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Weight management for individuals with intellectual and developmental disabilities: Rationale and design for an 18 month randomized trial

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Abstract

Weight management for individuals with intellectual and developmental disabilities (IDD) has received limited attention. Studies on weight management in this population have been conducted over short time frames, in small samples with inadequate statistical power, infrequently used a randomized design, and have not evaluated the use of emerging effective dietary strategies such as pre-packaged meals (PMs). Low energy/fat PMs may be useful in individuals with IDD as they simplify meal planning, limit undesirable food choices, teach appropriate portion sizes, are convenient and easy to prepare, and when combined with fruits and vegetables provide a high volume, low energy dense meal. A randomized effectiveness trial will be conducted in 150 overweight/obese adults with mild to moderate IDD, and their study partners to compare weight

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loss (6 months) and weight maintenance (12 months) between 2 weight management approaches: 1. A Stop Light Diet enhanced with reduced energy/fat PMs (eSLD); and 2. A recommended care reduced energy/fat meal plan diet (RC). The primary aim is to compare weight loss (0–6 months) and weight maintenance (7–18 months) between the eSLD and RC diets. Secondarily, changes in chronic disease risk factors between the eSLD and RC diets including blood pressure, glucose, insulin, LDL-cholesterol, and HDL-cholesterol will be compared during both weight loss and weight maintenance. Finally, potential mediators of weight loss including energy intake, physical activity, data recording, adherence to the diet, study partner self-efficacy and daily stress related to dietary change will be explored.

Keywords

intellectual and developmental disability; weight management; pre-packaged meals; physical activity; weight maintenance; Stop Light Diet

1.0. Introduction

The rate of obesity among individuals with intellectual and developmental disabilities (IDD) is higher than in the general population [1–4] and higher in those living in the community compared with those living in institutions. Community dwelling individuals with IDD likely adopt physical activity [1, 5, 6] and dietary characteristics [7–9] of the general population which promote weight gain [10–12] and its associated co-morbidities [6, 13–23]. The severity of obesity in individuals with IDD has been recognized [24]; however, the limited data for weight loss in this group using energy reduced meal plans (~1.5 to 3% from baseline) are discouraging and are considerably less than National Heart Lung and Blood Institute guidelines (10%) [18] and that observed in weight loss trials in the general population [25]. Lack of success may be due in part to the difficulty of teaching, administering and maintaining compliance with a typical energy reduced meal plan diet among individuals with IDD.

Preliminary to this study our group conducted a 12-month pilot weight loss trial to evaluate an alternative dietary strategy in 73 individuals with mild to moderate IDD (BMI = 37.0 ± 8.4, age =31.6 ± 9.6 yrs., 56% female) [26]. Approximately 30% of participants lived at home, while others were in supported living consisting of 1–4 residents. Energy restriction (500–700 kcal/day below requirements) was achieved using an enhanced Stop Light Diet (eSLD). The SLD, originally developed by Epstein [27] has been successful for weight loss in children [27–29] and may be appropriate for use among individuals with IDD. The SLD categorizes foods by energy content: green (low energy: consume freely), yellow (moderate energy: consume in moderation) and red (high energy: consume sparingly). SLD was enhanced by encouraging consumption of high volume, low energy, pre-packaged meals (PMs: entrees/shakes) and 5 fruits/vegetables each day to control portion size and reduce both energy and fat intake. Results for the 66 participants who completed the study (10% loss to follow-up) demonstrated weight loss of 6.4%, and 8.7% from baseline at 6 and 12 months, respectively. These levels of weight loss are similar to the results from the successful Diabetes Prevention Program [25] and exceed the 3% minimum weight loss

suggested as clinically relevant in the American College of Sports Medicine Position Stand "Appropriate physical activity intervention strategies for weight loss and prevention of weight regain for adults,"[31]. These encouraging results led to the development of the current trial designed to compare both weight loss and weight maintenance between the eSLD and a recommended care (RC) meal plan diet in adults with IDD.

2.0. Methods and materials

2.1. Overview of study design

One hundred sixty overweight/obese adults with mild to moderate IDD and their study partners will be randomized to an 18 month effectiveness trial with 6 months weight loss and 12 months weight maintenance to compare two approaches for weight management [eSLD vs. RC] [32]. Following the 6-month weight loss period, both groups will be encouraged to either continue the weight-loss protocol with the eSLD or RC or to continue at a level of energy intake designed to provide weight maintenance. Both groups will be asked to wear a step counter and record steps walked, with an eventual goal of 150 minutes per week. The primary aim is to compare weight loss (months 0–6) between the eSLD and RC diets. Secondary aim one is to compare weight maintenance (months 7–18) between the eSLD and RC diets. Secondary aim two is to compare changes in chronic disease risk factors including blood pressure, glucose, insulin, and LDL and HDL-cholesterol between the eSLD and RC diets both weight loss and weight maintenance. Secondary aim three is to explore potential mediators of weight loss including energy balance variables (energy intake, physical activity), process variables (self-monitoring, dietary and physical activity adherence) and psychosocial variables (study partner self-efficacy and daily stress related to dietary change).

2.2. Participant eligibility

Caregivers play an important role in the lives of individuals with IDD and provide assistance with food shopping and meal planning and preparation. Therefore a caregiver for the individual with IDD that is either a parent/guardian, a member of the support staff who assists in their residence, or a person who assists the individual with the purchase of food will be recruited with each participant. We refer to this person as the participant's "study partner," The study partner agrees to participate in each of our meetings with the participant, and to support the participant in following the diet. To enhance the generalizability of our results individuals who use medications for elevated health risks commonly associated with overweight and obesity, such as elevated blood pressure or lipids are not excluded as these conditions are prevalent in individuals with IDD and are likely to be improved with weight loss and increased physical activity. Likewise, individuals who are taking medications that may induce weight gain or inhibit weight loss are not excluded as these medications are frequently prescribed for individuals with IDD. Randomization should insure that medication use is equally distributed across the 2 study groups. Specific participant eligibility criteria are presented in Table 1.

2.3. Recruitment procedures/randomization

An information brochure that describes the project will be mailed/emailed to case managers, service providers and Community Developmental Disability Organizations in the recruitment area. Upon request, meetings with these groups, including potential participants, will be scheduled to allow project staff to present details regarding the project and answer questions. Potential participants will be contacted by a member of the investigative team who is familiar with the sensitive issues regarding recruitment of individuals with IDD. Home-visits will be scheduled to verify eligibility and answer any remaining questions. Written informed consent will be obtained from either the participant (self as guardian) or their legal guardian and their study partner. Randomization, stratified by gender and by living arrangement (i.e., number of participants in a residence) to assure balanced allocations, will be completed after written consent and written physician clearance are obtained. Treatment allocation sequences will be generated by computer software using block randomization with equal allocation to the eSLD and RC groups.

2.4. Intervention components: Diet

2.4.1. Enhanced Stop Light Diet (eSLD)—The original Stop Light Diet (SLD), developed by Epstein [27], is an effective weight loss strategy for children [27–29] as indicated by a Grade 1 ranking (strong, consistent, supporting evidence) from The Academy of Nutrition and Dietetics Evidence Analysis Library [30]. The SLD categorizes foods by energy content: green (low energy: consume freely), yellow (moderate energy: consume in moderation) and red (high energy: consume sparingly). This approach is easy for children and individuals with IDD and their caregivers to understand and adopt. In this study, lists and/or pictures of foods will be provided and are color-coded to the stoplight system for use in meal planning, shopping and snacking. As in the pilot, the SLD will be enhanced (i.e., eSLD) by encouraging consumption of high volume, low energy, pre-packaged meals (PMs: entrees/shakes) with at least 5 fruits/vegetables each day. PMs are effective to control portion size and reduce both energy/fat intake. Participants using eSLD will be taught to shop for entrees with approximately 300kcal or less. The use of PMs consistently demonstrates significantly greater weight loss when compared with conventional reduced energy diets [33–36]. The Academy of Nutrition and Dietetics Evidence Analysis Library indicates Grade I support for the use of PMs in individuals who have difficulty with self-selection of food and portion control [30]. PMs simplify meal planning, food shopping and meal preparation for both individuals with IDD and their caregivers. This may be especially important considering that caregivers frequently have limited formal education, not specific to nutrition, and the rate of turnover among paid caregivers is high [37]. Participants wanting food outside of the PMs plus 5 servings of fruits and vegetables, will be encouraged to use the SLD color-coded food lists to select additional servings of reduced-energy foods. Low-energy, high-volume shakes, which can be consumed as snacks or as a drink with a meal, will be provided by the project (two per day) during the 6-month initial weight-loss phase. The shakes are available in chocolate and vanilla flavors and can be mixed with fruits, diet sodas, flavor extracts, and other low energy items to expand flavor variety. Participants randomized to either the eSLD or recommended care diets who achieve a BMI

of 22 kg/m^2 any time during the weight loss phase will be transitioned to the maintenance level of energy intake.

2.4.2. Recommended care (RC) diet—RC will be a conventional reduced energy, meal plan diet as recommended by the United States Department of Agriculture, Center for Nutrition Policy and Promotion dietary guidelines [38]. Energy intake during weight loss will be reduced to 500 to 700 kcal below daily resting energy expenditure as estimated using the equation of Mifflin-St Jeor [39] multiplied by 1.4 to 1.6 to account for physical activity. It is recognized that this, or any equation for estimating daily energy expenditure, was not developed for use in individuals with IDD and that body composition and energy metabolism among individuals with IDD may differ from those in the general population. However, this estimate should provide a reasonable starting point for prescribing a reduced energy diet. Further adjustments in energy intake will be made in response to weight loss or gain by increasing or decreasing the targeted energy intake. Participants and their study partners will work together to prepare the proper foods in portions appropriate for each participant's energy requirements. Compliance with a conventional meal plan diet requires selecting, purchasing, and preparing appropriate foods from an unlimited array of options, as well as serving a portion size for the appropriate reduction of energy intake.

2.4.3. Energy intake during weight maintenance (months 7 to 12)—During the weight maintenance phase participants will be able to choose if they want to continue to lose weight or work to maintain their weight. Although a participant may choose to continue to lose weight they will no longer be provided PM's (eSLD), fruit/vegetable money (RC), or receive incentives for losing weight. Energy intake for weight maintenance for both the eSLD and RC diets will be estimated using the equation of Mifflin-St Jeor [39] multiplied by 1.6 to 1.8 to account for physical activity. If weight gain is documented during monthly home visits by study staff (section 2.6.4) suggestions will be provided to improve compliance to the prescribed level of energy intake for weight maintenance.

2.4.4. Volumetrics—Both the eSLD and RC diets will employ the "volumetrics" concept (i.e., choosing foods high in volume and low in energy) which has been shown to improve weight loss and weight maintenance [40]. Well-controlled, lab-based studies have repeatedly demonstrated that the weight or volume of food, rather than energy content, determines the degree of satiety, and that individuals tend to eat the same volume of food over time regardless of its energy content [41, 42]. Volumetric strategies to reduce energy intake include increasing water content of meals, either through consumption of water-rich fruits and vegetables or the incorporation of soups, adding more fiber through fruits and vegetables, and fiber-rich grains, and reducing fat content by using low-fat, low-calorie substitutions (e.g., using skim milk instead of whole milk) and using low-fat cooking techniques [43]. For example, the volume of a RC meal of low-fat pasta salad and yogurt could be increased, and energy density decreased by adding vegetables to the salad and fruit to the yogurt. The same strategy can be applied to the eSLD using a single serving PM entree mixed with additional vegetables and a high volume shake blended with fruit for a smoothie.

2.5. Intervention components: Physical activity

Participants will be encouraged to accumulate at least 30 minutes per day of moderate intensity physical activity at least 5 days per week with a target of 150 minutes per week. We are aware that some agencies recommend greater levels of physical activity for weight loss and especially for weight maintenance [31, 44]. These guidelines were written for the general population; however, our experience from the pilot indicates 150 minutes per week is a reasonable target for individuals with IDD. To achieve this goal, participants will walk with a step counter and gradually accumulate ~30 minutes of walking a day. Walking as a recommended mode of physical activity has several advantages. First, it fits easily into the daily routine and work day of most individuals. Second, walking ranks as the top preference for physical activity among individuals with IDD, most likely because it can be done in any amount or intensity, and can be used as a form of transportation [5]. Third, walking can be performed alone or with others if a social component is desired. Fourth, the intensity of walking is relatively easy to control compared to games or sports. Fifth, walking is very safe form of activity with the potential for injury generally limited to soreness or mild strains, sprains, etc. Intermittent activity will be encouraged as it fits well into the work day (i.e. work breaks, lunch time etc.), allows de-conditioned participants to accumulate a greater volume of activity sooner compared to a continuous activity program, and may diminish the perception of fatigue due to the shorter activity time and the rest that occurs between activity bouts. Therefore, intermittent physical activity may be especially well suited for the initiation of a physical activity program for sedentary individuals with IDD.

2.6. Intervention implementation

2.6.1 Participant and Study Partner Training—Both participants and study partners will be trained to implement the intervention and to comply with the study requirements for data reporting. Training will be conducted by study staff during a 60–90 minute home visit conducted at baseline and at a 30-minute home visit at about two weeks after initiating the diet. The frequency and duration of research staff and participant/study partner contact are equal for the eSLD and RC groups across the 18-month study. Training for both the eSLD and RC groups will include information regarding meal planning (energy levels/fat content/ portion size), as well as food shopping and meal preparation. The eSLD group will be introduced to the food color categorization approach of the SLD through a chart provided at baseline training. Participants and study partners will be trained to use the color coded chart to aid in meal planning, grocery shopping, decisions regarding snack foods, and compliance with the diet while traveling and eating away from home (i.e., restaurants, parties etc.). The chart provides a neutral “third party” to facilitate discussions between participants and study partners. For example, the study partner may avoid confronting a participant who makes an inappropriate snack choice with words such as “you shouldn’t eat that,” by instead pointing to healthy snack food items on the chart as a better alternative. Participants and study partners in both diet groups will be taught problem solving/relapse prevention strategies for complying with the diets and the physical activity component of the intervention. Participants and study partners will be instructed how the step counters should be worn (at hip), the counts recorded and the counters reset. Participants and study partners will be instructed to record steps walked and minutes of alternative physical activities on a data

sheet provided by project staff. Participant and study partner training will be conducted by study staff when the diet assignment is revealed (60–90 min), during a 30 min session at about two weeks after the individual initiates participation, and again as needed during regular monthly home visits (section 2.6.2). The frequency and duration of research staff and participant/study partner contact are equal for the eSLD and RC groups across the 18 month study.

2.6.2. Weekly tracking of compliance data—Participants, with assistance from their study partners, will be asked to complete data recording cards that are specific to their study group (eSLD/RC) across the 18 month study. Based on our pilot study it is anticipated data recording and reporting will require approximately 5 minutes per day to complete [26]. Daily data regarding the use of meal plans, the number of PMs (entrees/shakes), fruits, and vegetables consumed and physical activity (pedometer steps: pedometer provided/minutes) recorded by participants and their study partner and weekly totals will be summarized by study staff. Furthermore, any reactive behavior or adverse events will be recorded by study partners and passed onto study staff at home visits. Data cards will be picked up by study staff during monthly ~1 hour home visits conducted across the 18 month study. Monthly home visits are designed to answer questions and problem solve regarding compliance with the intervention and to assess body weight to provide feedback to participants regarding their progress with weight management. Body weight will be assessed with participants wearing a t-shirt, shorts, and no shoes. Data from the weekly tracking sheets will be used for process evaluation, to determine qualification for incentives and to identify areas to be addressed by study staff during subsequent monthly meetings.

2.6.3. Participant incentive—Individuals with IDD are often more able to meet their own expectations, as well as the expectations of others, when participating in a formal incentive system, often referred to as contingency management systems or positive behavior support programs. Participants in these programs earn a modest incentive in the form of cash, special activities or special privileges etc., for completing specific behaviors. The modest incentive provides motivation to meet the goal and receive reinforcement, but is not large enough to be coercive. To improve compliance with the study in the first 6 months, participants with assistance from their study partners, will be asked to record daily consumption of their prescribed meal plan on a pictorial recording form specific to either the eSLD or RC diets. During each monthly meeting study staff will review the records and provide a small monetary incentive (≤ $16.00/month) for recording consumption of foods/beverages consistent with the study diets. Furthermore, monetary incentives ($10.00) will be provided when a participant's BMI is reduced by 1 unit and ($5.00) will be provided for each 100,000 steps recorded. During the weight maintenance period (months 7–18), participants will no longer be paid for recording foods eaten, loss of a BMI point, or steps walked. A flat fee ($20) will be paid for attending each monthly meeting. Participants will have the potential to receive a maximum of ~$560 in incentives over the 18 month intervention.

2.6.4. Behavioral reactivity—Participants with IDD may display behavioral reactivity to either the dietary or physical activity components of the intervention ranging from insistence

that a study partner provide a high calorie snack to refusal to engage physical activity. The incentive programs will be our primary means of preventing reactive behavior; nevertheless, it may occur. If reactive behavior is indicated on weekly reports or in monthly meetings, co-investigators (RS, MS) will offer suggestions for minimizing the problem in the future, such as agreeing on a new approach to negotiating food choices or changes in approaches to shopping or food preparation. Reactive behavior will be noted in monthly meeting notes.

2.6.5. Medical management—Physician clearance via a consent form will be required for participation in this trial. To facilitate medical management, study staff will alert the participant's personal physician, who is responsible for any adjustments in medication necessitated by change in weight (~10%) resulting from participation in this trial. We chose this approach rather than using a dedicated study physician as this system represents how medial management would be conducted outside the constraints of a research trial.

2.7. Outcome assessments

Major outcomes including anthropometrics (weight/height/BMI/waist circumference), blood pressure, blood chemistry and physical activity (accelerometer) will be assessed at baseline, following weight loss (month 6) and at months 12 and 18 during weight maintenance. Blood chemistry will only be assessed if consent is granted by the participant. All outcomes (including blood samples) will be assessed at the participant's home during a single visit by study staff blinded to condition; the same protocol we used successfully in the pilot [26]. Based on the pilot study we estimate these assessments will require approximately 75 minutes to complete with the exception of accelerometry that will be assessed across 7 days. A schedule for all assessments is presented in Table 2.

2.7.1. Anthropometrics (Weight/height/waist circumference/BMI)—Participants will be weighed in a hospital gown between 8 and 10 AM, in duplicate, on a calibrated scale (Model #PS6600, Belfour, Saukville, WI) to the nearest 0.25 kg, following an overnight fast (~12 hours). Standing height will be measured in duplicate with a portable stadiometer (Model #IP0955, Invicta Plastics Limited, Leicester, UK). BMI will be calculated as weight (kg)/height (m^2). Waist circumference, as a surrogate for abdominal adiposity, will be assessed using the procedures described by Lohman et al. [45]. Three measurements will be taken with the outcome recorded as the average of the closest 2 measures.

2.7.2. Blood pressure/blood chemistry—Blood pressure will be measured using a Dinamap automated sphygmomanometer (Pro Care 100, GE HealthCare, Madison, WI) between 8 and 10 AM, subsequent to the assessment of height, weight, and waist circumference. The participant will be seated with the arm bared, supported, and positioned at the heart level. Measurement will begin following 5 minutes of quiet rest. The appropriate size cuff will be used such that the rubber bladder encircles at least 2/3 of the arm. Two measures will be averaged and additional measures will be obtained if those measures differ by more than 5 mmHg [46, 47]. Fasting blood samples (12h overnight fast) for the assessment of blood lipids, glucose, and insulin will be obtained by a phlebotomist experienced in working with individuals with IDD, subsequent to the measurement of blood pressure. Blood samples will be placed on ice and immediately transported to our laboratory

where plasma will be separated by centrifugation for 15 min at 2000g. Plasma will be transferred to cryogenic vials and stored at −70° C for later analysis. Total serum cholesterol and triglyceride concentrations will be measured using an automated analyzer (Du Pont Co), using standard enzymatic techniques. HDL will be measured after removal of VLDL and LDL by precipitation with phosphotungstate [48]. Glucose will be measured using an autoanalyzer (Beckman) and insulin will be measured using a double-label antibody technique [49].

2.7.3. Energy and macronutrient intake—Energy and macronutrient intake is assessed by a 3-day food record (2 weekdays, 1 weekend-day). Participants and study partners are trained (section 2.6.3) to complete the records, and a trained staff member will review the records with the participant and parents using portion guides and food models to obtain more accurate details. The energy and nutrient content of dietary information will be determined using the current version of the Nutrition Data System for Research (NDSR, University of Minnesota; Minneapolis, MN). To assist with counseling on weight loss and maintenance 24-hour multi-pass dietary recalls will be obtained at each monthly client/staff meeting.

2.7.4. Physical activity-accelerometer—Participants will wear an ActiGraph GT1X portable accelerometer (ActiGraph LLC, Pensacola, FL) on a belt over the non-dominant hip for 7 consecutive days (5 week days and 2 week-end days) at each assessment time point. Accelerometer data will be collected in 1-min epochs with a minimum of 12 hours constituting a valid monitored day. Accelerometers will be distributed to the participant on Wednesdays, worn Thursday-Wednesday and returned on Thursdays using pre-addressed and stamped padded envelopes. Study partners will be asked to assist in achieving compliance with the monitoring protocol. The main outcome variable will be the average ActiGraph counts/min over the 7-day period. In addition, the average number of min/day over 7-days spent at various activity levels will be assessed applying the cut-points used in the National Health and Nutrition Examination Survey as described by Troiano et al. [50].

2.8. Process evaluation

We will document and evaluate the program components required to administer the intervention. This information will be important for both future trials and the translation of our intervention to agencies that provide support services for individuals with IDD.

2.8.1. Implementation and reach—We will track the extent to which the intervention was implemented and received by both participants and their study partners. Following initial training, the degree to which study partners feel adequately trained and confident to perform intervention requirements (e.g., develop meal plans, use PMs as part of eSLD, control portion size, assist with data recording, encourage physical activity etc.) will be assessed using a modified version of the study partner self-efficacy scale originally developed by Heller et al. [51]. Study partners will be asked to rate their level of confidence to perform each of the intervention requirements on a 5-point scale (0= not at all confident to 5= completely confident).

2.8.2. Fidelity—We will monitor the extent to which specific program components were implemented as originally planned by examining weekly self-monitoring logs (e.g., dietary intake and physical activity).

2.8.3. External or competing factors—Potential threats to internal validity of the intervention, such as a residence adopting a new weight loss or physical activity program, change in residence or study partner, or any changes in agency policies that may influence diet or physical activity will be tracked by research staff during the monthly home visits. At the same home visit, research staff will also track changes in prescription medications such as anti-hypertensives, psychotropics, diuretics etc., which might influence weight.

2.8.4. Program satisfaction and acceptability—Study partners will complete a 4-point Likert scale (strongly agree to strongly disagree) at 6, 12 and 18 months to assess the acceptability, ease/burden of administration, and perceived usefulness of study staff for the intervention. Focus groups will be conducted with study partners at the end of the study. Focus groups will address whether the program interfered with usual daily routines, level of burden for meal planning and preparation, difficulty staying within the prescribed calorie range, and the appropriateness of the diet and physical activity intervention for individuals with IDD. In addition, we will track the frequency of notations of behavioral reactivity written in the monthly meeting notes.

2.9. Analysis plan and statistical power

Sample demographics and all outcome measures will be summarized by descriptive statistics; means and standard deviations for continuous variables and frequencies and percentages for categorical variables. The primary analysis will be based on the intention-to-treat principle. We will determine if factors such as treatment group, baseline weight, age, gender etc. are associated with the rate of missing data. Data that are missing at random are not problematic when using mixed linear regression and Generalized Estimated Equation Longitudinal models. However, we will also use model based imputation, if deemed necessary, to impute missing data longitudinally and obtain model estimates and inference. Per protocol analysis which will include only participants who complete ≥ 75% of both weekly reports and outcome assessments will be performed to compare between group differences in both weight loss and weight maintenance. All statistical analysis will be conducted using SAS versions 9.2 or higher with a type 1 error rate of 5%.

2.9.1. Analysis plan: Weight Loss—Two sample t-tests will be used to compare differences in weight change (month 6 minus baseline weight) between the eSLD and RC groups. Multiple linear regression will be used to assess the impact of covariates including age, gender, living arrangement, number of care givers, race, ethnicity, baseline weight, energy and fat intake, physical activity etc. while controlling for treatment group. We will also assess the impact of the number of individuals with IDD residing in the home on weight change. Although we will enroll only 1 individual with IDD per home, the number of residents per home may impact the level of adherence, compliance, and loss to follow-up in the trial. The residence per home variable (range 1–4) will be treated as a covariate in all analysis.

2.9.2. Analysis plan: Weight Maintenance—A linear mixed model will be used to evaluate the weight change over 12 months following weight loss (i.e., months 7–18). The group by time interaction will be tested controlling for covariates including age, gender, and baseline weight. A significant interaction would indicate group differences in weight change following weight loss. A contrast will also be performed to determine if there are significant between group differences in weight change over months 7 – 18. Mixed linear models will be used to assess the impact of covariates such as age, gender, living arrangement, number of individuals living in the home, race, ethnicity, physical activity, energy/fat intake etc., while controlling for treatment.

2.9.3. Analysis plan: chronic disease risk factors—Between group changes in chronic disease risk factors including blood pressure, glucose, insulin, LDL and HLD cholesterol will be assessed both during weight loss and weight maintenance using the same analysis strategy described previously for body weight (2.9.1, 2.9.2).

2.9.4. Analysis plan: explore potential mediators of weight loss—Potential mediators for weight loss including energy balance variables (energy intake, physical activity), process variables (data recording, adherence), and psychosocial variables (study partner self-efficacy) [51], daily stress (related to dietary change) [52] will be examined using the approach of Baron and Kenny [53], and further extended by MacKinnon [54] and Brown [55]. Mediation requires satisfaction of the following 4 criteria: 1) significant between group differences in outcome (weight change); 2) significant between group difference for potential mediators; 3) significant association between potential mediators and outcome; and 4) the association between intervention group and the outcome (i.e., intervention effects) must be attenuated by the presence of the mediators in the statistical model. Analysis to satisfy criteria #1 and #2 have been previously described (2.9.1, 2.9.2). To evaluate criteria #3, a sequence of independent linear mixed model equations will be constructed. For each potential mediating variable, we will determine if change in that variable is associated with change in our primary endpoint (weight) using a linear mixed model. For each of the potential mediators satisfying criteria #3, we will proceed to criteria #4. We will create a linear mixed model including the potential mediator and intervention group with a change in weight. An attenuation of the association between intervention group and outcome when potential mediators are included in the model indicates some level of mediation. These steps enable us to determine if full mediation or partial mediation is present. If there are two or more potential mediators after primary mediation analysis a structural equation model will be constructed for the full or partial mediation. If there is only one, then the original linear mixed model used to determine if that variable is a potential mediator will be used.

2.9.5. Analysis plan: process—Monitoring the extent and quality of implementation will prevent “Type III error” in which an intervention that is not fully implemented as planned, is not a true test of the experimental hypotheses [56]. Descriptive statistics will be used to provide a general description of the context in which the interventions are conducted. All focus group session will be moderated by a trained interviewer, audiotaped, and transcribed. In addition, a recorder will take notes to ensure that the transcriptions are

accurate. Focus group data will be coded and organized using ATLAS.ti (version 5.2) software. The codes will be compared and discrepancies will be resolved through discussion among the research staff. Coding will facilitate content analysis of particular topics and the identification of common themes.

2.9.6. Statistical power—Assuming an equal variance for the change in weight over 6 months in both intervention groups of 4.9 kg, 57 participants/group will provide 80% power to detect a between group difference of 2.6 kg using a two-sided two sample t-test with alpha=0.05. In the pilot, attrition was 10% at 6 months. In order to account for greater attrition due to the longer length of the proposed study and to be conservative, we will use an attrition rate of 30%, so we will recruit 150 subjects in total to assure the power of the study.

3.0. Discussion

Individuals with IDD are an underserved group with higher levels of obesity and chronic disease risk than the general population, and have received very little attention for weight management. The limited number of studies on weight management that have been completed in this population have been conducted over short time frames, in small samples with inadequate statistical power, infrequently used a randomized design, and have not evaluated the use of emerging effective dietary strategies such as PMs [60]. In the general population weight loss with interventions employing PMs have been shown to be superior to conventional reduced energy and fat diets [33–36]. PMs may be well suited for weight management in individuals with IDD for those living at home with parents and/or siblings or in supported living environments. Interviews with participants and study partners in the pilot study indicated that convenience of meal planning and preparation was a major consideration in complying with a dietary recommendation. Individuals with IDD and their study partners generally have limited knowledge and skill regarding meal planning, preparation and portion control and are likely to find planning, preparing and serving an appropriate portion size of a conventional low energy/fat diet challenging compared to the use of low energy/fat PMs and shakes, which simply require heating or mixing. Low energy/low fat PMs simplify meal planning, limit undesirable food choices, teach appropriate portion sizes, are convenient and easy to prepare, and when combined with fruits and vegetables provide a high volume, low energy dense meal (i.e., volumetrics). The use of PMs also allows for a variety of dietary choices as there are an ever increasing number of reasonably priced, low energy/fat PMs products available at most grocery stores.

In this trial we will compare weight loss (0–6 months) and weight maintenance (7–18 months) between a conventional reduced energy/fat diet (RC) and a reduced energy/fat diet delivered using an enhanced version of the Stop Light Diet (eSLD). Both arms of this trial provide reduced energy/fat, high volume/low energy density diets (i.e., volumetrics), emphasize consumption of easily chewed fruits and vegetables, and participation in physical activity. Thus, we will compare two dietary strategies which both have a reasonable chance of improving the health of the participants rather than using a classic non-intervention control group for the following reasons. First, we believe it is predictable that individuals with IDD randomized to a non-intervention control group will continue to exhibit increased

levels of obesity and health risk as there are no data in the IDD literature to suggest otherwise. Second, we were concerned with the ethics of using a non-intervention control in a group of overweight/obese individuals with IDD, an under-served and vulnerable group, who are clearly in need of effective strategies for weight management. Third, a reduced energy/fat diet combined with physical activity is considered to be “recommended care,” for weight loss [31]. We expect clinically significant and greater weight loss and less weight regain in the eSLD compared to the RC group. However, the RC intervention may result in weight loss of a magnitude sufficient to improve chronic disease risk. If so, RC may be considered as an approach for weight management in individuals with IDD.

The interventions in this trial will be delivered within the existing system that is responsible for the health and well-being of individuals with IDD. Individuals with IDD are assisted in their weight management efforts by parents/and or siblings with whom they live or by study partners. Therefore, if successful it would be possible to scale and deliver the intervention through the existing organizational and administrative structure to provide services for individuals with IDD.

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Abbreviations

eSLD	enhanced Stop Light Diet
IDD	intellectual and developmental disabilities
PM’s	pre-packaged meals
RC	recommended care

References

1. Rimmer JH, Braddock D, Marks B. Health characteristics and behaviors of adults with mental retardation residing in three living arrangements. Res Dev Disabil. 1995; 16:489–499. [PubMed: 8584768]
2. Rimmer JH, Wang E. Obesity prevalence among a group of Chicago residents with disabilities. Arch Phys Med Rehabil. 2005; 86:1461–1464. [PubMed: 16003681]
3. Harris N, Rosenberg A, Jangda S, O'Brien K, Gallagher ML. Prevalence of obesity in International Special Olympic athletes as determined by body mass index. J Am Diet Assoc. 2003; 103:235–237. [PubMed: 12589332]
4. Yamaki K. Body weight status among adults with intellectual disability in the community. Ment Retard. 2005; 43:1–10. [PubMed: 15628929]
5. Draheim CC, Williams DP, McCubbin JA. Prevalence of physical inactivity and recommended physical activity in community based adults with mental retardation. Ment Retard. 2002; 40:436–444. [PubMed: 12408746]
6. Beange H, McElduff A, Baker W. Medical disorders of adults with mental retardation: a population study. Am J Ment Retard. 1995; 99:595–604. [PubMed: 7632427]

7. Mercer KC, Ekvall SW. Comparing the diets of adults with mental retardation who live in intermediate care facilities and in group homes. J Am Diet Assoc. 1992; 92:356–358. [PubMed: 1552140]
8. Robertson J, Emerson E, Gregory N, Hatto C, Turner S, Kessissoglou S, et al. Lifestyle related risk factors for poor health in residential settings for people with intellectual disabilities. Res Dev Disabil. 2000; 21:469–486. [PubMed: 11153830]
9. Green EM, McIntosh EN. Food and nutrition skills of mentally retarded adults: assessment and needs. J Am Diet Assoc. 1985; 85:611–613. [PubMed: 3989179]
10. Bechtel JJ, Schreck KA. Balancing choice with health considerations in residential environments. Ment Retard. 2003; 41:465–467. [PubMed: 14588055]
11. Rimmer JH, Yamaki K. Obesity and intellectual disability. Ment Retard Dev Disabil Res Rev. 2006; 12:22–27. [PubMed: 16435329]
12. Melville CA, Hamilton S, Hankey CR, Miller S, Boyle S. The prevalence and determinants of obesity in adults with intellectual disabilities. Obesity Reviews. 2007; 8:223–230. [PubMed: 17444964]
13. Carnethon MR, Gidding SS, Nehgme R, Sidney S, Jacobs DR Jr, Liu K. Cardiorespiratory fitness in young adulthood and the development of cardiovascular disease risk factors. JAMA. 2003; 290:3092–3100. [PubMed: 14679272]
14. Neter JE, Stam BE, Kok FJ, Grobbee DE, Geleijnse JM. Influence of weight reduction on blood pressure: a meta-analysis of randomized controlled trials. Hypertension. 2003; 42:878–884. [PubMed: 12975389]
15. Woloshin S, Schwartz LM. Press releases: translating research into news. JAMA. 2002; 287:2856–2858. [PubMed: 12038933]
16. Grotto I, Huerta M, Kark JD, Shpilberg O, Meyerovitch J. Relation of parental history of coronary heart disease to obesity in young adults. Int J Obes Relat Metab Disord. 2003; 27:362–368. [PubMed: 12629564]
17. Fontaine KR, Redden DT, Wang C, Westfall AO, Allison DB. Years of life lost due to obesity. JAMA. 2003; 289(2):187–193. [PubMed: 12517229]
18. National Heart L, and Blood Institute. Clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in adults. The evidence report: National Institutes of Health. 1998
19. Evenson KR, Stevens J, Cai J, Thomas R, Thomas O. The effect of cardiorespiratory fitness and obesity on cancer mortality in women and men. Med Sci Sports Exerc. 2003; 35:270–277. [PubMed: 12569216]
20. Parker ED, Folsom AR. Intentional weight loss and incidence of obesity-related cancers: the Iowa Women's Health Study. Int J Obes Relat Metab Disord. 2003; 27:1447–1452. [PubMed: 14634673]
21. Hensrud DD. Dietary treatment and long-term weight loss and maintenance in type 2 diabetes. Obes Res. 2001; 9(Suppl 4):348S–353S. [PubMed: 11707564]
22. Draheim CC, Williams DP, McCubbin JA. Physical activity, dietary intake, and the insulin resistance syndrome in nondiabetic adults with mental retardation. Am J Ment Retard. 2002; 107:361–375. [PubMed: 12186577]
23. U.S. Department of Health and Human Services Public Health Service. The surgeon general's call to action to prevent and decrease overweight and obesity 2001. Rockville: U.S. Department of Health and Human Services; 2001.
24. U.S. Department of Health and Human Services OotSG. , editor. U.S. Department of Health and Human Services. The Surgeon General's call to action to improve the health and wellness of persons with disabilities. Rockville, MD: 2005.
25. Knowler WC, Barrett-Connor E, Fowler SE, Hamman RF, Lachin JM, Walker EA, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. N Engl J Med. 2002; 346:393–403. [PubMed: 11832527]
26. Saunders RR, Saunders MD, Donnelly JE, Smith BK, Sullivan DK, Guilford B, et al. Evaluation of an approach to weight loss in adults with intellectual or developmental disabilities. Intellect Dev Disabil. 2011; 49:103–112. [PubMed: 21446873]

27. Epstein, L.; Squires, S. The Stoplight Diet for Children: An Eight-Week Program for Parents and Children. Boston: Little Brown & Co; 1988.
28. Epstein LH, Valoski A, Wing RR, McCurley J. Ten-year follow-up of behavioral, family-based treatment for obese children. JAMA. 1990; 264:2519–2523. [PubMed: 2232019]
29. Epstein LH, Valoski A, Wing RR, McCurley J. Ten-year outcomes of behavioral family-based treatment for childhood obesity. Health Psychol. 1994; 13:373–383. [PubMed: 7805631]
30. ADA Evidence analysis library.
31. Donnelly JE, Blair SN, Jakicic JM, Manore MM, Rankin JW, Smith BK. American College of Sports Medicine Position Stand. Appropriate physical activity intervention strategies for weight loss and prevention of weight regain for adults. Med Sci Sports Exerc. 2009; 41:459–471. [PubMed: 19127177]
32. Seagle HM, Strain GW, Makris A, Reeves RS. Position of the American Dietetic Association: weight management. J Am Diet Assoc. 2009; 109:330–346. [PubMed: 19244669]
33. Ditschuneit HH, Flechtner-Mors M. Efficacy of replacement of meals with diet shakes and nutrition bars in the treatment of obesity and maintenance of body weight. Int J Obes. 1996; 20(S4):57.
34. Wing RR, Jeffery RW, Burton LR, Thorson C, Nissinoff KS, Baxter JE. Food provision vs structured meal plans in the behavioral treatment of obesity. Int J Obes. 1996; 20(1):56–62.
35. Wing RR, Jeffery RW. Food provision as a strategy to promote weight loss. Obes Res. 2001; 9(Suppl 4):271S–275S. [PubMed: 11707553]
36. Heymsfield SB, van Mierlo CA, van der Knaap HC, Heo M, Frier HI. Weight management using a meal replacement strategy: Meta and pooling analysis from six studies. Int J Obes Relat Metab Disord. 2003; 27:537–549. [PubMed: 12704397]
37. Humphries K, Traci MA, Seekins T. Nutrition Education and Support Program for Community-Dwelling Adults with Intellectual Disabilities. Intellect Dev Disabil. 2008; 46:334–345.
38. USDA. Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, 2010. 2010
39. Mifflin MD, St Jeor ST, Hill LA, Scott BJ, Daugherty SA, Koh YO. A new predictive equation for resting energy expenditure in healthy individuals. Am J Clin Nutr. 1990; 51:241–247. [PubMed: 2305711]
40. Rolls BJ, Drewnowski A, Ledikwe JH. Changing the energy density of the diet as a strategy for weight management. J Am Diet Assoc. 2005; 105:S98–S103. [PubMed: 15867904]
41. Rolls BJ. The role of energy density in the overconsumption of fat. J Nutr. 2000; 130 Suppl.(2): 268S–271S. [PubMed: 10721885]
42. Bell EA, Roe LS, Rolls BJ. Sensory-specific satiety is affected more by volume than by energy content of a liquid food. Physiol Behav. 2003; 78:593–600. [PubMed: 12782213]
43. Rolls, B. The Volumetrics Eating Plan. New York, New York: HarperCollins Publishers Inc.; 2005.
44. Institute of Medicine. Preventing childhood obesity: Health in the balance. Washington, DC: National Academies Press; 2005. Committee on Prevention of Obesity in Children and Youth.
45. Lohman, TG.; Roche, AF.; Martorell, R. Anthropometric Standardization Reference Manual. Champaign, Ill: Human Kinetics Books; 1988.
46. U.S. Department of Health and Human Services P. The 1988 report of the Joint National Committee on detection, evaluation and treatment of high blood pressure. Washington, D.C.: U.S. Government; 1988. NIH Publication No. 88-1088
47. Luepker RV, Jacobs DR, Prineas RJ, Sinaiko AR. Secular trends of blood pressure and body size in a multi-ethnic adolescent population, 1986 to 1996. J Pediatrics. 1999; 134:668–674.
48. Burnstein M, Scholnick HR, Morfin R. Rapid method for the isolation of lipoproteins from human serum by precipitation with polyanions. J Lipid Res. 1970; 11:583–595. [PubMed: 4100998]
49. Morgan CR, Larner J. Immunoassay of insulin: two antibody system: plasma insulin levels of normal, subdiabetic rats. Diabetes. 1963; 12:115–126.

50. Troiano RP, Berrigan D, Dodd KW, Masse LC, Tilert T, McDowell M. Physical activity in the United States measured by accelerometer. Med Sci Sports Exerc. 2008; 40:181–188. [PubMed: 18091006]

51. Heller T, Miller AB, Hsieh K. Impact of a consumer-directed family support program on adults with disabilities. Fam Relat. 1999; 48:419–427.

52. Hatton DC, Haynes RB, Oparil S, Kris-Etherton P, Pi-Sunyer FX, Resnick LM, et al. Improved quality of life in patients with generalized cardiovascular metabolic disease on a prepared diet. Am J Clin Nutr. 1996; 64:935–943. [PubMed: 8942420]

53. Baron RM, Kenny DA. The moderator-mediator variable distinction in social psychological research: conceptual, strategic, and statistical considerations. J Pers Soc Psychol. 1986; 51:1173–1182. [PubMed: 3806354]

54. MacKinnon DP. Analysis of mediating variables in prevention and intervention research. NIDA Res Monogr. 1994; 139:127–153. [PubMed: 8742555]

55. Brown RL. Assessing specific mediational effects in complex theoretical models. Struct Equ Modeling. 1997; 4:142–156.

56. Basch CE, Sliepcevich EM, Gold RS, Duncan DF, Kolbe LJ. Avoiding type III errors in health education program evaluations: a case study. Health Ed Q. 1985; 12:315–331.

Table 1

Participant Eligibility Criteria for an 18-month Weight Loss and Maintenance Intervention in Adults with Intellectual and Developmental Disabilities

Inclusion	
Residential Status:	Live with parents or in supported living in North East Kansas (≤ 50 miles from Lawrence, KS) with a maximum of 4 other individuals with IDD.
Age:	≥ 18 years
Diagnosis:	Mild to moderate IDD as determined by a Community Service Provider operating in Kansas under the auspices of a Community Developmental Disability Organization (CDDO).
Overweight/obese:	BMI > 25 kg/m^2
Ambulatory:	Must be able to walk.
Health status:	Must provide physician clearance to participate.
Communication:	Potential participants must be able to communicate preferences (e.g., foods liked and disliked), wants (e.g., more to eat, drink), and needs (e.g., assistance with food preparation) through spoken language, sign language, or augmentative and alternative communication systems, such as voice output communication aides.
Ability to consent:	Potential participants will be judged competent to give informed consent by their CDDO or will have a guardian with power of attorney. If a guardian indicates consent but the individual with IDD does not want to participate, the individual will not be enrolled
Exclusion	
Health concerns:	Individuals with uncontrolled hypertension, severe heart disease, cancer, HIV, etc. Individuals with diabetes will be receiving a special diet per state regulatory statute and thus are not eligible. Individuals who are currently being treated for depression or eating disorders.
Recent weight loss:	Participation in a weight loss program within the past 6 months.
Pregnancy:	Individuals who become pregnant during the study will be dropped and referred for appropriate services.

Table 2

Assessment schedule

Assessment	Weekly	Monthly	Baseline	6 month	12 month	18 month
Anthropometrics [a]			x	x	x	x
Blood chemistry & blood pressure [b]			x	x	x	x
Physical activity (7-day accelerometer)			x	x	x	x
Dietary intake (3- day food record)			x	x	x	x
Overall program satisfaction & acceptability				x	x	x
Study partner self-efficacy			x	x		
Daily stress for dietary change			x	x		
Dietary intake (24hr recalls)		x				
External or competing factors		x				
Body weight (for feedback/counseling)		x				
Self-monitoring data (diet, physical activity)	x					
Behavioral reactivity	x					

[a] Anthropometrics includes height, weight, waist circumference, and BMI.

[b] Blood chemistry includes lipids, insulin, and glucose.