Remote Delivery of Weight Management for Adults with IDD

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Protocol and Analysis Plan

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Aims and Hypothesis

Adults with intellectual and developmental disabilities (IDD) represent an underserved segment of the US population with a high prevalence of obesity, obesity related chronic disease, and limited options for weight management. Multicomponent weight management, which involves on-site group behavioral counseling, reduced energy intake, and increased physical activity (PA) is problematic for adults with IDD. On-site group sessions may be inappropriate for adults with IDD who have diverse cognitive, communication and social skills, and depend on caregivers for transportation to meeting sites/exercise facilities, and assistance with meal planning, food shopping and meal preparation. Our group, and others, have demonstrated that adults with IDD living with a parent, or in supported living, can achieve clinically meaningful weight loss (3-5%) in response to multicomponent home-based interventions, i.e., face-to-face (FTF). For example, we have evaluated the effectiveness of an enhanced Stop Light Diet (eSLD) as part of a FTF weight management intervention in adults with IDD in 2 previous trials. The eSLD simplifies meal planning, food shopping and meal preparation making it potentially useful for adults with IDD and their caregivers. The eSLD included 2 ~ 200 kcal portion-controlled entrées/d, 2 ~100 kcal shakes/d, 5 one-cup servings of fruits/vegetables/d, and ad-libitum non-caloric beverages. Additional low energy foods were selected using the SLD system: green (low energy), yellow (moderate energy), and red (high energy). Our single arm pilot trial in adults with IDD (n=66) found the eSLD, plus monthly at-home FTF behavioral sessions (adult + caregiver), plus increased PA, achieved weight loss of -6.4% and -8.7% at 6 and 12 mos., respectively. Based on this data we conducted an adequately powered 18 mo. trial (6 mos. weight loss/12 mos. maintenance) (DK83539) in adults with IDD who were randomized to an eSLD (n=77) or a conventional diet (CD, n=72). Both groups completed monthly at-home FTF behavioral sessions (participants & caregiver) and received recommendations for increased PA. Six-month weight loss was significantly greater in the eSLD (-7.0%) compared with the CD group (-3.8%, $p<0.001$); however, both groups had similar weight loss at 18-mos. (eSLD = -6.7%, CD = -6.4%, $p=0.82$). The FTF intervention produced significant weight loss; however, the time and cost associated with FTF delivery (travel + sessions) limits the potential for scaling and dissemination. This suggests the need for the evaluation of alternative strategies, such as remote delivery using video conferencing, which may produce significant weight loss at lower cost with improved potential to reach greater numbers of this underserved group. Therefore, we propose a 24 mo. randomized trial (6 mos. weight loss, 12 mos. maintenance, 6 mos. no-contact follow-up) to compare 2 weight management interventions delivered to adults with IDD in their home, either remotely (RD) via video conferencing (Zoom software) on a tablet computer (iPad mini), or during FTF home visits. Both intervention arms will include monthly at-home behavioral sessions (adult + caregiver), an eSLD, and increased PA. The RD arm will include group PA delivered using video conferencing (2 session/wk.) and will use commercially available web-based applications for self-monitoring/participant feedback for diet (Lose it!), PA (Fitbit activity tracker), and weight (Wi-Fi scales). The FTF arm will be identical to the intervention shown to be effective in our previous trial (DK83539) and will include self-directed PA, self-monitoring of diet and PA using paper/pencil logs, and weight assessed during monthly home visits. We will address the following aims:

Primary aim: To determine if weight loss (0-6 mos.) in the RD group is non-inferior to FTF group. Non-inferiority will be declared if mean weight loss for RD is no worse than FTF, within statistical variability, by a margin of -3 kg which represents the maximal between group difference that would yield clinically meaningful weight loss in the RD group

Secondary aims: We will compare changes between the RD and FTF groups in the following variables across 24 mos.: 1) Mean weight loss; 2) The proportion of participants who achieve clinically meaningful weight loss (≥ 5%); and 3) Quality of life. We expect similar changes in the RD and FTF groups for each of these secondary aims. We will also conduct cost, cost-effectiveness and contingent

valuation analyses to compare the RD and FTF groups. We expect reduced costs in the RD compared with the FTF group.

Exploratory aim: We will examine the influence of the following process variables/participant characteristics to identify salient factors impacting weight loss across 18 mos.: behavioral and PA session attendance, compliance with recommendations for diet (energy intake, number of entrées/shakes, servings of fruits/vegetables, PA (min of moderate-vigorous PA), self-monitoring of diet and PA, sex, age, IDD diagnosis, caregiver self-efficacy/turnover, and obesogenic medications.

Background and Significance

Obesity: Causes, and consequences in adults with IDD. Intellectual and developmental disabilities (IDD), are characterized by significant limitations in both intellectual functioning (IQ <75) and in adaptive behavior including conceptual skills (e.g. language and literacy, self-direction), social skills (e.g. interpersonal skills, ability to follow rules) and practical skills (e.g. personal care, use of money/phone) which originate before the age of 18 (1). Individuals with IDD represent ~1 to 3% of the US population (1, 2) with a prevalence of obesity (BMI ≥ 30 kg/m^2) equal to (3) or greater than the general population (4-6). Lack of regular physical activity (PA), sedentary behavior (7-9), and unhealthy dietary choices (3, 5, 10, 11) are associated with weight gain in the general population, and in adults with IDD. In addition, genetic predisposition (12), the use of obesogenic medications (3, 4, 13), and living arrangement (e.g. institution, group home, family home) (3, 6, 13), all contribute to weight gain in this group. Adults with IDD have a higher prevalence of obesity associated health conditions including cardiovascular disease (CVD), risk factors for CVD, CVD mortality (14-16), type 2 diabetes (17, 18), and rates of hospitalization related to type 2 diabetes (18) compared with their non-IDD peers.

Weight management in adults with IDD. Reports from government agencies (19-21) and professional organizations (22) have recommended efforts to reduce the prevalence of overweight/obesity and related chronic disease in adults with IDD. However, in the most recent systematic review on weight management in adults with IDD, Spanos et al (23) identified only a limited number of trials (n=22), generally conducted over short time frames (8-12 wks.), using non-randomized designs, in small (n < 25), non-powered, heterogeneous samples. The majority of trials (21/22, 95%) were not conducted in accordance with current weight management guidelines which recommend a multicomponent approach, i.e., "≥ 6 mos. in a comprehensive lifestyle program that assists participants in adhering to a lower-calorie diet and in increasing PA through the use of behavioral strategies" (24), and not unexpectedly, reported minimal weight loss (< 3%). In contrast, our group (25) and others (26, 27) have observed clinically meaningful weight loss of ≥ 5%, and successful weight maintenance using multicomponent interventions in adults with IDD. Melville et al. (26) completed a 9 session multicomponent non-randomized trial (over ~26 wks.) in 47 obese adults with IDD. Mean weight loss was 4.5 kg, with 36% of participants losing ≥ 5% from baseline. Spanos et al (28) conducted a 12 mo. multicomponent weight maintenance trial (monthly meetings) in a sample of 28 volunteers who achieved ≥ 3% weight loss as participants in the Melville et al trial (26). Results indicated 72% of participants maintained (± 3%) or lost weight. Martinez-Zaragoza et al. (27) reported clinically meaningful weight loss (~8 kg) in response to a 17-week intervention consisting of reduced energy intake, PA and a token economy motivational system, in a sample of 33 adults with IDD attending a community occupational therapy day center. Our group has completed 2 trials in adults with IDD to evaluate the effectiveness of multi component weight loss/maintenance interventions using an enhanced Stop Light Diet (eSLD) (29). The eSLD included daily consumption of 2 portion-controlled entrées (PCMs, ~200 kcal each), 2 low-calorie shakes (~100 kcal each), 5 servings of fruits/vegetables (F/V), and ad-libitum non-caloric beverages. Participants were asked to select additional low energy food, if desired, using the SLD system: green (low energy), yellow (moderate energy), and red (high energy). The eSLD simplifies meal planning, food shopping and meal preparation, making it potentially

useful for adults with IDD and their caregivers. First, we evaluated the effectiveness of the eSLD for weight loss (6 mos.) and maintenance (6 mos.) in combination with monthly, at-home, face-to-face (FTF) behavioral sessions with participants and a caregiver, and increased PA, in a sample of 66 overweight/obese adults with IDD (25). Mean weight loss was -6.4% and -8.7% at 6 and 12 mos., respectively. We recently completed an 18 mo. trial to compare the effectiveness of the eSLD with a conventional meal plan diet (CD) as part of a multicomponent intervention for both weight loss (0-6 mos.) and maintenance (7-18 mos.) in adults with IDD (DK83539). Overweight/obese adults (BMI ≥ 25 kg/m^2) with mild to moderate IDD, living either in the community with parents/guardians, or in supported living with a paid caregiver, who served as a "study partner", were randomized to either an eSLD (n=77) or CD (n=72). In addition to an energy reduced diet, participants were asked to increase PA (150 min./wk.), self-monitor diet and PA, and attend behavioral counseling/educational sessions conducted by a health educator during monthly home visits. The sample was 57% female, 17% Down Syndrome, with a mean age and BMI of 36.5 yrs. and 36.9 kg/m^2, respectively. The majority of participants (~74%) lived in a group situation with support from paid staff. Weight loss (6 mos.) was significantly greater in the eSLD (-7.0%) compared with the CD group (-3.8%, $p<0.001$). The proportion of participants achieving weight loss of ≥ 5% at 6 mos. was significantly greater in the eSLD (62.7%,) compared with the CD group (40.3%, $p=0.013$). However, at 18 mos. mean weight loss between groups did not differ significantly (eSLD = -6.7%; CD = 6.4% $p=0.82$). Among participants completing the 18 mo. intervention 57.4%, and 48.9% achieved ≥ 5% weight loss from 0 to 18 mos. in the eSLD and CD groups, respectively. Weight change across 18 mos. did not differ by the type (family vs. paid staff) or number of study partners, the number of participants living in a residence, the use of obesogenic medications, or between adults with or without Down Syndrome. These results suggest the robustness of this approach in adults with IDD. In sum, the results from our 12 and18 mo. trials were encouraging; however, the logistical burdens and costs associated with delivering a weight management intervention to individuals in their home greatly limits the potential for scaling and implementation of this approach by community and other agencies serving adults with IDD. Thus, alternative strategies for delivering weight management to adults with IDD are needed.

Delivery of weight management. With the exception of the short-term trial (17-wk.) reported by Martinez-Zaragoza et al (27), which was delivered in an occupational therapy day center, the multicomponent trials that have resulted in clinically meaningful longer-term weight loss (6-18 mos.) in adults with IDD, including our recently competed trial (DK84539), have been delivered FTF to individual participants and a caregiver (25, 26, 28). Individual FTF sessions conducted at home may be better suited for adults with IDD than the traditional approach to weight management which involves on-site group behavioral sessions, in conjunction with reduced energy intake and increased PA. On-site group sessions, although more cost efficient, may present a significant barrier for adults with IDD who have diverse cognitive, communication and social skills, may require individualized instruction, and who depend on a caregiver for transportation to meeting sites/exercise facilities.

Alternative delivery strategies. Alternative strategies for the delivery of weight management, including phone, text messages, internet etc. eliminate barriers and may increase the availability of cost effective weight management for larger segments of the population. The 2013 American Heart Association (AHA)/American College of Cardiology (ACC)/The Obesity Society (TOS) guidelines for weight management (24), cites moderate evidence for the effectiveness of electronically delivered weight loss interventions in typically developed adults. However, the effectiveness of alternative strategies for the delivery of weight management in adults with IDD is unknown. Approximately 25 yrs. ago, Parette et al (30) suggested the potential for technology to facilitate and automate therapeutic regimens/educational activities for individuals with IDD. Technologies, such as desktop/tablet computers, have been used successfully in individuals with IDD across a variety of tasks including improved vocational, transition and employment skills (31), and living (32) and academic skills (33). Computers are widely available for individuals with IDD (34, 35), but are underutilized in regards to

health promotion (31). Randomized trials comparing the effectiveness of strategies for the delivery of weight management for individuals with IDD are not available. As described in preliminary studies, our group has demonstrated the potential for the delivery of weight management interventions to individuals with IDD using tablet computers (iPad) and self-monitoring using commercially available applications, the approach that will be evaluated in the proposed trial.

Premise/summary of significance/impact. The premise of this trial is that adults with IDD represent an underserved segment of the US population with a high prevalence of obesity, obesity related chronic disease, and limited options for weight management. On-site group sessions, widely used to deliver weight management in typically developed adults, may be inappropriate for this group who have diverse cognitive, communication and social skills, and who depend on a caregiver for transportation to meeting sites/exercise facilities, and for assistance with meal planning, food shopping and meal preparation. We have demonstrated clinically meaningful 6 mo. weight loss (-7%; 63% ≥ 5%) with minimal weight regain at 18 mos. (-6.7%; 57% ≥ 5%) with a multicomponent intervention that included an energy reduced diet (eSLD), PA, and behavioral sessions delivered to participants/caregiver during monthly FTF home-visits. Although effective, the logistical burdens and costs associated with individual FTF home-visits, greatly limits the potential reach, scaling and implementation of this approach by agencies serving adults with IDD. Thus, alternative strategies for the delivery of weight management to increase accessibility, reduce costs, and potentially improve outcomes for adults with IDD are warranted. Therefore, the primary aim of this trial is to determine whether a multicomponent weight management intervention delivered remotely (RD) to adults with IDD using video conferencing (Zoom software) on a tablet computer (iPad mini) is non-inferior to weight management delivered FTF. Both intervention arms will include individual monthly at-home behavioral sessions (participant & caregiver), delivered either FTF or video conferencing, an eSLD, and increased PA. The RD arm will include group PA sessions (2 session/wk.) delivered using video conferencing and will use commercially available web-based applications for self-monitoring/participant feedback for diet (Lose it!), PA (Fitbit activity tracker), and weight (wireless scales). As required in a non-inferiority trial, the FTF arm will be identical to the intervention shown to be effective in our previous trial (DK83539) and will include a prescription for self-directed PA, self-monitoring of diet/PA using paper/pencil logs, and weight assessed during home visits.

PRELIMINARY STUDIES

In addition to the two weight management trials in adults with IDD previously described, we have experience with all aspects of the proposed intervention including weight management in general, remote delivery of weight management and PA interventions, and self-monitoring of diet, PA and weight using technology.

Remote delivery/self-monitoring with technology. Our group has experience with weight management/PA interventions delivered by telephone, tablet computer, social media (Facebook), and via desktop computer in a virtual reality environment, and using commercially available apps/devices for self-monitoring diet (Lose it!) and PA (Fitbit). We recently completed 2 pilot trials directly relevant to this proposal. First, we compared weight loss in adolescents with IDD randomized to an eSLD (n=10) or a CD (n=10) over 2 mos. (36). Weekly behavioral sessions were delivered individually to adolescents and a parent via video chat on a tablet computer (iPad). Self-monitoring of diet (Lose it!) and PA (Fitbit activity tracker) were completed using the iPad. There were no significant differences in 2 mo. weight loss between the eSLD (-4.6%) and CD (-3.3 %). Second, we conducted a 3 mo. trial funded by the Healthy Weight Research Network for Children with Autism Spectrum Disorders and Developmental Disabilities to determine the feasibility of delivering 30 min. real-time PA sessions, 3 days/wk. via video conferencing (Zoom) on an iPad mini, to groups of 5-6 adolescents with IDD (n = 31) in their homes. Participants attended 77% of possible sessions with an average heart rate (Garmin Vivofit) of ~124 beats/min. This approach promoted interactions between both the group leader and participants

(24/session), and between individual participants (12/session), suggesting the potential to provide social support. Additionally, we are currently conducting a 3 mo. pilot trial in 30 young adults (18-40 yrs.) with Down Syndrome to evaluate the feasibility and effectiveness of an at-home, group-based intervention delivered by video conferencing on a tablet computer (2-60 min session/wk.) combined with brief weekly individual educational and support sessions (1-15 min session/wk.) to increase weekly moderate-to-vigorous physical activity (MVPA, goal 150 min/wk.). Preliminary results from 8 adults (~27 yrs.) indicated attendance at group and individual sessions was 88 % and 86%, respectively with 69% of participants meeting the MVPA goal. We have also demonstrated the equivalency of group phone and FTF group sessions for both weight loss (6 mos.) and maintenance (12 mos.) in a sample of 295 overweight/obese adults (DK76063, Donnelly, PI) (37, 38), and are nearing completion of an 18 mo. trial to compare weight maintenance interventions (12 mos.) delivered by group conference calls or by group sessions conducted in a virtual reality environment (Second Life) (DK93833, Donnelly, MPI) (39). In a recently completed pilot trial we demonstrated similar weight loss (~6%) in 72 obese adults randomized to a 6 mo. weight loss intervention delivered by group conference call or through social media (Facebook) (40). Self-monitoring of diet (MyFitnessPal™), PA (Fitbit) and weight (wireless scales) in this trial was completed using commercially available web-based applications and devices.

Research Plan and Design

Study Objectives. This is a randomized trial designed to test to determine if weight loss (0-6 mos.) in the RD group is non-inferior to FTF group.

Overview of approach. We propose a 2-arm randomized trial (RD vs. FTF) using intent-to-treat principles. Both arms will include individual monthly behavioral sessions (participant & caregiver), an eSLD, and increased PA. The RD arm will include group PA (2 session/wk.) delivered using video conferencing and will use commercially available web-based applications for self-monitoring and participant feedback for diet (Lose it!), PA (Fitbit activity tracker), and weight (wireless scales). The FTF arm will include a prescription for self-directed PA, and self-monitoring of diet and PA using paper/pencil self-reports modified for use with adults with IDD. The primary outcome (weight) will be assessed during home visits at baseline (mo. 0), following weight loss (6 mos.), during (12 mos.) and following maintenance (18 mos.) and after 6 mos. of no contact follow-up (24 mos.).

Table 1: Design Overview	**INTERVENTION GROUPS**	
	Remote Delivery	**Face-to-Face Delivery (FTF)**
Behavioral sessions		
Delivery method	Individual video conferencing (Zoom on the iPad)	Individual FTF home visit
Meeting frequency /session duration		
Weight loss (0-6 mos.)	Monthly/45-60 min.	Monthly/45-60 min.
Maintenance (7-18 mos.)	Monthly/45-60 min	Monthly/45-60 min .
Diet	eSLD (portion controlled entrées and low kcal shakes + SLD)	eSLD (portion controlled entrées and low kcal shakes + SLD)
Supervised MVPA		
Delivery method	Group video conferencing (iPad mini) (10-12 participants)	NA
Session frequency /duration		
Weight loss (0-6 mos.)	2x/wk./30 min	NA
Maintenance (7-18 mos.)	2x/wk./30 min	NA

MVPA (supervised + unsupervised) (0-18 mos.)	150 min/wk.	150 min/wk.
Self-Monitoring (Diet)	Lose it! app	Self-report/pencil/paper
Self-Monitoring (PA)	Fitbit	Self-report/pencil/paper
Self-Monitoring (Weight)	Wireless scales	Portable scale-monthly FTF visit
eSLD=enhanced Stop Light diet; MVPA = Moderate-to-vigorous physical activity, NA = not applicable		

Participant eligibility. *Inclusion criteria*: *1)* Age 18 yrs. and older (at least 50% female) with a diagnosis of mild to moderate IDD as determined by a Community Service Provider operating in Kansas under the auspices of a Community Developmental Disability Organization (CDDO). Participants will be judged competent to provide informed consent by their CDDO, or will have a guardian with power of attorney. Participants will not be enrolled without providing assent, regardless of guardian consent. *2)* BMI ≥25 kg/m^2 and body weight ≤400lbs. *3)* Sufficient functional ability to understand directions, communicate preferences (e.g. foods), wants (e.g. more to eat/drink), and needs (e.g. assistance with food preparation) through spoken language. *4)* Living at home with a parent/guardian, or in a supported living environment with a caregiver who assists with food shopping, meal planning, and meal preparation and agrees to serve as a study partner. *5)* No plans to relocate outside the study area over the next 24 mos. *6)* Internet access in the home. *Exclusion criteria. 1)* Unable to participate in MVPA. *2)* Insulin dependent diabetes as this condition requires medical monitoring beyond the scope of this study. *3)* Participation in a weight management program involving diet and PA in the past 6 mos. *4)* Serious food allergies, consuming special diets (vegetarian, Atkins etc.), aversion to common foods (e.g., unwilling to consume dairy products, vegetables), diagnosis of Prader-Willi Syndrome. *5)* Pregnancy during the previous 6 mos., currently lactating or planned pregnancy in the following 24 mos. Participants who become pregnant will be removed from the study and referred to appropriate agencies for consultation. *6)* Serious medical risk, e.g., cancer, recent heart attack, stroke, angioplasty as determined by the PCP. *7)* Unwilling to be randomized.

Withdrawal/Termination. The subject's participation will be terminated by the investigator if the diet does not appear to be in their best interest or if the subject becomes aggressive towards the study team. To withdraw from the study subject's guardian must contact the PI in writing. Once withdrawal has been received information will no longer be collected from them.

Recruitment/randomization. Individuals recruited for this study will have mild to moderate IDD and will live with a parent or in a supported home. Potential participants will be recruited through local community programs serving adults with IDD, and with print and web advertisements in our target area. Potential participants or their staff will be asked to contact Dr. Ptomey via email, our website (www.ebl.ku.edu), or a dedicated study phone number that will be included in all recruitment materials. Questions from interested parents will be addressed and initial eligibility screening will be completed online, indicating interest in the study. Home visits, phone calls, or remote video chat sessions (skype) will be scheduled with participants, caregivers, and their legal guardian (if applicable) deemed to be initially eligible to describe the project in detail, answer questions, verify eligibility, and to obtain participant consent or, if the participant is not their own legal guardian, guardian consent and participant assent. Prior to the consenting session, the participant will be sent the consent form and cover letter through Kansas University Medical Center's (KUMC) secure email system. For participants choosing to consent remotely, study staff will set up a virtual skype meeting that allows for remote video chat. Study staff will "share screen" the consent document and walk through each section, noting questions that arise, and answer these questions fully. Time and date of this conversation will be recorded. Participants will be asked to print the consent document and sign the form if they are willing to participate. Participants will scan or take a picture of the signed consent form and securely email it to study staff. Study staff who conducted the consent meeting will sign and date with today's date, noting

for discrepancies if the dates are different due to remote consent. If participants are unable to print the electronic document, a blank consent form will be mailed along with a stamped, self-addressed envelope. The participant will sign the form if they are willing to participate and mail it back in the provided envelope. Once this is received, study staff who conducted the consent meeting will sign and date with today's date, noting the discrepancy on the consent form due to phone consent. Study staff will provide the participant with a full-signed consent form for their records at the baseline testing meeting. Project staff will send a form to potential participant's primary care physician which describes the study and to request clearance for participation. Overweight/obese individuals found to be ineligible will be referred to other available weight management options. All participants will be randomized by computer with equal allocation to the RD or FTF groups. Allocation will be concealed in envelopes and delivered to the study coordinator

Intervention overview

Caregiver role. We will recruit either a parent/guardian, residential support staff, or an individual who assists with food shopping/meal preparation to serve as a study partner for each participant. Study partners will be allowed to assist multiple adults, provided all adults are in the same intervention group. Study partners will be asked to attend all monthly behavioral sessions, and to support, encourage, and assist participants in complying with the study protocol, including selection and preparation of foods consistent with the eSLD, supporting opportunities for increased PA, and assisting with self-monitoring of diet, PA and weight. However, study partners will not be asked to diet or increase their PA, as we feel this approach would be difficult, if not impossible, to successfully implement in an agency setting.

Orientation. Two, 90 min. home visits will be conducted by a health educator with participants and their study partner prior to initiating the intervention. These sessions will provide detailed descriptions of both the dietary (eSLD) and PA components of the intervention and the respective delivery system (FTF or RD). Participants and parents in the RD groups will be oriented to the use of Zoom™, and the use of both the Lose it! and Fitbit applications for self-monitoring of diet and PA. Health educators will provide a tutorial on general use of the iPad, internet connectivity, etc. Participants and parents in the FTF group will be shown how to self-monitor diet and PA using hard copy records.

Meeting schedule. Behavioral sessions (45-60 min) will be conducted monthly in both the RD and FTF groups across the 18 mo. active intervention. During each session, health educators will review self-monitoring data for diet, PA and weight (described below), answer questions, problem-solve, and provide support.

Behavioral lesson content. Lessons on behavioral strategies to improve weight loss/maintenance will be presented at each session. Topics include social support, self-monitoring, planning, environmental control, self-efficacy, etc. Each lesson will be loaded into the iPad (RD) or provided as paper copy (FTF). During each meeting, we will also review diet and PA data, current weight status, answer questions, problem-solve, and provide support. Sessions will be recorded (FTF-audio recording, RD-Zoom sessions will be recorded using Zooms recording software). The recordings will be used to ensure all sessions are delivered according to protocol. The audio or video recordings will be saved on our secure server, which is protected behind a firewall. The file name will be their de-identified study ID and date of the recording. The only people who have access to this server are the study investigators and the study coordinator. These videos may remain on the server indefinitely.

Diet. *eSLD-Weight Loss (months 0-6)***.** Participants will be asked to consume a minimum daily total of 2 entrées (~200 to 300 kcal each, saturated fat ≤ 3g), 2 shakes (~100 kcal each), 5 one-cup servings of F/V, and ad libitum non-caloric beverages. Participants/study partners will be trained to use a color coded chart which categorized foods based on the Stop Light system (green, yellow, red) to assist in

meal planning, grocery shopping, decisions regarding snack foods, and compliance with the diet in special situations such as eating away from home (restaurants, parties, etc.). Participants will be asked to purchase portion controlled entrées from a list meeting the caloric/fat requirements, as well as F/V, and non-caloric beverages. Recommended PCMs are available at most grocery stores at a cost of $2.00-$4.00 each. 2 low-calorie shakes/day will be provided as part of the eSLD only during weight loss (0-6 mos.). Shakes will be shipped to the participant's residence every 2 weeks. *eSLD–weight maintenance (7-18 months).* During weight maintenance (mos. 7-18), participants will be encouraged to continue using PCMs and will be encouraged to consumed 5 one-cup servings of F/V a day. In addition to the PCMs and F/Vs, participants will be counseled to continue to use the SLD to make daily food choices and will receive education on portion control.

Prescribed PA: We will target 150 min/wk. of MVPA (≥ 3 METs) for both the RD and FTF groups as recommended for all adults by the American College of Sports Medicine (61) and the US Department of Health and Human Services (62). Recommended PA 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. 24. Accumulated PA in bouts ≥ 10 min will be permitted.

PA delivery- RD group. PA sessions delivered by video conferencing to groups of 4-5 adults with IDD in their homes. The feasibility of this approach was demonstrated in 2 pilot trials described in preliminary studies. Sessions will be scheduled between 4 and 7 PM on non-consecutive days. Each session will include a warm-up (~5 min), MVPA (~30 min.) and cool-down/stretching (~5 min.) and will be delivered by a health educator trained and supervised by. PA will be accompanied by music, and will include walking/jogging in place, dancing, imitating animal movements, vertical/horizontal jumps, squats and involve throwing scarves/spot markers as appropriate. Activities will be modified for participants having difficulty with completing specific movements. The intensity of the initial sessions will be light, and increase to moderate or greater at ~ 6 weeks and remain at that level across the 18 mo. active intervention. Health coaches will encourage interactions between participants supportive of their peer's efforts to increase MVPA, and also provide feedback to participants relative to their level of weekly MVPA as assessed by the Fitbit (described below). As the intervention progresses, participant volunteers will be asked to create and lead the group in a brief (3-5 min) MVPA bout, an activity that was well received in our pilot trials. Health educators will provide weekly challenges in the form of meeting a goal for increased steps, trying a new activity, or creating and performing their own activity routine etc. to assist participants in achieving the 150 min./wk. goal. All group PA sessions will be recorded. Recorded videos will be remotely uploaded to participant's iPads using a dropbox server for them to repeat on their own to help them meet their 150 min./wk. goal, if desired. The number of times participants access a video will be tracked utilizing dropbox analytics.

PA delivery- FTF group. Participants in the FTF group will receive written materials and resistance bands, and will be asked to complete the 150 min./wk. MVPA recommendation on their own. Participants in both the RD and FTF groups will be provided information describing public resources for PA in their areas (community centers, walking trails, etc.) and appropriate exercise videos (Appendix F).

Self-monitoring: All groups will monitor their daily diet and PA behaviors over the course of the 18 mo trial either by traditional pen and paper records or via iPad applications. Additional details regarding self-monitoring are described below.

Self-monitoring-RD group. *Diet.* Participants will log food/beverages (meals/snacks) using Lose it! by entering the food name and selecting the portion size, or by scanning the bar code of the food item using the iPad. A bar graph displays calories consumed compared with the goal providing immediate feedback (Appendix G). *PA***.** Participants will wear a Fitbit Charge HR (size 35.5 x 28 mm) wireless

activity tracker on their wrist. The Fitbit records time spent in light, moderate or vigorous PA, based on step counts and heart rate (71). Data is automatically transferred to the Lose it! app via Bluetooth connectivity when the device is near the iPad, thus eliminating manual data recording. Lose it! provides immediate feedback on accumulated PA relative to participant goals via a graphic display. We successfully used the Fitbit in our adolescent IDD pilot trial (36). *Body weight*. Participants will self-weigh during monthly behavioral counseling video sessions using the wireless digital scale provided by the study which automatically syncs with the Lose it! app and updates a visual display of weight change. *Reminders*. Reminders will be sent via the Lose It! app if no information is reported for a given meal or goal (i.e., PA time). *Diet/PA/weight data management.* Diet and weight data on the Lose it! app are securely and automatically transferred to the Lose it! for Wellness Professionals web site that is accessible to the health educator. Fitbit data is automatically transferred to cloud storage (Fitabase, San Diego, CA). Diet and PA data will be accessible to health educators for use in behavioral sessions and will be exported to a data base for inclusion in exploratory analyses.

Self-monitoring-FTF group. *Diet/PA.* Participants in the FTF group will be provided with a pedometer (Omron HJ-320, Lake Forest, IL) to self-monitor PA. The FTF group will enter diet (entrées, shakes, F/V) and PA data (type, duration, pedometer steps) on paper pictorial tracking sheets designed specifically for adults with IDD. *Body weight* will be assessed/recorded by the health educator on a calibrated scale during monthly home visits. *Diet/PA data management***.** Diet/PA tracking sheets will be collected by health educators during monthly home visits and will be used as motivation, to inform participant counseling for the FTF group, and entered in a database for inclusion in exploratory analysis.

Incentives. Participants in both groups who complete self-monitoring for diet and PA on 5 of 7 d/wk. will be allowed to choose an iTunes song which will be uploaded weekly to the participant's iPad by study staff. Additionally, participants will receive a $5.00 gift card for each behavioral session attended, $20 for completing each of the 5 outcome assessments, and will be allowed to keep the iPad and Fitbit/pedometer on study completion (18 mos.). Study partners will receive gift cards ($50.00) at 6, 12, and 18 mos. to compensate for the additional burden associated with participation in this trial.

Cost to Participants. All study cost will be paid for by the study including the iPad, fitbit, and exercise equipment. Participants and their families will not be charged if the participant loses any of the equipment, but must return them at the end of the study.

Intervention Deviations: As this study is intent-to-treat, all participants will be encouraged to follow the intervention described above, however they may choose not to follow the prescribed diet, track diet /PA, attend meetings, or weigh themselves. If a participant chooses not to follow the intervention as described, it will be recorded as process data and will not be considered an intervention deviation.

Assessments

Table 2: Assessment schedule

Study Month	**0**	**6**	**12**	**18**	**24**
Outcomes: Primary/Secondary					
Weight/height/WC	X	X	X	X	X
Quality of life	X	X	X	X	X
Cost Analysis	→				

Demographics/health history	X			X	X
Outcomes: Exploratory					
Compliance-Diet/PA	X	X	X	X	
Behavioral session attendance	→				
Self-Monitoring-Diet/PA	→				
Study partner self-efficacy	X	X	X	X	
Medications	X	X	X	X	X

Note: WC = waist circumference

Most outcomes will be assessed during a single home visit; however; some assessments will occur across the 18 mo. active intervention (Table 2). Weight, height and waist circumference will be obtained between 7-10 a.m. following a minimum 12-hr. fast. Assessments will be completed by trained staff blinded to condition. Our experience with similar trials suggests the proposed assessments will require ~30 min. Staff will receive refresher training and complete reliability assessments for physical measures 2-3 times/yr.

Demographic data: Basic demographic information (age, race/ethnicity, sex, current PA level) for both participants and their study partners will be collected at baseline.

Anthropometrics (Weight, height, BMI%ile, waist circumference) Participants will be weighed in shorts and a t-shirt between 7 and 10 AM, in duplicate, on a calibrated scale (Model #PS6600, Belfour, Saukville, WI) to the nearest 0.1 kg. Standing height will be measured in duplicate with a portable stadiometer (Model #IP0955, Invicta Plastics Limited, Leicester, UK). BMI%ile will be calculated using the CDC BMI%ile calculator for children and teens (http://apps.nccd.cdc.gov). Waist circumference will be assessed using the procedures described by Lohman et al. Three measurements will be obtained with the outcome recorded as the average of the closest 2 measures.

Quality of life. QOL will be assessed with the Personal Well-Being Index-Intellectual Disability.

Energy and macronutrient intake. Diet intake will be assessed during 3 consecutive days (2 wk days and 1 wk end day) starting the weekend prior to the outcome assessment date using standard proxy assisted 3-day food records augmented with food photos. IDD. Participants with assistance from a caregiver (if necessary) will be asked to take before and after photos of all food and beverages consumed at home over 3 days with the iPad camera. Participants will complete hard-copy proxy-assisted (parent) diet records to account for details about food and beverage not available from photos such as skim or whole milk, etc. To facilitate accurate recording, instructions developed by Dr. Sullivan ("How to record your food record") that describes the food record and provides detailed examples to assist with the estimation of portion size, as well as instructions on how to take food photos, will be loaded into the iPad. Calendar prompts will be programmed into the iPad to remind all participants to comply with the photo/record protocol. The iPad automatically date and time stamps all photos for easy identification. During the outcome visit the 3-day food record and photos will be reviewed to clarify food record entries. The energy and macronutrients of the diet record information will be assessed using Nutrition Data System for Research (NDSR version 2016, University of Minnesota, Minneapolis, MN).

Medication Record. At each assessment period of baseline and months 6, 12, 18 all medications the participant is currently taking will be documented. The information gathered will include the medication name, reason for taking, amount and frequency of dosage as well as the cost of the medication. This information will be collected to monitor any cost changes in medication throughout the study and will be included in the cost analysis. .

PA. Compliance with PA recommendations will be assessed using an accelerometer (min. of MVPA) over 7 consecutive days at baseline, 6, 12 and 18 mos. Participants will be asked to wear the accelerometer belt on their non-dominate hip. A minimum of four 10-hr. days at each time point will be considered a valid observation (85).

Attendance: The health coach will record attendance at all health education sessions. The participant will only be considered present if they complete session.

Semi-structured interview: Dr. Szabo-Reed will conduct structured interviews by phone with a 20% random sample of participants and study partners from both intervention groups following completion of the intervention to gather information which might be useful in improving the intervention and/or implementing the intervention in settings serving adults with IDD. Topics will include, preference for FTF or RD, intervention length, difficulties in complying with intervention components, suggestions for improving the intervention, overall satisfaction, including the diet and PA recommendations, behavior sessions, and satisfaction with health educators. All interviews will be recorded and transcribed verbatim. Data will be entered into a qualitative data software program (Atlas.ti 7, Berlin, Germany). Any coding disagreements will be brought to the research team for review and discussion until 100% agreement is reached. A content analysis of the transcribed interviews will be conducted using the method suggested by Miles and colleague (91) and further described by Ryan and Bernard (92) to explore trends and identify common themes across interviews using an inductive method.

Study Partner Questionnaire. Study partner self-efficacy for providing assistance with weight management will be assessed using the 6-item scale developed by Heller et al. (89). Each statement is rated from 1 (strongly disagree) to 5 (strongly agree). Cronbach's alpha = 0.77.

Cost Analysis. Our previous trial comparing FTF and RD (group phone) for weight management (38) suggests higher costs in the FTF group due to costs for both travel and time associated with home visits. We will conduct a cost effectiveness analysis using between group differences in mean weight loss at 6 and 18 mos. (76). The cost perspective for all analyses will be societal. We will collect data on both program (health educator time, supplies, iPads) and participant/study partner costs (time), prospectively. Time is a component of intervention cost, as time devoted to an intervention cannot be used for work or leisure (77). Participant and study partner time will be valued at the local median hourly wage. These costs, which may be half of the total costs (78, 79), will be gathered via survey (80). We will conduct sensitivity analyses that vary the value of participant/study partner time from $0.00 to the median hourly wage. The gold standard for measuring cost is a time study, based on a validated flowchart (81, 82). We will validate flowcharts for both study arms and use time studies to measure health educator time and program records to measure cost of supplies. Weight management programs have effects in addition to weight loss (e.g., increased vitality or enhanced attractiveness), thus the value of a program to clients may be imperfectly measured by objective outcomes (weight). Contingent valuation, in which participant's express preferences for programs, will be used to examine the perceived worth of the RD and FTF formats at 6 and 18 mos. (83). If the preference questions have acceptable psychometric properties conditional logistic regressions, with adjustments for clustering by health educator, will be used to analyze how differences in client attributes, anticipated costs/gains affect preferences for delivery formats.

COVID 19: During the Covid-19 pandemic restrictions all assessment materials will be delivered to participant homes. All materials will be disinfected beforehand and will be delivered to participant's homes. A stamped, self-addressed envelope will be included to allow participants to mail surveys and accelerometers back. All face-to-face meetings will be conducted by phone.

Statistical Methods

Analysis plan. *Primary aim.* We will construct a two-sided 95% confidence interval for the difference in mean 6 mo. weight loss between the RD and FTF groups. If the lower limit of the confidence interval is >-3 and the upper limit is > 0 we can conclude that RD is non-inferior to FTF. If we find that 6 mo.

weight loss in the RD group is superior to FTF, i.e. the lower limit of a 2-sided 95% confidence interval for the difference in weight loss is >0 and the upper limit is > 4, we will compare process variables/participant characteristics, i.e., behavioral session attendance, compliance to diet/PA and self-monitoring of diet/PA between the 2 groups and also include these variables in a regression model to determine if they explain/attenuate the treatment effect. *Secondary aim 1*. We will compare mean weight loss between groups across 24 mos. using linear mixed modeling assuming an autoregressive correlation structure over time. *Secondary aim 2.* Generalized estimating equations will be used to longitudinally compare the proportion of participants who achieve ≥ 5% weight loss between groups across 24 mos. Participants with missing weight at any time point will be classified as not meeting the ≥ 5% goal at that time point. *Secondary aim 3.* We will compare between group changes in quality of life across 24 mos. using linear mixed models assuming an autoregressive correlation structure over time. *Exploratory aims.* If our non-inferiority hypothesis for weight loss at 6 mos. is supported, and there are no between group differences in the longitudinal change in weight across 24 mos. we will use linear mixed models to examine the association of process variables/participant characteristics i.e., behavioral and PA session attendance, compliance to diet (energy intake, number of entrées/shakes, servings of fruits/vegetables) and PA (min of moderate-vigorous PA) recommendations, self-monitoring of diet and PA, sex, age, IDD diagnosis, caregiver self-efficacy/turnover, and obesogenic medications with weight change across 18 mos.; i.e. the end of the intervention. However, if we find a between group difference in longitudinal weight change across 24 mos. (Secondary aim 1) we will use linear mixed models to determine if the previously listed process variables/participant characteristics explain/attenuate the treatment effect. Some covariates are assessed only at baseline (sex, age, IDD diagnosis), some will be summarized across the trial (behavioral and PA session attendance, self-monitoring diet and PA) while others are assessed at specific time points (energy intake, number of entrées /shakes, servings of F/V, MVPA, medications). Thus, we will carefully examine our models to assure the appropriateness of the analysis. Differences between treatment groups in variables summarized across the trial will be compared using a two-sample t-test for continuous measures or chi-square test for discrete measures. Variables assessed at specific time points will be compared longitudinally using mixed linear models for continuous, or generalized estimating equations for discrete outcomes. *Other statistical considerations*. Randomization dictates baseline differences in covariates would be due to chance, and thus will not be compared statistically as recommended by CONSORT guidelines (93). We are aware that some households may enroll more than one participant. In this case, as was done in our completed trial in adults with IDD (DK83539), all participants in the household will be assigned to the same treatment group. The intra-class correlation (ICC) for 6-mo. weight loss in our completed trial was essentially zero and had no impact on the outcome. If an ICC is found in this trial, we will evaluate the impact of the ICC on our primary outcome. If an effect is detected, a random effect for household will be included in all analysis.

Missing data. Analysis of our primary aim will be based on intent-to-treat principles using imputation for missing data. If the proportion of participants lost to follow-up differs by treatment 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 demographic characteristics, we will use model based multiple imputation; otherwise, we will use traditional multiple imputation (k=5). Statistical procedures will be performed using SAS version 9.4 or higher.