Official Title: Weight Management for Adults with Mobility Related Disabilities

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AIMS AND HYPOTHESES

Individuals with mobility related disabilities (MRDs) represent a sizeable and growing segment of the U.S. adult population, with high rates of obesity, and limited options for successful weight management. Obesity in adults with MRDs increases the risk of chronic disease, and may limit the ability to ambulate, either with or without assistive devices (wheelchair, cane etc.), perform transfers (wheelchair users), increase the risk for pressure sores, respiratory problems, carpal tunnel syndrome, and interfere with self-care, and reduce participation in daily activities. Adults with MRDs face numerous barriers to participation in traditional weight management programs including the lack of affordable, accessible transportation to attend on-site meetings or engage in physical activity (PA), lack of accessible recreational facilities with accessible fitness equipment, and difficulty with food shopping and meal preparation. The 2005 Surgeon General's Call to Action to Improve the Health and Wellness of Persons with Disabilities, and numerous subsequent government sponsored reports, have highlighted the need for accessible health promotion efforts to reduce health disparities between adults with and without MRDs. However, a limited number of intervention strategies, specific to weight management in adults with MRDs, have been developed and evaluated. As described in this proposal, our group has evaluated an enhanced version of the Stop Light Diet (eSLD = SLD+portion-controlled meals and low calorie shakes) for weight management in a sample of 126 adults with MRDs. The eSLD simplifies meal planning, food shopping and meal preparation. When prescribed in conjunction with a monthly behavioral intervention, delivered in an individual home visit format, the eSLD resulted in significantly greater weight loss when compared with a conventional meal plan diet at 6 mos. (eSLD = -4.1%, meal plan = -2.3%, p=0.02) and 12 mos. (eSLD = -6.2%, meal plan = -0.6%, p=0.005). Although these results are encouraging, alternative strategies to improve outcomes and to deliver weight management to larger numbers of adults with MRDs in a cost-effective manner, are warranted. Thus, the proposed two-arm randomized trial will compare weight loss (6 mos.) and maintenance (18 mos.) between an individual home visit intervention (*IH*), using an enhanced version of the protocol used in our previous trial, and an intervention delivered remotely via video conferencing to groups of overweight/obese adults with MRDs in their homes (*GR*). Both interventions will be delivered in a format that eliminates the transportation barrier, prescribed an eSLD, and will self-monitor body weight using electronic scales. The *GR* arm will include group behavioral counseling and group PA delivered remotely via video conferencing (Zoom™ software) on a tablet computer (iPad mini) to participants in their homes, and use commercially available web-based applications for self-monitoring/participant feedback for diet (Lose It! software) and PA (Fitbit activity tracker). This approach reduces barriers to both behavioral session attendance and PA, provides timely feedback relative to diet and PA, and promotes interaction and support in a group who are often socially isolated. The *IH arm*, which represents a modified version of the protocol used in our previous trial, will include behavioral counseling delivered during individual home visits, a prescription for self-directed PA, and self-monitoring of diet and PA using conventional paper and pencil self-reports. Both groups will receive identical attention with 2 interventions having the potential for clinically meaningful weight loss, i.e., ≥ 5%. This trial will address the following primary, secondary and exploratory aims.

Primary aim: *To compare mean weight loss between the GR and IH arms across 6 mos.* We expect significantly greater weight loss in the *GR* compared to the *IH* arm.

Secondary aims. *To compare the GR and IH arms on the following: 1) Mean weight loss (0-18 mos.)*; 2) *The proportion of participants* who achieve clinically significant weight loss (≥ 5% from baseline) at 18 mos.; *3) Changes in cardiovascular disease risk factors* (blood pressure, total, HDL and LDL cholesterol, triglycerides, HbA1c for diabetics, waist circumference) from 0-6 and 0-18 mos.; *4*) *Changes in quality of life* from 0-6 and 0-18 mos. We expect more favorable changes in all secondary outcomes in the *GR* compared with the *IH* arms. *5)* C*ost and contingent valuation analysis* to compare costs between the *GR* and *IH* arms. Based on our experience with remote delivery for weight management using both group phone (DK76063) and virtual reality formats (DK94833), we expect *GR* to be less expensive than the *IH* arm.

Exploratory aims. *Initial weight loss is highly predictive of longer-term weight loss; therefore, we will examine the influence of the following variables on weight loss at 6 and 18 mos*.: behavioral session attendance, compliance with the recommendations for diet (energy intake, number of meals /shakes, servings of fruits/vegetables), PA (min of moderate-vigorous PA, min sedentary time), and self-monitoring of diet and PA, self-efficacy for dietary change and PA, dietary self-regulation, social support for diet/PA, barriers to PA, sleep, and medications.

BACKGROUND/SIGNIFICANCE

Mobility related disabilities (MRDs)-Prevalence/descriptive characteristics. MRDs are the most frequently reported type of disability in U.S. adults (1-6). The estimated prevalence of MRDs in the U.S. varies across surveys due to differences in sampling strategies, definitions of disability, and age ranges reported (7). For example, data from the 2013 Behavioral Risk Factor Surveillance System (BRFSS) indicated the prevalence of MRD was 13% in individuals ≥18 yrs. (1), while the prevalence of mobility limitations in the same age group was 6.1% in the 2011-2014 National Health Interview Survey (NHIS) (3). Data from the U.S. Census Bureau's 2015 American Community Survey indicated 6.6% of adults age 18-64 yrs. reported an ambulatory disability (6), while data from the US Census Bureau Survey of Income and Program Participation (May-August 2010) indicated 12.6% of individuals ≥ age 15 yrs. reported limitations in ambulation (2). Regardless of the variation in prevalence estimates, adults with MRDs represent a sizeable segment of the U.S. population. Increased survival rates from traumatic injuries or premature birth, increased life expectancy for both congenital and acquired disabilities, and the aging of the population, will contribute to future increases in the prevalence of MRDs. The prevalence of MRDs is higher in females, older individuals, ethnic minorities, the unemployed, and in adults with lower levels of education and annual household income (1, 7). Adults with MRDs are less likely to be physically active (8-13), more likely to have poor diet quality (14, 15), higher rates of chronic conditions (16-20), risk factors for chronic conditions (16, 21-24), and an increased risk for all-cause mortality (25, 26), compared with their non-disabled counterparts.

Obesity prevalence/consequences. The prevalence of obesity (BMI ≥ 30 kg/m^2) in adults with MRDs is significantly greater than their non-disabled counterparts (6, 7, 16). However, the *prevalence of obesity* varies by data source, definition of MRD, and the use of self-report or measured height and weight for the calculation of BMI. Similar to non-disabled adults (27, 28), those with MRDs tend to overestimate height and underestimate weight (29) resulting in an

underestimate of obesity prevalence. Self-report data from the 2015 BRFSS survey indicated a higher prevalence of obesity in individuals with (39.9%) compared to those without disability (25.4%) (6). NHIS data indicated a higher prevalence of obesity in those reporting mobility (54.5%) compared with non-mobility limitations (34.5%) (8). The prevalence of obesity in adults with MRDs (≥ 20 yrs.) from the NHANES 1999-2010, using height and weight measured at a mobile clinic, was 50.9% (16). Similar to non-disabled adults, obesity in adults with MRDs is associated with unfavorable chronic disease risk factors (higher blood pressure, total cholesterol, glucose, CRP and lower HDL-cholesterol) (16), and contributes to higher rates of cardiovascular disease and other chronic conditions (19). The combination of MRDs and obesity may limit the ability to ambulate and perform transfers (wheelchair users) (30), increases the risk for pressure-sores (4, 31), respiratory problems (32), carpal tunnel syndrome (33), and interferes with self-care, reduces quality of life, and increases health care expenditures (34-36).

Health promotion. The 2005 Surgeon General's Call to Action to Improve the Health and Wellness of Persons with Disabilities, and subsequent reports from agencies including the Institute of Medicine (37), the National Council on Disability (38), Healthy People 2010 and 2020 (39, 40), and the Patient Protection and Affordable Care Act (2010) (41) suggest that *disability* and *health* are not mutually exclusive, and have highlighted the need for accessible health promotion efforts to prevent secondary conditions and reduce health disparities among individuals with disabilities. In response, programs addressing physical activity (PA) (42-44), healthy eating, stress management, and the development of supportive interpersonal relationships, such as Living Well with a Disability (45-47), Healthy Lifestyles for People with Disabilities (48), and others (31, 49, 50) have been implemented. These programs have reduced the prevalence of secondary conditions (51) and health care expenditures (46), increased general health behaviors (47), increased self-efficacy for a variety of life skills (49, 50), and increased PA (42, 44). However, few interventions have specifically addressed weight management, or compared the effectiveness of different weight management strategies, in adults with MRDs.

Weight management. A 2014 systematic review (52) identified 15 weight loss trials in adults with mobility-impairing neurological and musculoskeletal conditions. The majority of these trials (60%) involved older adults with osteoarthritis and reported weight loss that failed to exceed the ≥ 5% threshold defined as clinically meaningful (53). Similar results were shown in trials including ambulatory and non-ambulatory, and both younger and older individuals with MRDs. For example, Rimmer et al (54) completed a 9 mo. trial in 102 overweight/obese adults (age~47 yrs.) with MRDs (~63% non-ambulatory) randomized to 1 of 3 groups: personalized PA plan, personalized PA+nutrition plan, or non-intervention control. The nutrition plan included increased consumption of fruits, vegetables and fiber, and reduced consumption of fat, but did not specify a level of energy intake. Interventions were delivered by individual phone calls conducted by health coaches assisted by a web-based computer support system. Participants received weekly calls to develop/implement a PA or PA+nutrition plan, monitor progress, and resolve barriers. Call frequency was reduced to 2/mo. (mos. 5-7) and 1/mo. (mos. 8-9). Results from the 91 participants completing the trial indicated a small weight reduction in the PA only group (-2.4%, $p<0.05$), while weight was unchanged in the PA+nutrition group (-0.6%, $p > 0.05$), and significantly increased in controls (+3.1%, $p <0.05$). Chen et al. (55) evaluated a 12 wk. weight loss intervention that included an energy reduced diet, increased PA, and weekly on-site

group behavioral counseling in 16 overweight/obese adults with chronic spinal cord injury (SCI, ≥ 1 yr., age ~ 44 yrs., 100% non-ambulatory) with a 12 wk. follow-up. Results indicated small, but statistically significant weight loss at both 12 (-3.8%, $p< 0.0004$) and 24 wks. (-3.0%, $p<0.01$). Betts & Froehlich-Grobe (56) recently reported -4.8% weight loss in a 20-wk. trial in a small sample (n=10) of adults (age ~49 yrs.), with MRDs (80% non-ambulatory) using the Diabetes Prevention Group Lifestyle Balance program delivered by weekly group phone calls (1-12 wks.), with 3 additional calls over the following 8 wks. Radomski et al (57) reported a median weight loss of 5.7% in a small sample of adults (n=10, age ~ 53 yrs.) with SCI (100% non-ambulatory) following a 12 wk. exercise and education intervention consisting of individualized diet and exercise recommendations, weekly on-site group nutrition and exercise education, and twice weekly exercise sessions (both group and individual). Our group recently published results from a 12 mo. trial (6 mos. weight loss, 6 mos. maintenance, NIDRR 133G090230, M. Saunders, PI) in a sample of 126 low income (~83% unemployed), overweight/obese (BMI ~ 44 kg/m^2), adults (age ~ 51 yrs.) with MRDs, 71% used wheelchair or an assistive device for walking (58). Participants were randomized to a behavioral weight loss intervention that included monthly home visits by a health educator and a reduced energy conventional meal plan, or an enhanced Stop Light Diet (eSLD; 1,200-1,500 kcal/d), self-monitoring (logs), and optional PA. The Stop Light Diet, developed for use in children (59), categorizes foods by energy content corresponding to a traffic light, i.e., red (eat sparingly), yellow (eat moderately), and green (eat freely). We enhanced the SLD by encouraging daily consumption of 2 portion-controlled meals (≤ 300 kcal each), 2 high volume low energy shakes (100 kcal each), and ≥ five 1-cup servings of fruits/vegetables. Mean percent weight loss was significantly greater in the eSLD compared with the meal plan groups at 6 mos. (eSLD = -4.1%, meal plan = -2.3%, $p = 0.024$) and 12 mos. (eSLD = -6.2%, meal plan = -0.6%, $p = 0.005$). The percentage of randomized participants achieving ≥ 5% weight loss at 6 mos. did not differ by group (eSLD = 36%, meal plan = 23%, $p = 0.15$). However, the percentage of participants losing ≥ 5% of baseline weight at 12 mos. was significantly higher in the eSLD (36%) compared with the meal plan groups (13%, $p = 0.003$).

Barriers to weight management. The lack of affordable, accessible transportation represents a significant barrier for both attending on-site meetings required in traditional weight management programs, and for engaging in PA (30, 60-62). Dr. Nary and colleagues completed a web-based needs assessment survey of 182 practitioners who provide services to adults with physical disabilities through Centers for Independent Living (63). Transportation was reported as the most frequent barrier to health care by 89% of respondents, while 78% and 65% reported their consumers could use information on diet and nutrition, and weight monitoring, respectively. Adults with MRDs may have a limited understanding as to what constitutes a healthy diet, and experience difficulty with food shopping and meal preparation (64-66). A survey of 1,096 women with disabilities indicated that ~33% experienced barriers to achieving optimal nutrition. Being too tired to cook was most frequently reported (~55%) (67). In addition to barriers to PA experienced by the general population, e.g., lack of time and motivation, adults with MRDs are confronted with inaccessible recreational facilities, lack of affordable and accessible fitness equipment, and poor infrastructure (lack of sidewalks and curb cuts, narrow/damaged sidewalks etc.) (62, 68-70). As described in detail in subsequent sections, remote or home visit delivery, and the use of a diet, that simplifies food shopping and preparation, will eliminate/reduce these barriers in the proposed interventions.

RATIONALE

Premise/summary of significance/impact. The premise of this study is that adults with MRDs represent a sizeable and growing segment of the population, with a high prevalence of overweight/obesity, and limited empirically based options for effective weight management. The majority of weight loss trials (60%) that have included both ambulatory and non-ambulatory adults with MRDs have used 1-group, pre-post designs, in small samples (n ≤ 16), over relatively short time frames (≤ 20 wks.) (55-57). These trials have shown unimpressive results in terms of both mean weight loss, and the percentage of participants losing ≥ 5% of baseline weight. In contrast to previous work, results from our 12 mo. trial in adults with MRDs suggested the potential effectiveness of a simplified dietary approach (eSLD) combined with monthly, home visit behavioral sessions (58). Although these results are encouraging, alternative strategies to provide weight management to greater numbers of adults with MRDs, potentially improve outcomes, and reduce costs are warranted. The proposed two-arm randomized trial will compare weight loss (6 mos.) and maintenance (12 mos.) between an individual home visit intervention (*IH*), using a protocol similar to our previous trial, and an intervention delivered remotely via video conferencing to groups of overweight/obese adults with MRDs in their homes (*GR*), and utilizing available technology for self-monitoring and increasing PA. We expect clinically meaningful weight loss in both intervention arms, i.e. ≥ 5%, with significantly greater weight loss in the *GR* arm. If successful, the *GR* intervention has the potential to be implemented in a variety of settings to provide effective weight management for adults with MRDs at a reasonable cost.

STUDY TYPE AND DESIGN

We propose a 2-arm randomized trial (group remote (*GR*) vs. individual home visit (*IH*)) using intent-to-treat principles, to compare body weight following weight loss (6 mos.) and maintenance (18 mos.) in overweight/obese adults with MRDs. interventions will be delivered by trained health educators and will include behavioral sessions, a reduced energy diet (eSLD), increased PA, and self-monitoring of weight using electronic scales. The *GR* arm will be delivered via video conferencing (Zoom™ software) on a tablet computer (iPad mini) with self-monitoring of diet and PA using commercially available technologies. Participants in the *IH* arm will self-monitor diet and PA using paper and pencil records. Due to COVID-19, all Cohort 1 IH intervention meetings will be held by phone per CDC social distancing recommendations. Participants are asked to send pictures of the tracking sheets to the health educator prior to the phone meeting. The primary outcome (weight) will be assessed during home visits at baseline (mo. 0), following weight loss (6 mos.), during (12 mos.) and at the end of maintenance (18 mos.). Our group has experience with all proposed intervention components and outcome assessments from previously completed (44, 58, 71, 78, 88, 89) or on-going trials (DK83589, HD79642). The following design attributes, described in detail subsequently, ensure the scientific rigor of the proposed trial: *1)* Randomized design with equal allocation to groups, with allocation assignment concealed. *2)* Adequate statistical power to address the primary aim. *3)* Strategies to ensure the recruitment of sufficient participants to achieve our desired sample size. *4)* Retention/incentive strategies to reduce loss to follow-up. *5)* Controlling for attention by maintaining equal contact in both groups. *6)* Secondary/exploratory aims to maximize the use of data, e.g., analysis to examine the impact of process variables/participant characteristics on

weight change. *7)* The use of a theory-based intervention delivered by trained health educators. *8)* Delivery of both intervention arms by the same health educator to cohorts of participants to minimize potential health educator effects. *9)* Procedures to ensure intervention fidelity. *10)* Assessments completed by trained staff blind to intervention arm. *11)* Evaluation of staff inter-rater reliability for all physical assessments (2-3 times/yr.). *12)* A novel assessment of diet to improve data quality. *13)* Structured interviews at both 6 and 18 mos. to gather information that might be useful in improving the intervention and/or implementing the intervention in settings serving individuals with MRDs.

SUBJECT CRITERIA

Primary care physician (PCP) clearance will be required of all participants. To enhance generalizability, individuals receiving treatment for prevalent chronic diseases, or with risk factors such as hypertension, tobacco use, lipid abnormalities, DM2, etc., will be allowed to participate with PCP clearance.

Inclusion criteria: 1) A permanent MRD (≥ 1 yr. duration) requiring the use of a wheelchair or resulting in the inability to walk 0.25 miles without stopping, with or without assistive devices, as documented by 7 items from the NHANES Physical Function Survey (113), and confirmed by the PCP. Individuals with MRDs, associated with, but not limited to spinal cord injury (SCI), spina bifida, multiple sclerosis, cerebral palsy, stroke, muscular dystrophy, and lower limb amputation will be included. *2)* Age 18 and older. Weight management for younger individuals requires different behavioral strategies. *3)* Body mass index (BMI) >25 kg/m^2 and body weight ≤400lbs. Individuals with a BMI <25 kg/m^2 are not overweight, and individuals over 400lbs may require more aggressive weight loss interventions, e.g., surgery, medication, etc. We are aware of the difficulty in the assessment of BMI, and issues related to the use of BMI for classifying overweight/obesity in individuals with SCI or amputations (114-116). Thus, in questionable cases we will defer to the PCP regarding eligibility based on weight status. *4)* Wireless internet access in the home.

Exclusion criteria: *1)* Unable to participate in light-to-moderate intensity PA, e.g., seated aerobics, resistance exercise, or physically unable to use the iPad. *2)* Participation in a structured weight loss or exercise program in the previous 6 mos. These proximal experiences may influence this trial. *3)* Current exercise (> 3, 30-min bouts of planned exercise/wk.) *4)* Not weight stable (±4.6 kg) for 3 mos. prior to intake. *5)* Unwilling to be randomized. *6)* Pregnancy during the previous 6 mos., currently lactating, or planned pregnancy in the following 18 mos. *7)* Serious medical risk, e.g., cancer, recent heart attack, stroke as determined by the PCP. *8)* Current use of antipsychotics, untreated depression, or other psychiatric illness that would preclude participation in weight management, as determined by the PCP. Psychiatric co-morbidity may limit the benefits from health education. Addressing psychiatric issues is beyond the scope of this study. *9)* Cognitive, visual, or hearing impairments that may interfere with compliance to the study protocol as determined by the PCP. *10)* Adherence to specialized diets, e.g., food allergies, vegetarian, macrobiotic. *11)* Binge (Binge Eating Scale) (117) or other eating disorders (EATs-26) (118). *12)* Living in the same household as another study participant.

INTERVENTION DESCRIPTION

Orientation. Health educators will conduct home visits (~90 min) with all participants prior to initiating the intervention to provide a detailed description of both the dietary (eSLD) and PA components of the intervention and delivery formats (remote or home visit). All participants will be provided with an iPad mini tablet computer and electronic wireless scales. Access to non-study related materials, e.g., web browsing, app store etc., will be blocked on all iPads until completion of the study. iPads for the *GR* arm will be pre-loaded with the video conferencing (Zoom™ software), the Lose It! and Fitbit applications, and behavioral session materials (described later). Participants in the *IH* arm will be provided with hard copies of the intervention materials and will be shown how to self-monitor diet and PA using hard copy records. During orientation, both intervention arms will receive a tutorial on the use of the iPad and electronic scales, and procedures for making digital photographs of meals, to be used in the assessment of dietary intake (described in assessment section). Participants in the *GR* arm will be oriented to the video conferencing software and both the Lose it! and Fitbit apps/devices used for self-monitoring diet and PA. Time will be allotted for practice and questions. Per inclusion/exclusion criteria, those unable to perform these tasks will be ineligible. Tutorials describing trouble shooting for common technical problems, e.g., internet connectivity, data entry using Fitbit, Lose It!, will be loaded on the iPad. Technical issues can also be resolved during behavioral sessions, or by contacting research staff by phone or email. The *GR* arm will be provided with an HDMI adaptor allowing video conference sessions to be displayed on a larger TV screen, if desired. Reminders regarding upcoming behavioral/PA sessions etc., or to prompt participants in the *GR* arm who are non-compliant with the study protocol, will be sent via the iPad.

*Diet (0-6 mos.)***.** The original SLD, developed for use in children (59), categorizes foods by energy content. The SLD is easy to understand and implement when compared with a meal plan diet. Meal plan diets require choosing appropriate foods from an unlimited array of options, making it difficult to prepare a nutritionally adequate reduced energy diet on a consistent basis. We will "enhance" the Stop Light Diet (eSLD) using a combination of commercially available portion-controlled meals (PCMs- meals/shakes) and fruits and vegetables. PCMs include nutritional information on the label (calories, fat, protein etc.) making it easier to adhere to specific energy and nutrient prescriptions. Participants will be asked to consume a minimum daily total of 2 meals (~200 to 300 kcal each, saturated fat ≤ 3g), 3 shakes (~100 kcal each), five 1-cup servings of fruits/vegetables, and ad libitum non-caloric beverages. Participants will be asked to purchase PCMs (meals/shakes) from a list meeting these caloric/fat requirements, as well as fruits/vegetables, and non-caloric beverages. The recommended PCMs are affordable and available at most grocery stores at a cost of $2-$4 each, which may be an important consideration for individuals with MRDs where household income is often low (1). Dr. Ptomey, RDN will assure all diets are energy and nutritionally adequate, and will follow the AND Evidence Library Nutritional Guidelines for individuals with SCI (121).

Diet (7-18 mos.). During weight maintenance participants will be encouraged to continue using the eSLD, or transition to a meal plan, or combination eSLD/meal plan diet. At the end of the weight loss phase (mo. 6) counseling will include tips for complying with a conventional diet, i.e., meal planning, food shopping, meal preparation, portion control, etc.

Energy intake-weight loss (0-6 mos.). Energy intake will be prescribed at 1,200-1,500 kcal/d for women and 1,500-1,800 kcal/d for men as recommended by current weight management guidelines from the American Heart Association/American College of Cardiology/The Obesity Society (53). We are aware that these recommendations were not designed specifically for adults with MRDs, and may be inappropriate for individuals with SCI due to variable reductions in energy expenditure associated with level and duration of injury, adrenergic function, and fat-free-mass (123-126). We will estimate energy needs for individuals with paraplegia (27.9 kcal/kg/d) and tetraplegia (22.7 kcal/kg/d) as recommended by Cox et al (127) with upward adjustment for individuals with pressure ulcers as suggested by the AND Evidence Library Nutritional Guidelines for individuals with SCI (121). The proposed levels of energy intake provide a reasonable starting point, and will be adjusted based on the observed weight change and participant feedback regarding hunger/satiation. Participants for whom additional weight loss would be contraindicated, e.g., BMI of ≤ 22 kg/m^2 or losing > 20% of baseline weight, will be placed on a weight maintenance diet at any time during the intervention. Those who continue to lose weight will be referred to appropriate health professionals/agencies, and may be dismissed from the trial if necessary.

Energy intake-weight maintenance (7-18 mos.). Energy intake for weight maintenance will be based on the RMR equation of Mifflin-St Jeor (128) adjusted for activities of daily living (RMR x 1.4-1.6) as participants will have a routine PA program. As described for weight loss, we will use the energy need estimates of Cox et al (127) and the AND Evidence Library for individuals with SCI (121). In our experience, some participants not meeting their weight loss goals (0-6 mos.) will volitionally attempt additional weight loss during maintenance (7-18 mos.); which will not be encouraged or discouraged. Participants experiencing weight gain will be counseled to improve compliance with the diet and PA protocols. We have successfully employed this approach for prescribing energy intake for weight loss/maintenance in previous trials in adults with MRDs (58), and in adults with (73, 89), and without IDD (71).

Behavioral session/frequency/duration (Table 1). *GR arm*. Behavioral sessions (10-15 individuals) will be conducted using video conferencing (Zoom^{TM} software) 2/mo. during weight loss and the first 6 mos. of maintenance (mos. 0-12), and 1/mo. during the last 6 mos. of maintenance (mos. 13-18). *IH arm*. Behavioral sessions will be conducted with individual participants during home visits. Behavioral sessions in the IH arm will follow the same frequency as the GR arm and will occur 2/mo. during weight loss and the first 6 mos. of maintenance (mos. 0-12), and 1/mo. during the last 6 mos. of maintenance (mos. 13-18). Meeting duration will be 45-60 min. for both groups across the intervention. Due to COVID-19, all Cohort 1 IH intervention meetings will be held by phone per CDC social distancing recommendations. Participants are asked to send pictures of the tracking sheets to the health educator prior to the phone meeting

Behavioral session content-weight loss. Behavioral sessions will be identical between groups and will include a review of participants self-monitored data for diet, PA, and weight recorded since the previous session, a question to generate discussion regarding diet and PA, a lesson on a weight management topic, and an experiential learning assignment requiring problem solving or the practice of behavioral strategies, to be completed prior to the next session. Lessons will also include topics such as cost and time efficient strategies for food shopping and

preparation, specific strategies for increasing daily PA and decreasing sedentary time, and maintaining adequate hydration, eating away from home etc., with examples and discussion questions specific to individuals with MRDs.

Behavioral session content-weight maintenance. Behavioral sessions during maintenance will focus on planning and following a meal plan diet, with or without incorporation of PCMs, and cardinal behaviors for successful weight maintenance, such as self-monitoring, regular PA, eating on weekends/vacations, and controlling energy intake on special occasions and holidays, etc.

PA prescription. We will target 150 min./wk. of moderate-intensity aerobic activity (3-6 METs), and 2 d/wk. of resistance training (RT) for intervention arms as recommended for adults with/without disabilities by the American College of Sports Medicine (129) and the U.S. Department of Health and Human Services (130). This level of exercise is well within the capability of adults with MRDs, including those with SCI (131, 132); however, participants unable to complete 150 min. /wk. will be encouraged to exercise to their individual capacities. We recognize that 150 min./wk. is less than the 300 min./wk. recommended for weight management (133). However, given the limits to the levels of energy expenditure, from what will be predominantly upper extremity exercise, and the increased potential for overuse injuries with higher volumes of exercise (134), we felt that 300 min./wk. would be unrealistic in this sample. Aerobic exercise will progress from 60 min/wk. (3 d/wk., 20 min./d) to 150 min. /wk. (5 d/wk., 30 min./d) at the beginning of mo. 4, and remain at 150 min./wk. through mo. 18. RT (3 sets/8-10 reps, 4-5 exercises) using resistance bands (8 levels) provided by the study (Theraband, Akron OH) will be prescribed. RT, as well as a stretching regime, will focus on scapular stabilizers and posterior shoulder muscles, and major lower extremity muscles for participants with this capability. During the first 2 wks., participants will use a band that provides a resistance allowing completion of 3 sets with minimal fatigue. Resistance will be increased to the next level at wk. 3, and increased subsequently, when participants are able to complete 3 sets of 8-10 reps with minimal fatigue. The negative health consequences of sedentary behavior (135, 136) may be especially relevant for individuals with MRDs (62, 137). Therefore, strategies for decreasing sedentary time, such as increasing sit-to-stand transitions and standing time, in those who are able, and increasing non-exercise upper extremity activity, e.g., daily light activities for wheelchair users, will be recommended.

PA delivery. *Participants in the GR arm* will be asked to attend 30-min group exercise sessions conducted using video conferencing (Zoom™ software) 2 x/wk. during weight loss (0-6 mos.) and 1x/wk. during maintenance (7-18 mos.) Exercise sessions will be conducted in conjunction with behavioral sessions when schedules coincide. In such cases the total session time (behavioral+exercise) will not exceed 60 min. Group sessions will include a warm-up, 20 min. of moderate intensity aerobic activity, 10 min of RT, and stretching and cool-down. Exercise sessions will include individuals with a range of functional abilities, e.g., wheelchair users/ambulatory. Dr. Greene, an adapted PA specialist, will modify activities, as necessary, to insure they are applicable for all participants. Our trial in adolescents with IDD demonstrated the feasibility of the home-based group video conference approach for delivering exercise to groups varying widely in physical abilities (preliminary studies). Group sessions will provide 40 minutes of the 150 min./wk. recommendation for aerobic activity. To assist participants in both study

arms in meeting the 150 min./wk. goal, all group sessions will be video recorded and uploaded remotely to participant's iPads where they can be accessed for use at any time. In addition, information regarding exercise resources available from the National Center on Health, Physical Activity and Disability, Craig Hospital, and the Christopher and Dana Reeve Foundation will be pre-loaded on the iPad of participants in all study groups. *The IH arm* will be asked to complete the exercise recommendations on their own, as is customary in standard care weight management. Participants in the *IH* arm will receive brief (5-10 mins.) support/problem solving phone calls (1x.wk.) and iMessages (1x/wk) from the health educator an approach that has been shown to increase exercise in adults with MRDs (44).

OUTCOME MEASURES

Weight/Height: Ambulatory participants. Weight will be measured in duplicate with a portable, calibrated digital scale. (Model #PS6600, Befour, Saukville, WI.). Standing height will be measured in duplicate with a portable stadiometer (Model #IP0955, Invicta Plastics Limited, Leicester, UK).

W*eight/Height: Wheelchair users*. Weight will be measured in duplicate using a portable calibrated, digital wheelchair scale (Model MX420, Befour, Saukville, WI.). Participant weight will be calculated as participant + chair weight minus chair weight. Digital photos of the chair will be obtained at baseline to ensure that the same chair (and accessories) is used for subsequent assessments, thus negating the need for repeated assessments of chair weight. Supine height will be assessed with a metal tape with legs outstretched and feet in dorsiflexion. If contractures prevent assessment of supine height, we will estimate total height based on knee height as described by Froehlich-Grobe et al (87).

Waist circumference will be assessed using the procedures described by Lohman et al. (144). Three measurements will be obtained with the outcome recorded as the average of the closest 2 measures.

Blood pressure will be obtained with an automated sphygmomanometer (DinaMap ProCare 100, General Electric) using the NHANES blood pressure protocol (145).

Quality of life will be assessed with the SF-36E, a version of the SF-36 (147, 148) in which the PA section has been modified for individuals with MRDs (149). The SF-36E has acceptable psychometric properties (149).

Demographics. In addition to basic demographics/health history, we will assess type/duration of MRD, living arrangement (alone/with others), employment status, and level of responsibility for food shopping and preparation.

Cost analysis (Dr. Lee). A cost analysis may be considered premature. However, this may be the only opportunity we will have to complete such analyses, which can be done at minimal expense, in a large sample of adults with MRDs. Based on a previous weight loss trial (71) we expect higher costs associated with health educator travel required in the *IH* arm. Mean weight loss at 6 mos. will serve as our measure of effectiveness. We expect greater weight loss and lower costs in the *GR* compared with the *IH* arms (150). We will then calculate the cost per additional kg of weight loss. Contingent valuation analysis, in which participants express preferences for programs, will be used to examine the perceived worth of the *GR* and *IH* formats at 6 and 18 mos.(151). Conditional logistic regressions, with adjustments for clustering by health educator, will be used to analyze how differences in client attributes, anticipated costs, and anticipated gains affect preferences for the 2 intervention arms. The cost perspective for all

analyses will be societal. We will collect data on both program and participant costs prospectively. The gold standard for measuring cost is a time study based on a validated flowchart (152, 153). We will validate flowcharts for both study arms and use time studies to estimate health educator time, and program records to measure cost of supplies. Participant time, valued at the local median hourly wage, is also a component of intervention costs (154) as time devoted to an intervention cannot be used for work or leisure. These costs may be half of the total costs (155, 156) and will be gathered via survey (157).

Energy Expenditure of Remote Exercise Sessions (optional). Energy expenditure of the remote sessions will be assessed in a volunteer sample using a previously validated portable, open-circuit indirect calorimeter (Cosmed, Italy) which measures breath-by-breath ventilation, expired oxygen, and carbon dioxide. The flow turbine will be calibrated using a 3.0-L syringe. The lightweight (~1.5 kg) portable system will be attached by a harness around the waist and shoulders of the participant before each assessment. During exercise sessions, participants will breathe into a facemask that directs air into the unit housing the O2 and CO2 analyzers. Data will be retrieved for analysis via a serial port interface and software provided with the calorimeter, and aggregated over 20-second epochs for the calculation of 1-min averages. MET levels will be age corrected using the Schofield equation (88) as recommended by McMurray et al (89). Participants will be asked to wear wrist ActiGraphs during the assessment for comparison of physical activity levels between devices.

SAMPLE SIZE, STATISTICAL METHODS, AND POWER CALCULATION

Power/sample size. The mean 6 mo. weight loss in our completed trial in adults with MRDs, using a protocol similar to the *IH* arm in the proposed trial, i.e., eSLD and behavioral counseling delivered by monthly home visits, was 5.5 kg (58). This does not reach the 8.5 kg (~5%) average 6 mo. weight loss defined as clinically meaningful by current weight management guidelines (53). We expect 6 mo. weight loss in the *GR* arm, which includes weekly group counseling and group exercise, will reach or exceed 8.5 kg. To detect a clinically meaningful difference of 3 kg (133, 176-180) in 6 mos. weight loss between the *IH* and *GR* arms, with 80% power and a type 1 error rate of 0.05, assuming a common standard deviation of 6 kg, will require 64 participants/group. Secondarily, we will have 70% power to detect a 3 kg difference in a completer analysis with an attrition rate of 20%; however, we expect attrition will be lower based on experience (71, 78, 181), and our use of retention/incentive strategies to minimize loss to follow-up. Thus, a sample of 64/group will provide adequate power for both our primary intent-to-treat analysis with imputed missing data (power = 80%) and our secondary completer only analysis (70%).

Analysis plans. *Primary aim* will use a 2-sample independent t-test *to compare 6 mo. weight loss between the 2 intervention arms* in both an intent-to-treat, and completer only analysis. Procedures for handling missing data are described below. We will examine the impact of baseline characteristics (age, sex, race/ethnicity, weight, type of MRD, wheelchair use, employment status, living situation, food shopping and preparation) on weight change using linear regression controlling for treatment. We will examine the main effects of each of these variables, as well as the potential interaction effect with treatment.

Secondary aim 1, a *comparison of 18 mo. weight loss*, will mirror the analysis for the primary aim. We will use a 2-sample t-test to compare weight change (0-18 mos.) between the 2 intervention arms. Mixed linear models will be used to compare weight change from 0-18 mos.

between intervention arms controlling for intervention arm and baseline weight. We anticipate greater loss to follow-up over time; however, we expect data to be missing at random. Under this assumption, mixed linear models will provide unbiased treatment comparisons. We will assume an autoregressive correlation structure of the dependent variable (weight) over time, and evaluate the potential for time-by-treatment interactions.

Secondary aim 2, a between arm comparison of the proportion of participants achieving ≥ 5% weight loss (0-18 mos.) will be evaluated using a chi-square test. Participants without an 18 mo. weight will be classified as not meeting the ≥ 5% weight loss goal. We will also examine the impact of baseline characteristics, as previously defined, on 18 mo. weight loss using logistic regression.

Secondary aims 3 and 4, between arm comparison of change in risk factors and quality of life (0-6 and 0-18 mos.) will be evaluated using a 2-sample t-test.

Exploratory aims will examine the influence of the following on weight loss at 6 mos.: behavioral session attendance, compliance with the recommendations for diet (energy intake, number of meals/shakes, servings of fruits/vegetables), PA (min of moderate-vigorous PA, min sedentary time), self-monitoring of diet and PA, sleep, and medications assessed over the time period of interest, i.e. (0-6 and 0-18 mos.) and the change in self-efficacy for PA and dietary change, dietary self-regulation, social support for diet/PA, and barriers to PA from 0-6 mos. We will examine the influence of these factors as covariates, in addition to treatment, on weight loss at 6 mos. As we have 128 observations with a rule of thumb of at least 30 observations for each variable in the model, judicious model selection will be completed as we can only expect to identify ~4 variables that are related to weight loss in a single model. First, we will assess if these variables differ by treatment at the 0.10 level and if they do they will be considered for future modeling. If in a two-factor model, the variable and treatment have a potential interaction at the 0.10 level that interaction will be considered for future modeling. Subsequently, the main effects and interaction effects along with treatment will be examined in a joint model. Given the pitfalls of forward and backward selection, we will utilize best subsets criteria based upon Mallow's Cp statistic to produce the most parsimonious and least biased model of weight loss at 6 months. This should allow us to identify what variables most highly influence our outcome along with treatment and/or the mechanism(s) of action that are impacting weight loss. We will do the same for weight loss at 18 months, as this measure may have similar or different variables that impact this long-term outcome.

Missing Data/ imputation. All analyses will be based on intent-to-treat principles and missing data for analyses of the primary aim will be imputed; therefore, oversampling for attrition is not needed. We will determine if the proportion of participants lost to follow-up differs by treatment. If so, we will determine if there are differences in demographic characteristics (sex, age, baseline weight, p <0.05) between completers and those lost to follow-up. If missing data are related to treatment and/or these demographic characteristics, we will use model based multiple imputation; otherwise, we will use traditional multiple imputation. Statistical analysis will be completed with SAS version 9.4 or higher.

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