Weight Management for Adolescents with Intellectual and Developmental Disabilities

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Protocol and Analysis Plan

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Aims and Hypothesis

Rates of obesity and obesity related chronic health conditions are higher in adolescents with Intellectual and Developmental Disabilities (IDD) than in the general population. Current data also indicate that many of the negative health consequences observed in obese adults are already present in obese adolescents with IDD. Healthy People 2020, the National Institute on Disability and Rehabilitation Research, and the Surgeon General's Report on Health and Wellness of People with Disabilities all recommend additional efforts to decrease the high prevalence of obesity among children, adolescents, and adults with disabilities. To further illustrate the need for and interest in effective strategies to reduce obesity in individuals with special needs, NIH has recently released FOA PA-11-039 "Understanding and Treating Co-Morbid Conditions in Adolescents with Intellectual and Developmental Disabilities," and PAR-13-213 "Outcome Measures for use in Treatment Trials for Individuals with Intellectual and Developmental Disabilities." This has been followed by an RFA from the Maternal and Child Health Bureau "Research Network on Promoting Healthy Weight among Children with Autism Spectrum Disorders and other Special Health Care Needs," (HRSA-13-184). The NIH RePORTER System includes only 4 studies (1 experimental trial) examining weight management for adolescents with IDD. In preliminary studies, we have demonstrated clinically significant weight loss with behavioral interventions guided by Social Cognitive Theory using energy restriction via an enhanced Stop Light Diet (eSLD = SLD + portion-controlled meals) and increased physical activity (PA) in both adults (DK83539-ongoing) and adolescents with IDD. In both our adult pilot and our on-going NIH adult trial we delivered the intervention (diet/PA) to the participant and their care provider during a face-to-face (FTF) home visit, and used conventional paper and pencil data reporting (diet/PA) for self-monitoring and participant feedback. In our recently completed 2 mo pilot weight loss trial in 20 adolescents with IDD we delivered the behavioral intervention to the participant and a parent using FaceTimeTM via an iPad and used commercially available web-based applications for self-monitoring and participant feedback for both dietary intake (Lose it!) and daily PA (Fitbit electronic step counter). Based on the encouraging results from our adolescent pilot using a technology driven intervention, which allowed for timely and targeted participant feedback and the need for effective, scalable weight management programs for adolescents with IDD, we are proposing an adequately powered, 18 mo trial (6 mo weight loss; 12 mo maintenance). We will randomize 123 adolescents with mild to moderate IDD to 1 of 3 groups: FTF delivery /conventional energy reduced meal plan diet (FTF/CD), technology delivery/CD (TECH/CD), and TECH/enhanced Stop Light Diet (TECH/eSLD). The FTF intervention will be delivered during home visits and self-monitoring will be completed using conventional paper and pencil reporting of diet and PA via pedometer. TECH groups will receive an identical weight management intervention delivered via FaceTimeTM using an iPad and commercially available web-based applications for self-monitoring and participant feedback for both dietary intake (Lose it!) and PA (Fitbit). Our study will compare 1) diets and 2) delivery systems and will address the following aims:

Primary aim: To compare weight loss from 0-6 months between groups randomized to FTF/CD, TECH/CD and TECH/eSLD. This design will provide comparisons of both delivery systems (FTF/CD vs.TECH/CD) and diets (TECH/CD vs. TECH/eSLD). We expect significantly greater weight loss for TECH/CD compared to FTF/CD and significantly greater weight loss for TECH/eSLD compared to TECH/CD.

Secondary aims. 1) Weight Maintenance. To compare weight maintenance from mos 7-18 between groups randomized to FTF/CD, TECH/CD, or TECH/eSLD. We expect significantly greater weight maintenance for TECH/CD compared to FTF/CD and greater weight maintenance for TECH/eSLD compared to TECH/CD. 2) Cost Analysis. We will conduct a cost analysis and contingent valuation analysis to compare costs between the FTF and TECH delivery systems. Based on our experience in delivery of weight management with technology ("Equivalent weight loss with phone or clinic weight management programs" DK76063, "Virtual reality to improve weight maintenance" DK94833), we expect TECH/CD to be less expensive compared to the FTF/CD intervention.

Exploratory aims. We will examine energy balance variables (dietary intake, PA), process variables (self-monitoring, meeting attendance), parental diet and PA, parental baseline weight and weight change, and psychosocial variables (parents beliefs and attitudes regarding nutrition and PA) to assess their influence on weight loss (mos 0-6) and on weight maintenance (mos 7-18).

Rationale

There is virtually no information regarding the comparative effectiveness of dietary approaches or methods of delivery for weight management (loss/maintenance) in adolescents with IDD. As previously described, the characteristics of adolescents with IDD, and the altered dynamics of interactions with parents and siblings preclude extrapolation of weight management results from trials of normally developed adults or adolescents to this population. We chose to compare a CD with the eSLD as the effectiveness of these diets in adolescents with IDD has not been established.

The information obtained from this study will be used to increase our understanding regarding strategies for the effective delivery of weight management to adolescents with IDD. The risks to participants in this study are small and the benefits to participants and other individuals with IDD in need of weight management are potentially large.

Both diets have the potential to result in clinically significant weight loss/maintenance; however, based on our short pilot trial (2 mos.) we expect greater weight loss/maintenance with the eSLD compared with the CD. Thus, if our expectations hold true, adolescents with IDD will have 2 proven weight loss/maintenance strategies from which to choose, depending on the magnitude of weight loss desired and personal dietary preferences. The traditional FTF-group delivery of weight management used in normally developed individuals presents burdens for time, cost, and travel and may not be feasible for parents and adolescents with IDD, and this may be exacerbated in rural and lower socioeconomic populations. Thus, alternative delivery strategies need to be evaluated in the IDD population. Although technology has been successfully used to deliver weight management in normally developed adolescents and adults there are no trials establishing the comparative effectiveness of weight management delivery systems in adolescents with IDD. Results from our 2 mo pilot trial demonstrated the feasibility of using currently available technology (iPad, LoseIt, Fitbit) for delivery and self-monitoring of weight management in this group. Therefore, we chose to compare the effectiveness of a CD delivered by what may be considered a usual care format (individual FTF meeting, self-monitoring by pencil and paper) with the same diet delivered using technology (individual meeting via FaceTime, self-monitoring via LoseIt! and Fitbit.). Thus, our 3 group design (FTF/CD, TECH/CD, TECH/eSLD) allows for comparisons of both diet (TECH/CD vs. TECH/eSLD) and delivery systems (FTF/CD vs. TECH/CD).

Research Plan and Design

Study Objectives. This is a randomized trial designed to test the two hypotheses: 1) the technology delivered intervention with CD (TECH/CD) is more effective for weight management in adolescents with IDD than FTF intervention with CD (FTF/CD) and 2) the technology delivered eSLD (TECH/eSLD) intervention is more effective than technology delivered CD (TECH/CD) for weight management in adolescents with IDD.

Overview of approach. This is a randomized trial. We propose to evaluate 2 of the major components of weight management interventions; delivery system and type of reduced energy diet. We will randomize 123 overweight/obese adolescents with mild to moderate IDD to one of 3 groups for an 18 mo trial (6 mo weight loss; 12 mo weight maintenance): Group 1: FTF delivery/CD; Group 2: TECH delivery/CD; Group 3: TECH/eSLD. All intervention sessions will be delivered to individual participant/parent dyads (not groups) to provide counseling for each parent/participants unique situation. All groups will be prescribed a program of increased moderate intensity PA. Participants and parents will attend optional 30-45 min sessions with a health educator every other week during weight loss (0-6 mos), twice per mo during the first 6 mos of weight maintenance (7-12 mos) and once per mo during the last 6 mos of weight maintenance (13-18 mos). The TECH based interventions will be delivered using FaceTimeTM which is an iPhone/iPad application (Apple Inc.,Cupertino,CA) that allows users to participate in real-time video conferencing. Self-monitoring for both diet and PA will be completed using web-based applications for diet (Lose it!) and PA (Fitbit). The FTF intervention will be delivered during home-visit meetings and self-monitoring will be completed by pencil and paper records. The primary outcome (body weight) will be assessed during a home visit by research staff in all groups on the following schedule: baseline (mo 0), after weight loss (mo 6), at midpoint (mo 12) and end of weight maintenance (mo 18)

During the COVID-19 restrictions the FTF group will meet with the HE by phone call. Health educators will call participants at a phone number designated by the participants and their parent, from a University issued cell phone.

Table 1. Approach overview by group

	TECH/eSLD	**TECH/CD**	**FTF/CD**
Diet	eSLD	CD	CD
Meeting Format	FaceTime	FaceTime	Face to face
Self-monitoring (Diet)	Lose it! Application	Lose it! Application	Pencil/Paper
Self-monitoring (PA)	Fitbit & Lose it!	Fitbit & Lose it!	Pedometer – Pencil/Paper
iPad Function	Intervention Delivery (FaceTime) Self-monitoring (diet/PA) Food photos (outcome)	Intervention Delivery (FaceTime) Self-monitoring (diet/PA) Food photos (outcome)	Food photos (outcome)

Technology Overview: All participants will be provided with an iPad tablet computer (Apple Inc., Cupertino, CA). The TECH groups ipads will be pre-loaded with both the video conferencing (Facetime), Lose it! and Fitbit applications. The FTF group will have an ipad that will be used for use of the photo-assisted food records, and to play games received as an incentive for participation in the study. Downloading of other applications or internet browsing will be restricted on all iPads. A Fitbit Flex (Model: Flex tracker, Fitbit Inc. San Francisco, CA) wireless PA monitor, to document the daily PA will also be provided to all participants in the TECH group. Data from the Fitbit is automatically uploaded to the iPad and will be transferred to the study database on a remote server. Participants will be allowed to keep the iPad and Fitbit at the completion of the study.

Recruitment: We will recruit participants through local community programs serving adolescents with IDD, and with print and web advertisements in our target area, university broadcast emails and the KUMC HERON database. Recruitment materials will include contact information (toll-free phone, email). Questions from interested parents will be addressed and initial eligibility screening will be completed via phone or email. Home visits will be scheduled with interested parents and potential participants to explain the project, answer questions, obtain parental consent and adolescent assent, and determine eligibility. Choice is a key element in programs for IDD populations; thus, if parent consent is obtained but adolescent assent is not obtained the adolescent will not be enrolled. Individuals found to be ineligible will be referred to appropriate weight management options.

Randomization: One hundred ten participants will be stratified by BMI%ile (<95%ile, >95%ile) and then randomized in a 1:1:1 allocation to either FTF/CD, TECH/CD or TECH/eSLD. Randomization will be completed by Dr. Mayo, the study statistician. Allocation will be concealed and group assignments will be placed in sealed envelopes and delivered to the study coordinator. The nature of our intervention precludes blinding of the health educators; however, investigators, data analysts and research assistants who collect outcome data will be blinded to condition.

Inclusion/exclusion criteria. Inclusion: 1) Age 13-21 yrs (at least 50% female) with mild (IQ of 74-50) or moderate (IQ 40-49) IDD. Individuals younger than age 13 will be excluded to avoid the differences in issues relative to weight management in younger children. A diagnosis of IDD will be determined by doctor's diagnosis or IQ test results. Parents must present documentation of diagnosis to the study team before the participant consents to be in the study. 2) Of 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. 3) Overweight or obese (BMI ≥ 85th%ile on CDC growth charts, or waist circumference to height ratio > 0.5 which indicates excess central adiposity in children and adolescents. 4) Living at home with a parent or guardian. 5) Internet access in the home. 6) No plans to relocate outside the study area over the next 18 mos 7) Physician consent for PA and diet. Exclusion: 1) Insulin dependent diabetes as they require medical monitoring beyond the scope of this study. 2) Participation in a weight management program involving diet and PA in the past 6 mos 3) Eating disorders, serious food allergies, consuming special diets (vegetarian, Atkins etc.), aversion to common foods (e.g., unwilling to consume any dairy products, vegetables), diagnosis of Prader-Willi Syndrome. 4) Currently pregnant, planning on/becoming pregnant during the study. Should pregnancy occur the participant will be removed from the study and referred

to the appropriate agency for consultation. 5) Unable to participate in moderate to vigorous PA. Note: Individuals on medication 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. Random assignment should provide equal distribution of medication use across groups.

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.

Intervention overview

The following intervention components are common to all 3 study groups.
Orientation: Two, 90 min. home visits will be conducted by a health educator with both parents and participants prior to initiating the intervention. These sessions will provide detailed descriptions of both the dietary (eSLD or CD) and PA components of the intervention and the respective delivery system (FTF or TECH). Participants and parents in the TECH groups will be oriented to the use of FaceTime™, 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: There will be a FTF visit in TECH at baseline to orient parents and participants to the diet, and visits at mos 6,12, and 18 to distribute gift cards (see Incentives below) and to maintain rapport with participants. No health education will take place during these visits. All FTF group meetings will follow an identical schedule. Meetings will occur twice a month during months 0-12, and monthly during months 13-18. Meeting attendance is encouraged but not required. Meeting attendance will be recorded.

Meeting duration: ~30-45 min. This duration was based on feedback from both participants and parents from the adolescent IDD pilot (Pilot 2).

Behavioral lesson content: Lessons on behavioral strategies to improve weight loss/maintenance have been adopted for adolescents with IDD from our completed pilot with adults with IDD, our ongoing study with adults with IDD (DK83539), and our adolescent IDD pilot (Pilot 2) previously described above. Topics include social support, self-monitoring, planning, environmental control, self-efficacy, etc. Each lesson will be loaded into the iPad (TECH) 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, TECH-Facetime sessions will be recorded using Quicktime 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.

Energy Intake for weight loss (0-6 mos): Energy intake will be reduced 500-700 kcal/d below total daily energy expenditure for both diet groups (CD and eSLD). Total daily energy expenditure will be estimated using the Dietary Reference Intake (DRI) total energy equation for overweight boys/girls age 13-18 yrs. Dr. Sullivan will assure diets are both energy and nutritionally adequate for growth and development (i.e., energy intake >1,200 kcal/d, >20% of total energy intake from fat, RDA vitamins, minerals).

Energy intake for weight maintenance (7-18 mos): Energy intake for weight maintenance will again be estimated using the DRI equation with consideration for growth and development and adjusted as required based on changes in weight. Participants experiencing weight gain will be counseled to improve compliance to their prescribed level of energy intake and PA during their regularly scheduled meetings with health educators. In our experience some participants who did not meet their weight loss goals will volitionally attempt additional weight loss during weight maintenance and this will neither be encouraged or discouraged.

Prescribed PA: As in our completed adolescent pilot, we will target 60 min/d of moderate intensity PA (3-6 METs) at least 5 days/wk (total 300 min/wk) as recommended by the CDC and American College of Sports Medicine. Participants will start with 45 mins/wk (or current PA level if higher) at week one and increase PA by 15 mins/wk until reaching the 300 min/wk goal. We will promote a variety of activities including walking, swimming, biking, active video games (Dance Dance Revolution, etc.), and recreational sports outside of school using guidelines and suggestions from the "Train at Home" program of the Special Olympics (http:/media.specialolympics.org). If requested, Dr. Greene, an adapted PE specialist, will be available to assist participants and parents in modifying activities to accommodate any special needs.

Self-monitoring: All groups will be encouraged to 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.

Role of parent: One parent will serve as the primary family contact and be asked to provide support and encouragement for the participant. Although a parent will be involved, the focus of our intervention will be directed towards the adolescent. The parent will attend the every other week meetings with the participant to be aware of diet, PA, and behavioral strategies we are promoting so as to be able to assist their child in complying with the intervention. Specifically, the parent will be asked to provide assistance if needed, in following the prescribed diet (e.g., meal planning and preparation), planning and promoting PA, and self-monitoring of diet and PA. We recognize some parents who need to lose weight may choose to diet with the participant. This reflects reality and will neither be encouraged or discouraged. The effect of parental factors, including changes in diet and PA on participant outcomes, will be captured by our process measures described later in this proposal.

Diet Intervention: eSLD. The original SLD, developed by Epstein for use in children (33), categorizes foods by energy content: red (high-avoid), yellow (moderate–consume sparingly) and green (low-consume freely) to correspond to a traffic light. The SLD is easy to understand/implement and thus is appropriate for adolescents with IDD with assistance from their parents. We will "enhance" the Stop Light Diet (eSLD) and encourage the consumption of 5 F/V/d and recommended high volume, low energy PCMs [2 entrees and 2 shakes/d; Health Management Resources (HMR), Boston, MA] which will be provided to participants during weight loss (mos 0–6) as part of the study protocol. PCMs from HMR are shelf-stable, do not require refrigerated storage, and can be prepared with a microwave (entrees) or blender (shakes). Participants will be encouraged to consume a minimum of 2 entrees (200-270 kcal each), 5 servings of F/V, and 3 shakes (~100 kcal each)/d. Non-caloric beverages will be allowed ad libitum. Participants experiencing hunger on this diet will be encouraged to supplement the diet with yellow or green foods per the SLD. If a participant is non-compliant with the diet protocol, both participant and parent will be counseled with strategies to improve compliance. PCMs will be provided as part of the eSLD **only** during weight loss (mos 0-6), and will be shipped to the participants homes biweekly. During weight maintenance (mos 7-18), participants will be encouraged **(not required)** to continue using PCMs. A list of recommended low calorie/fat PCMs will be provided to parents and participants at mo 7.

Dietary intervention: CD. Participants prescribed a CD (FTF/CD and TECH/CD) will be asked to consume a nutritionally balanced, reduced energy, high volume, lower fat (fat=20-30% energy) diet as recommended by the Academy of Nutrition and Dietetics and the USDA's MyPlate approach. Participants will be provided examples of meal plans consisting of suggested servings of grains, proteins, F/V, dairy, and fats based on their energy needs and will be counseled on appropriate portion sizes. As per the eSLD, the consumption of 5 F/V/d will be encouraged. Unlike the eSLD group (TECH/eSLD), participants in the CD groups will not receive PCMs during weight loss (mos 0-6). To help defray any cost above that of following a normal diet (i.e. cost for prescribed F/V) participants in CD groups will receive $2.00/d in the form of a grocery store gift card that will be recharged monthly.

Self-monitoring: Basics. Participants will monitor both diet and PA on a daily basis over the course of the 18 mo trial.

Self-Monitoring: TECH groups. Participants in both TECH groups will monitor diet and PA on an iPad provided as part of the study. The iPad will be preloaded with FaceTime™ (for intervention delivery) and the Lose it! application (FitNow, Inc., Boston, MA) to facilitate self-monitoring. As per the pilot, access to web browsing, app store etc. will be blocked. **Diet:** Participants will log all food and beverages consumed (meals/snacks) using the Lose it! application by entering the food name and selecting the portion size or by scanning the bar code of the food item using the iPad. As a food is entered a bar showing the recommended dietary intake goal for each participant is displayed, providing immediate feedback of how much food participants have consumed during the day and how much more or less they should consume. **PA:** Participants will be asked to wear a Fitbit Flex (Model: Flex tracker, Fitbit Inc. San Francisco, CA, size 35.5 x 28 mm) wireless activity tracker on their wrist. The Fitbit records time spent in moderate or vigorous PA that is automatically transferred to the Lose it! application via Bluetooth connectivity when the device is near the iPad, thus eliminating the need for manual data recording. The Lose it! application on the iPad provides immediate feedback on a participants accumulated PA relative to their goal via a graphic display. If participants engage in PA that cannot be recorded by the Fitbit (e.g. biking), they will be able to log the activity in the Lose it! application and record the information. **Reminders:** The Lose It! application allows reminders to be programed to prompt participants to record their self-monitoring PA/diet data. Reminders will be sent only if no information is reported for a given meal (e.g., breakfast, lunch, dinner) or goal (i.e., exercise time, steps, weight). **Diet/PA data management:** Diet and PA data on the Lose it! application are securely, immediately and automatically transferred via the web to the Lose it! for Wellness Professionals web site that is accessible to the health educator. This information will be used as motivation, to inform participant counseling for both TECH groups, and will be exported to a data base to be included in the process analysis described later.

Self-monitoring: FTF group. Diet: The FTF group will enter diet data on paper forms. These forms, currently used in our ongoing adult IDD project, contain pictorial displays of food items and calorie levels that the participant/parent mark after consuming a food/beverage item. **PA:** Participants will wear an electronic pedometer (Omron HJ-720 ITC, Omron Healthcare, Inc., Bannockburn, IL) and record their step data on paper forms provided. If a participant engages in PA that cannot be recorded by the pedometer (e.g. swimming, biking), they will be able to log the type and duration of activity on the forms provided. **Diet/PA data management:** Diet/PA records will be collected by health educators during home visits and be used as motivation, to inform participant counseling for the FTF group, and entered in a data base for inclusion in the process analysis.

Monitoring body weight. Participants' body weight will be obtained monthly to provide feedback regarding weight loss/gain over the course of the 18 mo trial. Procedures for obtaining outcome weights are described below. **TECH/CD and TECH/eSLD):** Participants in the TECH groups will self-weigh during a FaceTime™ session using a calibrated wireless digital scale (Model: Aria Wifi Smart Scale, Fitbit, Inc. San Francisco, CA) which automatically syncs with the Lose it! application and updates a visual display of weight change. **FTF/CD group:** During FTF meetings, participants will be weighed on a calibrated digital scale (Model #PS6600, Belfour, Saukville, WI). Health educators will provide personal weight loss "histograms" through bands of color coded weight ranges, with the ranges indicating approximately one BMI%ile.

Incentives. TECH groups will be provided with an iPad to be used for intervention delivery and self-monitoring. As an incentive they will be allowed to keep the iPad at the completion of the intervention. Participants in the FTF/CD group will be provided an iPad only for the purpose of taking meal photos for the dietary intake assessment (see assessments) during the intervention. As an incentive, they will also be allowed to keep the iPad at study completion. No diet or PA applications will be loaded in the iPad of the FTF/CD group. In both FTF and TECH groups restrictions will prevent additional application downloads or Internet browsing until completion of the study. At this time staff will unlock all basic iPad features. As an additional incentive, participants in all groups who complete self-monitoring for diet and PA on 5 of 7 days/wk will be allowed to choose an iPad app from a list of age appropriate applications or choose to receive $1.00 on their study Clincard. The apps will be loaded on participant's iPads during the monthly health educator home visits for the FTF group and remotely for the TECH groups. All participants and parents will receive gift cards ($15 participants, $10 parents) for completing outcome assessments at mos 0, 6, 12, and 18. Parents who complete the optional questionnaires will receive $10.00 for the completion of measures at baseline, $15.00 for three months,and $20.00 for the completion of the final assessment at six-months using graduated rates.

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 following the intervention described above, however they may choose not to follow the prescribed diet, track diet /PA, attend meetings, or weight 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

Outcome assessments will be obtained at the participant's home. Outcomes will be obtained at a single home visit (Table 3). From our experience with our adolescent IDD pilot (pilot 2) we estimate these assessments will require ~75 min. to complete (PA will be assessed across 7 days.) Assessments will be completed by trained study staff blinded to condition and supervised by the investigator named in parentheses below. All staff will receive refresher training and complete reliability assessments 2-3 times/yr.

Table 3. Outcomes Assessment Schedule

Outcome Measure	**Weight Loss (mo 0-6)**		**Maintenance (mo 7-18)**	
	0m	6m	12 m	18 m
Weight & Height	X	X	X	X
Waist Circumference	X	X	X	X
PA (accelerometer)	X	X	X	X
Energy & Macronutrient Intake	X	X	X	X
Process (Structured Interviews)				X
Process (Self-Monitoring: Diet/PA)	Continuous			

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.

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 parent (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 2013, 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-accelerometry. Participants will wear an ActiGraph Model GT3X+ accelerometer (ActiGraph LLC, Pensacola, FL) for 7 consecutive days on a belt over the non-dominant hip during all waking hrs. ActiGraphs

will be distributed during regularly scheduled home visits and returned via pre-paid mail. A minimum of 10 hrs will constitute a valid monitored day. Parents will be asked to assist in achieving compliance with the monitoring protocol. The outcome variables will be the average ActiGraph counts/min and the average min/day spent in moderate and vigorous intensity

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

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: Semi-structured interviews will be conducted in a random sample of 36 parent/participant dyads (12/group,~30% of total sample) at 18 mos to solicit feedback on a range of topics. For example, parents will be asked how they learned about the study, what motivated them to enroll, their perceptions of the intervention, and any challenges encountered during the study.

Additional assessments:

Parents. In exploratory analysis we will assess the influence of parental diet and PA, parental weight and weight change, and psychosocial variables (parent's beliefs and attitudes regarding nutrition and PA) on adolescent weight loss at mos 6 and 18. To minimize parental burden we will assess these factors only during home visits at mos 0, 6, and 18. Parent's diet: We will use the NCI all-day fruit and vegetable screener to assess changes in healthy eating over the course of the intervention.

Parent's PA: Parent PA will be assessed using the International Physical Activity Questionnaire short form which has been shown to provide valid assessments of moderate/vigorous PA over the past 7 days in adults. Parent's weight: To evaluate the effect of baseline parent weight and change in parent weight on change in adolescent weight we will assess parent weight using a calibrated scale (Model #PS6600, Belfour, Saukville, WI) at mos 0, 6, and 18.

Parent's beliefs/attitudes on diet and PA: Parent's beliefs/attitudes on diet and PA will be assessed with an adapted version of the Healthy Buddies Parent Nutrition and Physical Activity Survey which has been previously used with parents of adolescents with IDD. Survey items assess perceptions about the child's weight, beliefs about the importance and frequency of family meals, and the frequency of fast food consumption. Additional items will assess parents' beliefs, attitudes, and behaviors about their family's eating habits, and PA.

Note: During the COVID-19 restrictions, a scale, diet record, accelerometer, and the parent surveys will be delivered to the participants home with a return shipping envelope to return to the study team. Participants will be asked to weight themselves on the provided scale and take a photo of the weight on their iPad which will be remotely sent to the study team. Height and waist circumference will not be collected.

Statistical Methods

We chose a 3 group design (FTF/CD; TECH/CD; TECH/eSLD). We considered a 2 by 2 factorial (4 group) design (i.e. adding FTF/eSLD); however, the sample size required for that design was in excess of 240 participants and was considered impractical from a cost, logistical, and recruitment perspective. Our 3 group design allows us to compare both the effect of delivery system (FTF/CD vs.TECH/CD) and diet (TECH/CD vs. TECH/eSLD) in a cost efficient manner. Based on our preliminary data, we expect significantly greater weight loss for TECH/CD (- 4.0 kg) compared to FTF/CD (- 1.5 kg) and significantly greater weight loss for TECH/eSLD (-6.5 kg) compared to TECH/CD (- 4.0 kg) at 6 mos with a common standard deviation of 3.6 kg. Sample size estimates require 41 participants in each of the 3 groups, assuming the levels of weight loss described above with 80% power and a type 1 error rate of 0.025, for each of the 2 pair-wise comparisons. It should be noted, that if we were to run an overall ANOVA, the global test would have greater than 99% power. We have allowed for 20% attrition, approximately twice what occurred in the adult (8%) or adolescent pilots (10%).

Analysis plan

Analysis plan: Primary aim. Two separate two sample t-tests will be used to compare weight loss from 0-6 mos between groups randomized to FTF/CD and TECH/CD (i.e. effect of delivery system) and TECH/CD and TECH/eSLD (i.e., effect of diet). We will use an intent-to-treat analysis. Procedures for handling missing data are described below. We will examine the impact of baseline characteristics (age, sex, race/ethnicity, baseline BMI%ile, and severity of IDD) along with baseline weight on weight change using linear regression controlling for treatment. We will also examine the main effects of each of these variables as well as the potential interaction effect with treatment.

Analysis plan: Secondary aim 1. Weight Maintenance. In similar fashion to our primary aim, two separate two sample t-tests will be used to compare weight changes from 7-18 mos between groups randomized to FTF/CD and TECH/CD and TECH/CD and TECH/eSLD. We will use mixed linear models to compare weight change from 7-18 mos between treatment groups controlling for treatment and baseline weight. These assessments will be conducted in participants who provide a mo 6 weight since this value represents the baseline measure for weight maintenance. We anticipate greater loss to follow-up over time; however, we expect this missing data to be missing at random. Under this assumption, mixed linear models will provide unbiased treatment comparisons. We will assume an autoregressive correlation structure of the dependent variable (weight) over time, and determine if there are any time-by-treatment interactions.

Analysis Plan: Cost Analysis. Cost Analysis, including medication changes, will be completed by Dr. Lee who provided similar analysis for the Equivalent weight loss with phone or clinic weight management programs (DK76063) trial.

Analysis: Exploratory aims: We will examine energy balance variables (energy intake, PA), process variables (self-monitoring, meeting attendance), parental diet and PA, parental baseline weight and weight change, and psychosocial variables (parents beliefs and attitudes regarding nutrition and PA) to assess their influence on weight loss at mo 6 and on weight maintenance mos 7-18. To determine if treatment impacts these variables, we will compare changes in each variable during both weight loss (mos 0-6) and weight maintenance (mos 7-18) across the 3 intervention groups. We will use linear regression techniques to examine the impact of these variables, as well as baseline demographic characteristics (sex, age, race/ethnicity, BMI%ile and level of IDD), to identify the best subsets of variables that explain weight loss at mo 6 and weight maintenance (mos 7-18) while controlling for treatment. Note: We will examine main effects of each of these variables as well as the potential interaction effect with treatment.

Missing data: All analyses will be based upon the intent-to-treat principle; however, true change for our primary aim will only be measurable in participants with data at baseline (mo 0) and following weight loss (mo 6). Missing data for analyses of both our primary (weight loss 0-6 mos) and secondary aims (weight maintenance 7-18 mos) will be imputed using multiple imputations. For our longitudinal comparisons of endpoints during weight maintenance if the data is missing at random or covariate missing at random, then the mixed model estimates are unbiased in the presence of this missing data. Therefore, we will determine if missing data are related to treatment or initial amount of weight loss. If not, we will not impute, if so, we will use model based multiple imputation techniques. All statistical procedures will be performed using SAS version 9.3 or higher.

Outcome: The technology delivered intervention with CD (TECH/CD) is expected to be more effective for weight management in adolescents with IDD than FTF intervention with CD (FTF/CD) and the technology delivered eSLD (TECH/eSLD) intervention is expected to be more effective than technology delivered CD (TECH/CD) for weight management in adolescents with IDD. The end point of the study will conclude after all 123 study subjects have completed the study protocol.