ATP II diagnosis of metabolic syndrome
• **Mobility Disability:** disability defined as self-reported difficulty with walking ¼ mile, climbing stairs, lifting and carrying groceries, or performing other household chores such as cleaning and yard work
• **Stability of Residence:** does not plan to move out of the county of residence for the duration of the study
• **Agreeableness:** willing and able to participate in all aspects of the trial
• **Consent:** willing to give consent and sign an informed consent/HIPAA authorization form
Exclusion
• **Severe Symptomatic Heart Disease:** evidence of unstable angina, symptomatic congestive heart failure, or exercise induced complex ventricular arrhythmias
• **MI or cardiovascular procedure within the last 3 months**
• **Blood pressure:** a resting blood pressure >160/100mmHg
• **Blood glucose:** a fasting blood glucose ≥140mg/dL, diagnosis of type 1 diabetes, or diagnosis of type 2 diabetes and on insulin therapy
• **Severe Systemic Disease:** diagnosis of Parkinson's disease, chronic liver disease (cirrhosis, chronic hepatitis, etc), systemic rheumatic condition (rheumatoid arthritis, psoriatic arthritis, Reiter's disease, systemic lupus erythematosus, etc), end stage renal disease or other systemic diseases or abnormal laboratory values which would preclude participants from safely participating in the protocol or impair their ability to complete the study
• **Cancer:** active treatment for cancer other than non-melanotic skin cancer
• **Hearing or Sight Impairments:** significant visual or hearing impairments that cannot be corrected and results in the inability to use the telephone or hear normal conversation
• **Psychiatric Illness:** bipolar depression or schizophrenia (defined as self-reported treatment for these conditions), currently receiving lithium or neuroleptics
• **Participation in Other Trials:** currently participating in or planning to participate in another medical intervention study
• **Alcohol Intake:** consuming more than 14 alcoholic drinks per week or alcoholism
• **Functional Limitations:** unable to walk unassisted
• **English Literacy:** unable to speak or read English
• **Working (employment):** ≥21 hours per week
• **Clinical Center Staff Evaluation:** judged to be unsuitable for the trial for any reason by the clinic staff. A participant can be excluded prior to randomization because of some unspecified health problem that has been identified that would put the patient at risk for adherence or retention. These cases are discussed with a recruitment team consisting of the person who has raised the concern, an MD, and the study PIs.