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Remote Delivery of Weight Management for Adults with Intellectual and Developmental Disabilities: Rationale and design for a 24 Month Randomized Trial

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Abstract

Adults with intellectual and developmental disabilities (IDD) represent an underserved segment of the US population with a high prevalence of obesity and limited options for weight management. Previous research has demonstrated clinically meaningful weight loss of 7% of total body weight in adults with IDD using an enhanced Stop Light Diet (eSLD) in combination with monthly at-home face-to-face (FTF) behavioral sessions, and a recommendation for increased physical activity. However, the time and cost associated with FTF delivery (travel + sessions) limits the potential for scaling and implementation and suggests the need for the evaluation of less costly and burdensome strategies for intervention delivery. Therefore, we will conduct a 24-mo. randomized trial to compare a weight management intervention (6 mos. weight loss, 12 mos. maintenance, 6 mos. no-contact follow-up) delivered to 120 overweight/obese adults with IDD in their home, either remotely (RD) using video conferencing on a tablet computer, or during FTF visits. Our primary aim is whether RD is non-inferior to FTF for weight loss (0–6 mos.). Secondarily, we will compare the RD and FTF groups on mean weight loss, the proportion of participants who achieve clinically meaningful weight loss, and changes in quality of life across 24 months. We will also conduct cost analysis, cost-effectiveness, and contingent valuation analyses to compare the RD and FTF groups.

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Keywords

intellectual and developmental disability; weight management; technology; physical activity; Stop Light Diet

INTRODUCTION

Intellectual and developmental disabilities (IDD), are characterized by significant limitations in both intellectual functioning ($IQ < 75$) and in adaptive behavior including conceptual skills, social skills and practical skills, 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, 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.

Reports from government agencies [14–16] and professional organizations [17] have recommended efforts to reduce the prevalence of overweight/obesity and related chronic disease in adults with IDD. However, in a recent systematic review on weight management in adults with IDD, Spanos et al [18] identified only a limited number of trials ($n=22$). 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 physical activity through the use of behavioral strategies” [19], and not unexpectedly, reported minimal weight loss ($< 3\%$).

In contrast, our group [20, 21] and others [22–24] have observed clinically meaningful weight loss of $\sim 5\%$, and successful weight maintenance using multicomponent interventions in adults with IDD. Melville et al. [22] 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 $\sim 5\%$ from baseline. In a follow up study, Spanos et al [25] conducted a 12 mo. multicomponent weight maintenance trial (monthly meetings) in a sample of 28 participants who had achieved $\sim 3\%$ weight loss as in the Melville et al trial [22]. Results indicated 72% of participants maintained ($\pm 3\%$) or lost weight. Harris et al [24] completed 12 mo. weight management (6 mos. weight loss, 6 mos. weight management) in 50 adults with IDD comparing the multicomponent weight loss program used by Melville et al [22] to a commercial based program that follows basic health educator principals (WWToo). Results indicate that 50% of participants randomized to the multicomponent weight loss program lost $>5\%$ weight loss across the 12 months, compared to 20.8% in the WWToo. Martinez-Zaragoza et al. [23] reported clinically meaningful weight loss (~ 8 kg) in response to a 17-week intervention consisting of reduced energy intake, physical activity and a token economy motivational system, in a sample of 33 adults with IDD attending a community occupational therapy day center.

Our group previously completed an 18 month trial in adults with IDD to evaluate the effectiveness of multi component weight loss/maintenance interventions using an enhanced Stop Light Diet (eSLD) [26]. 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 physical activity, in a sample of 66 overweight/obese adults with IDD [20]. Mean weight loss was -6.4% and -8.7% at 6 and 12 mos., respectively. Then we 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 149 adults overweight/obese adults (BMI ≥ 25 kg/m²) with mild to moderate IDD, living in the community [21]. 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 $\geq 5\%$ at 6 mos. was also 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% $p = 0.82$).

While the results from previous multi-component weight loss trials are encouraging; 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. Remote interventions have the potential to overcome many of these barriers, and have shown moderate evidence for delivery of weight loss interventions in typically developing adults [19]. The need for alternative strategies for delivering weight management to adults with IDD led to the development of the current randomized trials designed to determine if a multicomponent weight management intervention delivered remotely is non-inferior to the same intervention delivered FTF.

METHODS AND MATERIALS

Overview of study design (Table 1)

One hundred twenty overweight/obese adults with mild to moderate IDD and their study partners will be randomized to a 24-month non-inferiority trial with 6 months weight loss, 12 months weight maintenance, and 6 months no-contact follow up to compare a weight management intervention delivered to adults with IDD in their home, either remotely (RD) via video conferencing (Zoom software) on a tablet computer (iPad), or during FTF home visits. Both intervention arms will include monthly at-home behavioral sessions (adult + caregiver), an eSLD, and increased physical activity. The RD arm will include group physical activity delivered using video conferencing (2 session/wk.) and will use commercially available web-based applications for self-monitoring/participant feedback for diet (Lose it!), physical activity (Fitbit activity tracker), and weight (Wi-Fi scales). To keep within the CONSORT guidelines for a non-inferiority trial [27], the FTF arm will be identical to the intervention shown to be effective in our previous trial [21] and will include self-directed physical activity, self-monitoring of diet and physical activity using paper/pencil logs, and weight assessed during monthly home visits. The primary aim is 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 aim 1 is to compare the RD and FTF groups on mean weight loss (kg) and the proportion of participants who achieve clinically meaningful weight loss (5%) across the 24 mos, including 6 (end of weight loss) and 18 mos (end of weight maintenance). Secondary aim 2 is to compare the RD and FTF groups on changes in quality of across 24 months in participants randomized to either RD and FTF. We will also conduct cost, cost-effectiveness and contingent valuation analyses to compare the RD and FTF groups. Lastly, we will also explore the influence of behavioral session attendance, compliance to recommendations for diet (energy intake, number of entrées/shakes, servings of fruits/vegetables, physical activity (min of moderate-vigorous physical activity), self-monitoring of diet and physical activity, sex, age, IDD diagnosis, caregiver self-efficacy/turnover, and obesogenic medications on weight loss across 18 months.

Intervention-Theoretical Model.

The intervention is based on Social Cognitive Theory [28]. Specifically, the proposed intervention will employ goal setting, self-monitoring, stimulus control, prompts, scheduling, environmental cues, modeling, positive reinforcement, behavioral contracting, and other self-regulatory techniques.

Participant Eligibility

Primary care physician (PCP) clearance will be required for all participants. To enhance generalizability, individuals on medications for common chronic diseases (i.e., depression, blood pressure, lipids, type 2 diabetes) or other medications that may compromise weight loss or induce weight gain will not be excluded, as this would diminish the generalization of the results. Inclusion/Exclusion criteria is presented in Table 2.

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 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 RD and FTF groups.

Caregiver Role

Caregivers play a potentially pivotal role in weight management for adults with IDD, e.g., assisting with decisions regarding meal planning, food shopping, and meal preparation, and assisting with scheduling and participation in appropriate physical activity [29]. Caregivers have been included in successful multicomponent weight management interventions by our group [20, 21, 30] and others [22, 23, 25]. 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 physical activity, and assisting with self-monitoring of diet, physical activity and weight. However, study partners will neither be encouraged or discouraged to diet or increase their physical activity. To facilitate study partner/participant/health educator interaction, we will use a scenario approach which scripts the flow of activity to assure personal choices and preferences, and that person-centered plan objectives are addressed [31, 32]. The health educator, study partner, and participant will work collaboratively to develop a written scenario outlining the specific types of foods to be included in the diet, and the specifics of the physical activity program (time of day, where, etc.) to reflect participant desires. Scenarios will be reviewed at monthly meetings and modified, if necessary.

Diet

Energy intake.—During weight loss (mos. 0–6) energy intake will be prescribed at 1,200–1,500 kcal/d for women and 1,500–1,800 kcal/d for men as recommended by AHA/ACC/TOS weight management guidelines [19]. Participants for whom additional weight loss would be contraindicated (e.g., BMI of ≥ 22 kg/m² or losing > 20% of baseline weight) will be placed on a weight maintenance diet at any time during the intervention. Those continuing to lose weight will be referred to appropriate health professionals/agencies and may be dismissed from the trial. Energy intake for weight maintenance (mos. 7–18) and the no-contact follow-up period (mos. 19–24) will be based on the resting metabolic rate (RMR) equation of Mifflin-St Jeor [35] adjusted for activities of daily living (RMR x 1.4–1.6) as participants will have a routine physical activity program. The goal of the maintenance period is to prevent weight regain, defined as >3% increase in body weight, as suggested by Stevens et al [36]. However, additional weight loss will neither be encouraged or discouraged. Participants who gain weight, as measured at monthly sessions, will be counseled to improve compliance to the diet and physical activity protocols.

eSLD.—The original Stop Light Diet, developed for use in children [26], categorizes foods by energy content. The Stop Light Diet is easy to understand and implement when compared with a CD, which requires selection of appropriate foods from an unlimited array of options, making it difficult to consistently prepare a nutritionally adequate reduced energy diet. We will “enhance” the Stop Light Diet (eSLD) using a combination of commercially available PCMs (entrées and shakes). Labels on PCMs include nutritional information (energy, fat,

protein etc.) making it easier to adhere to specific energy and nutrient recommendations. The simplicity of the eSLD may be especially relevant for adults with IDD as caregivers (study partners) frequently have limited formal education specific to nutrition, and the turnover rate among paid caregivers is high [33]. The Academy of Nutrition and Dietetics Evidence Analysis Library provides strong, consistent, supportive evidence (Grade I) that PCMs result in significantly greater weight loss and maintenance compared with CDs, and are especially useful in individuals who have difficulty with food selection and portion control [34]. During weight loss (mos. 06), 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 categorizes 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. Two lowcalorie shakes/day (Profile by Sanford Health, Sioux Falls, SD) 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. 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.

Behavioral Sessions

Behavioral sessions (45–60 min) will be conducted monthly in both the RD and FTF groups across the 18-mo. active intervention. During weight loss (months 0–6), health educators will review self-monitoring data for diet, physical activity and weight (described below), review a lesson related to weight loss (e.g. goal setting, benefits of fruits and vegetables, importance of exercise), answer questions, problem-solve, and provide support. Behavioral sessions during maintenance (months 7–18) will focus on transitioning to a conventional diet with strategic incorporation of PCMs and continued use of SLD principles. The monthly lessons will cover topics related to successful weight maintenance such as relapse prevention, self-monitoring, regular physical activity, eating on weekends/vacations, and controlling energy intake on special occasions and holidays, etc. Identical session lessons will be loaded on the iPads of the RD groups or provided as a booklet for the FTF group.

Physical Activity

All participants will be recommended to obtain 150 min/wk. of moderate to vigorous physical activity (3 METs) as recommended for all adults by the American College of Sports Medicine [37] and the US Department of Health and Human Services [38]. Recommended physical activity 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 physical activity in bouts 10 min will be permitted. We recognize that 150 min./wk. is less than the 300 min./wk. generally recommended for weight

management [39]. However, the physical activity level of adults with IDD is extremely low [9, 40, 41], making the 300 min/wk. goal unrealistic.

Physical Activity-RD.—Interventions to increase physical activity have been generally unsuccessful [21, 42–44]. Considering the general health benefits associated with increased physical activity [45, 46] and the importance of increased physical activity in long-term weight maintenance [39], we chose to offer an innovative approach for physical activity in the RD group. Participants will be asked to attend two 30min. physical activity sessions delivered by video conferencing to groups of 4–5 adults with IDD in their homes. The feasibility of this approach in individuals with IDD has been previously demonstrated [47, 48]. Multiple sessions will be available for each participant to choose from between 2 and 7 PM on nonconsecutive days. Each session will include a warm-up (~5 min), moderate to vigorous physical activity (~30 min.) and cool-down/stretching (~5 min.) and will be delivered by a health educator. Physical activity will be accompanied by music, and will include walking/jogging in place, dancing, imitating animal movements, vertical/horizontal jumps, squats, resistance band exercises, and movements 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, measured by Fitbit, will be light and increase to moderate or greater at ~ 6 weeks and remain at that level across the 18mo. active intervention. Health coaches will encourage interactions between participants supportive of their peer’s efforts to increase moderate to vigorous physical activity, and also will provide feedback to participants relative to their level of weekly moderate to vigorous physical activity as assessed by the Fitbit. As the intervention progresses, participant volunteers will be asked to create and lead the group in a brief (3–5 min) moderate to vigorous physical activity bout, an activity that was well received in our pilot trials. Participants attending both weekly physical activity sessions will have the potential to accumulate ~ 60 min. of moderate to vigorous physical activity a week. Thus, an additional 90 moderate to vigorous physical activity a week outside groups sessions will be required to meet their weekly 150 min/wk. goal. 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.

Physical Activity-FTF.—Participants in the FTF group will receive written materials and resistance bands and will be asked to complete the 150 min./wk. moderate to vigorous physical activity recommendation on their own, as would occur in usual care settings. Participants will be provided information describing public resources for physical activity in their areas (community centers, walking trails, etc.) and appropriate exercise videos.

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 medical management would be conducted outside the constraints of a research trial.

Intervention implementation

Health educator training.—Health educators will train by shadowing experienced educators for a minimum of 3 mos. All health educators will participate in weekly 2-hr. staff meetings to discuss issues related to intervention delivery. Recordings from all behavioral and group physical activity sessions (FTF-audio, RD-video) will be reviewed. Intervention content that was delivered, will be compared with a checklist of scheduled content (Figure 1). Health educators covering <80% of scheduled content or failing to deliver physical activity as prescribed, will receive additional training and will be dismissed if the problem recurs.

Orientation.—Health educators will conduct 2 home visits (~ 60 min. each) with participants and study partners prior to initiating the intervention. These sessions will include detailed descriptions of the diet (eSLD) and physical activity components of intervention, the respective delivery and self-monitoring formats, and the diet assessment protocol. Participants in both groups will be provided with an iPad (Apple Inc., Cupertino, CA) and props for use with the physical activity program (e.g. throwing scarves, spot markers, resistance bands). Access to non-study related materials, e.g. web browsing, app store etc. will be blocked on all iPads until completion of the study. iPads for the RD group will be pre-loaded with the video conferencing (Zoom Video Conferencing Inc. San Jose, CA), Lose It! (Fitnow Inc., Boston, MA), Fitbit (Fitbit Inc., San Francisco, CA) and wireless scale apps (Withings Inc., Cambridge, MA). The RD group will receive a tutorial on the use of the iPad and will be oriented to the video conferencing software, and the Lose it!, Fitbit, and wireless scales apps/devices used for selfmonitoring diet, physical activity, and weight. Time will be allotted for practice and questions. Tutorials describing trouble shooting for common technical problems (e.g., internet connectivity, data entry using Fitbit, Lose It!) will be loaded on the iPad. Technical issues will be resolved during behavioral sessions, or by contacting research staff by phone or email. The RD group will be provided with an HDMI adaptor which allows video conference sessions to be displayed on a larger TV screen, if desired. Reminders regarding upcoming behavioral/physical activity sessions etc. or prompts for participants in the RD group who are non-compliant with the study protocol, will be sent via the iPad. Participants in the FTF group will be shown how to self-monitor diet and physical activity using paper records specifically designed for use with adults with IDD.

Behavioral Sessions.—Behavioral sessions (45–60 min) will be conducted monthly in both the RD and FTF groups across the 18-mo. active intervention. During weight loss (months 0–6), health educators will review self-monitoring data for diet, physical activity and weight (described below), answer questions, problem-solve, and provide support. Behavioral sessions during maintenance (months 7–18) will focus on transitioning to a conventional diet with strategic incorporation of PCMs, continued use of SLD principles, and cardinal behaviors for successful weight maintenance such as self-monitoring, regular physical activity, eating on weekends/vacations, and controlling energy intake on special occasions and holidays, etc.

Self-monitoring-RD group.—Participants will monitor diet and physical activity on a daily basis and body weight monthly over the 18 mo. intervention. Participants will log

food/beverages (meals/snacks) using the iPad application 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 energy consumed compared with the energy goal providing immediate feedback. To monitor physical activity, participants will wear a Fitbit Charge 2 (size 35.5 × 28 mm) wireless activity tracker on their wrist. The Fitbit records time spent in light, moderate or vigorous physical activity, based on step counts and heart rate [49]. 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 physical activity relative to participant activity goals via a graphic display. 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 will be sent via the Lose It! app if no information is reported for a given meal or goal (i.e., physical activity time). Diet and weight data on the Lose it! app will be securely and automatically transferred to the Lose it! for Wellness Professionals web site that is accessible to the health educator. Fitbit data will be automatically transferred to cloud storage (Fitabase, San Diego, CA). Diet and physical activity data will be accessible to the health educator and will only be used to inform participant counseling during the monthly behavioral sessions.

Self-monitoring-FTF group.—Participants in the FTF group will be provided with a pedometer (Omron HJ-320, Lake Forest, IL) to self-monitor physical activity. The FTF group will enter diet (entrées, shakes, F/V) and physical activity 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/physical activity tracking sheets will be collected by health educators during monthly home visits and will only be used to inform participant counseling.

Incentives.—Reinforcement systems, known as positive behavioral support programs, have been successful in promoting behavioral change in individuals with IDD [50]. These strategies provide modest incentives to motivate participants to meet their goals, and were successfully used in our previous trials in both adolescents [30] and adults with IDD [20, 21]. Participants in both groups who complete self-monitoring for diet and physical activity 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.

Outcome assessments

Most outcomes will be assessed during a 30-minute home visit; however; some assessments will occur across the 18-mo. active intervention (Table 3). 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. Staff will receive refresher training and complete reliability assessments for physical measures 2–3 times/yr.

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 (m²). Waist circumference, as a surrogate for abdominal adiposity, will be assessed using the procedures described by Lohman et al. [51]. Three measurements will be taken with the outcome recorded as the average of the closest 2 measures.

Quality of life

Quality of life will be assessed with the Personal Well-Being Index-Intellectual Disability (PWI-ID) [52, 53]. Cronbach alpha of 0.76, and 1- to 2-wk. test–retest reliability of 0.58 have been reported in adults with IDD [52]. There are 7 items in the PWI-ID scale, each one corresponding to a quality of life domain as: standard of living, health, life achievement, personal relationships, personal safety, community-connectedness, and future security. The PWI-ID scale differs from the original Personal Well-Being Index (PWI-A) in that it incorporates a pre-testing protocol to determine whether, and to what level of complexity, respondents are able to use the scale. Questions on ‘satisfaction’ from the PWI-A are substituted by the term ‘happiness’. The ID version also uses more simple and concrete wordings. An additional question which asks how happy or sad the respondent is with life as a whole is included. A reduced choice format, illustrated as a series of outline faces, from very sad to happy, is provided to enhance comprehension and substitutes for the Likert scale used in the PWI-A version for people who cannot cope with the latter format [53].

Cost Analysis

We will conduct a cost effectiveness analysis using between group differences in mean weight loss at 6 and 18 mos. [54]. 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 [55]. Participant and study partner time will be valued at the local median hourly wage. These costs, which may be half of the total costs [56, 57], will be gathered via survey [58]. 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 [59, 60]. 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 (e.g., 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. [61]. Conditional logistic regressions, with adjustments

for clustering by health educator, will be used to analyze how differences in client attributes and anticipated costs/gains affect preferences for delivery formats.

Process variables/Exploratory aims.

Behavioral session attendance.—Behavioral session attendance will be obtained from health educator records and expressed as the percentage of possible sessions attended.

Adherence with diet recommendations.—Dietary compliance will be assessed using photo-assisted food records over 3 consecutive days (2 wk. days/1 wk. end day) starting the week prior to scheduled outcome assessments. Our group [62, 63], and others [33, 64] have demonstrated the utility of photo-assisted records in adults with IDD. Participants/study partners will take before and after photographs of all foods and beverages consumed using the iPad camera which automatically date and time stamps photos for easy identification. Hard copy records will be completed to account for details not discernible from photos (e.g. skim or whole milk). During outcome visits, a registered dietitian will review photos and food records and clarify ambiguities. If no photo is available for a particular meal, food record data will be used. To facilitate recording, instructions describing how to complete the food record and take food photos, and calendar prompts to remind participants to comply with the protocol, will be loaded/programmed on the iPad. A registered dietitian will calculate the average energy expenditure (kcal/d), macronutrient intake (% carbs, fat, protein), diet quality (Healthy Eating Index 2015), number of PCMs (entrées/shakes), and servings of F/V using the Nutrition Data System for Research (Version 2018, Minneapolis, MN).

Adherence with physical activity recommendations.—Physical activity will be assessed over 7 consecutive days using an ActiGraph Model GT3X+ portable accelerometer (ActiGraph LLC, Pensacola, FL). ActiGraphs will be distributed by the study coordinator during scheduled home outcome assessment visits and returned to research staff via pre-paid mail. Participants will be asked to wear the accelerometer on a belt over the non-dominant hip during all waking hours. A minimum of four 10-hour days at each assessment time point will be considered a valid observation [65]. Study partners will be asked to assist the participant in achieving compliance with the monitoring protocol. The outcome will be the average minutes per day spent in moderate-to-vigorous physical activity over the 7-day period, calculated using the age-specific intensity cut points suggested by Trost et al [66].

Adherence with self-monitoring of diet and physical activity.—Compliance with self-monitoring of diet and physical activity will be obtained assessed as the percentage of prescribed monitoring days completed across 18 mos., and will be obtained by the health educators at the monthly behavioral sessions.

Medication information—(name/frequency/amount) will be obtained by the study coordinator at each outcome assessment and classified (yes/no) as to their association with weight gain/loss [67].

Study Partner Assessment

Study partner self-efficacy for providing assistance with weight management will be assessed using the 6-item scale developed by Heller et al. [68]. Each statement is rated from 1 (strongly disagree) to 5 (strongly agree). Cronbach's alpha = 0.77.

Exit interviews

We will conduct structured interviews by phone with a 20% random sample of participants and study partners from both intervention groups following completion of the weight loss (6 mos.) and weight management (18 mos) interventions 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 physical activity 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 [69] and further described by Ryan and Bernard [70] to explore trends and identify common themes across interviews using an inductive method.

Analysis plan and statistical power

Power.—Our primary aim is to determine whether RD is non-inferior to (as good as) FTF for weight loss (0–6 mos.). Results from our previous IDD weight loss trial using FTF delivery [21], elicited 6 mo. weight loss of -6.8 ± 5.5 kg. Non-inferiority will be declared if mean weight loss for RD is no worse than FTF, within statistical variability, by a margin of -3.0 kg. The 3 kg margin represents the maximal between group difference that would yield clinically meaningful weight loss in the RD group [19]. Randomization of 120 participants, with equal allocation to RD and FTF groups, will provide 84% power to demonstrate non-inferiority assuming the 3 kg margin and a standard deviation of 5.5 kg, with a type I error rate of 2.5%.

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 after all data has been collected (end of the study).

Primary aim analysis.—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/physical activity and self-monitoring of diet/physical activity between the 2 groups and also include these variables in a regression model to determine if they explain/attenuate the treatment effect.

Secondary analysis.—For 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 and 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. For 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 analysis.—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 with weight change across 18 mos. However, if we find a between group difference in longitudinal weight change across 24 mos. we will use linear mixed models to determine if the process variables/participant characteristics explain/attenuate the treatment effect. 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.

DISCUSSION

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), physical activity, and behavioral sessions delivered to participants/caregiver during monthly FTF home-visits.

While the results from previous multi-component weight loss trials, including our own, are encouraging; 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. With the exception of the shortterm trial (17-wk.) reported by Martinez-Zaragoza et al [23], 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, have been delivered FTF to individual participants and a caregiver [20–22, 24, 25]. 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 physical activity.

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 [19], 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 [71] 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 [72], and living [73] and academic skills [74]. Computers are commonly used by individuals with IDD [75, 76], but are underutilized in regards to health promotion [72]. Randomized trials comparing the effectiveness of strategies for the delivery of weight management for individuals with IDD are not available.

This trial will determine whether a multicomponent weight management intervention delivered remotely (RD) to adults with IDD using video conferencing (Zoom software) on a tablet computer (iPad) 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 physical activity. There is virtually no information regarding the comparative effectiveness of weight management strategies for adults with IDD. The demographic, cognitive and social characteristics, and living arrangements of adults with IDD preclude extrapolation of results from weight management trials in typically developed adults to this group. We previously demonstrated the effectiveness of the proposed FTF intervention, thus it was selected as our comparison group. RD may provide weight loss that is non-inferior to FTF at a lower cost with potential for greater reach; thus, RD was selected as the experimental group.

We chose the eSLD for 3 reasons: 1) The eSLD simplifies meal planning, food shopping, and meal preparation which represent significant barriers to weight management for adults with IDD and their caregiver, compared with a CD. 2) The eSLD requires minimal training which enhances the probability of implementation and dissemination by providers of health-related services for adults with IDD. 3) The eSLD has consistently shown clinically meaningful weight loss in the range of 4% to 7% with minimal long-term weight regain in adults [21] and adolescents with IDD [30], and adults with physical disabilities [77]. Mean 6 mo. weight loss with the eSLD in our previous adult IDD trial (–7.0%) was significantly greater than a CD (–3.8%) with a significantly greater proportion of participants achieving 5% weight loss in the eSLD (~63%) compared with the CD group (~40%). Greater initial

weight loss has been associated with greater longer-term weight loss in typically developed adults [78, 79]; thus, greater initial weight loss with the eSLD offers a potential advantage.

Behavioral sessions will be conducted monthly in both the RD and FTF groups across the 18mo. intervention. We recognize that this session frequency is less than recommended for weight loss (i.e., 14 sessions in 6 mos.) by AHA/ACC/TOS guidelines [19]. However, our group [20, 21], and others [22] have shown clinically meaningful weight loss in adults with IDD with less frequent sessions (monthly, or every 2–3 wks.). Thus, we feel that the additional burden on participant's/study partners of more frequent sessions is unwarranted and is likely to reduce the potential for translation of the intervention. Self-monitoring in general, and increased PA are associated with improved weight loss and maintenance [19].

To maximize the potential of the technology used to deliver the behavioral sessions in the RD group we will also use technology for self-monitoring of diet (Lose it!), PA (Fitbit) and weight (wireless scales), and to deliver a group-based PA program (group video conferencing). These selfmonitoring/delivery apps/devices are commercially available, easy to use, interface seamlessly with the iPad being used for behavioral session delivery, and provide immediate participant feedback. We are aware of the inherent differences between the FTF and RD groups in self-monitoring and delivery of PA. These interventions were designed as separate packages that could be delivered by agencies serving this population, and thus we will be compared as such. However, the impact of level of compliance with both the self-monitoring protocol, level of PA, and attendance at group PA sessions on weight loss in each group will be evaluated in exploratory analysis.

Design and methodologic strengths of this trial include: 1) Randomized design with equal allocation to groups with allocation concealed; 2) Adequate statistical power to address the primary aim; 3) Strategies to ensure the recruitment of sufficient participants to achieve our desired sample size; 4) Retention/incentive strategies to reduce loss to follow-up; 5) Secondary and exploratory aims to maximize the use of data; e.g., analysis to examine the impact of process variables/participant characteristics on weight change; 6) The use of a theory-based intervention delivered by trained health educators; 7) Delivery of both arms of the intervention by the same health educator to cohorts of participants to minimize health educator effects; 8) Procedures to ensure intervention fidelity; 9) Assessments completed by trained staff blind to intervention arm; 10) Evaluation of staff inter-rater reliability for all physical assessments; 11) Novel assessments of diet improve data quality; 12) Exit interviews to obtain potentially useful information for improving and/or implementing the intervention 13) An analysis plan to adequately address study aims.

In summary, this trial will determine whether a multicomponent weight management intervention delivered remotely to adults with IDD is non-inferior to weight management delivered face to face. If successful, the remote delivery approach, using an eSLD, will provide a weight management option that is potentially scalable and cost-effective that could be implemented by agencies providing weight management for adults with IDD.

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Abbreviations:

eSLD	enhanced Stop Light Diet
IDD	intellectual and developmental disabilities
PCM's	portion controlled meals
RD	remote delivery
FTF	face to face

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**IDD Tech Weight Loss Study
Health Educator Observation Form**

Meeting Date: Meeting Month: Group: TECH FTF
HE: Participant:

Monthly Meeting Activities		Task Completed by HE?	
I.	Weigh In & Tracking of Progress		
	A. Obtain weight	YES	NO
	B. Plot weight and/or discuss progress	YES	NO
	COMMENTS:		
II.	Review diet and pa / Progress from previous meeting		
	A. Talk about progress from last session/beginning of program	YES	NO
	B. If barriers identified, help the participant problem solve	YES	NO
	C. FTF – review logs; TECH – access lose it data, provides feedback	YES	NO
	COMMENTS:		
III	Education / Lesson		
	A. Adequately covered the main points of the lesson	YES	NO
	B. Generated good discussion with participant (or study partner)	YES	NO
	C. Did not simply read from the lesson	YES	NO
	COMMENTS:		
IV	Goal Setting		
	A. Follow up on goals set at previous meeting	YES	NO
	B. Set new goals for the next month	YES	NO
	C. Did the HE involve the participant when setting the new goals?	YES	NO
	COMMENTS:		
V	Incentives		
	A. Were the incentives distributed and encouragement provided?	YES	NO
	B. Did the HE provide support and encouragement for a good next month?	YES	NO
	COMMENTS		
VII	Next Appointment		
	A. Was the next meeting scheduled?	YES	NO
	Total		

Other Comments:

Figure 1.
Health Educator Observation Form

Table 1:

Design Overview for the Active 18-Month Weight Management Intervention

	INTERVENTION GROUPS	
	Remote Delivery (RD)	Face-to-Face Delivery (FTF)
Behavioral sessions		
<i>Delivery method</i>	Individual video conferencing	Individual FTF home visit
<i>Meeting frequency /session duration</i>	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)
Physical Activity Recommendation	150 min/wk.	150 min/wk.
Group Physical Activity Sessions		
<i>Delivery method</i>	Group video conferencing (iPad) (10–12 participants)	NA
<i>Session frequency /duration</i>	2x/wk./30 min	NA
Self-Monitoring (Diet)	Lose it! app	Self-report/pencil/paper
Self-Monitoring (Physical Activity)	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

Table 2:

Participant Eligibility Criteria for an 24-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 no plans to relocate outside the study area over the next 24 months.
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 participate in physical activity.
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
Internet:	Internet access
Exclusion	
Health concerns:	Individuals with uncontrolled hypertension, severe heart disease, cancer, HIV, etc. Individuals with Insulin dependent diabetes as this condition requires medical monitoring beyond the scope of this study. Individuals with a diagnosis of PraderWilli Syndrome.
Recent weight loss:	Participation in a weight loss program within the past 6 months.
Specialized Diet	Serious food allergies, consuming special diets (vegetarian, Atkins etc.), aversion to common foods (e.g., unwilling to consume dairy products, vegetables),
Weight	Baseline weight >400lbs as these individuals require more aggressive interventions (e.g., surgery, medication, etc.).
Pregnancy:	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

Table 3

Assessment Schedule across the 24-Month Intervention Period.

Study Month	Continuous (Mos. 0–18)	0	6	12	18	24
Outcomes: Primary/Secondary						
Anthropometrics ^a		X	X	X	X	X
Quality of life		X	X	X	X	X
Cost Analysis	X					
Demographics/health history		X			X	X
Outcomes: Exploratory						
Compliance-Diet/physical activity		X	X	X	X	
Behavioral session attendance	X					
Self-Monitoring- Diet/physical activity	X					
Medications		X	X	X	X	X
Study partner self-efficacy		X	X	X	X	
Exit Interviews					X	

^a Anthropometrics includes height, weight, waist circumference, and BMI.