Contemporary Clinical Trials 36 (2013) 116–124

Contents lists available at ScienceDirect

Contemporary Clinical Trials

journal homepage: www.elsevier.com/locate/conclintrial

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

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ARTICLE INFO

Article history:
Received 15 April 2013
Received in revised form 13 June 2013
Accepted 16 June 2013
Available online 25 June 2013

Keywords:
Intellectual and developmental disability
Weight management
Pre-packaged meals
Physical activity
Weight maintenance
Stop Light Diet

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 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.

Abbreviations: eSLD, enhanced Stop Light Diet; IDD, intellectual and developmental disabilities; PMs, pre-packaged meals; RC, recommended care.

☆☆ Funding: National Institutes of Diabetes, Digestive and Kidney Diseases (R01-DK83539).
★ We acknowledge HMR for providing the pre-packaged meals.

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1551-7144/$ – see front matter
http://dx.doi.org/10.1016/j.cct.2013.06.007

1. 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% o 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. 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 month weight loss and 12 month 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 min 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 ensure 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.