



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



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ABSTRACT

Adolescents with intellectual and developmental disabilities (IDD) are an underserved group in need of weight management. However, information regarding effective weight management for this group is limited, and is based primarily on results from small, non-powered, non-randomized trials that were not conducted in accordance with current weight management guidelines. Additionally, the comparative effectiveness of emerging dietary approaches, such as portion-controlled meals (PCMs) or program delivery strategies such as video chat using tablet computers have not been evaluated. Therefore, we will conduct an 18 month trial to compare weight loss (6 months) and maintenance (7–18 months) in 123 overweight/obese adolescents with mild to moderate IDD, and a parent, randomized to a weight management intervention delivered remotely using FaceTime™ on an iPad using either a conventional meal plan diet (RD/CD) or a Stop Light diet enhanced with PCMs (RD/eSLD), or conventional diet delivered during face-to-face home visits (FTF/CD). This design will provide an adequately powered comparison of both diet (CD vs. eSLD) and delivery strategy (FTF vs. RD). Exploratory analyses will examine the influence of behavioral session attendance, compliance with recommendations for diet (energy intake), physical activity (min/day), self-monitoring of diet and physical activity, medications, and parental variables including diet quality, physical activity, baseline weight, weight change, and beliefs and attitudes regarding diet and physical activity on both weight loss and maintenance. We will also complete a cost and contingent valuation analysis to compare costs between RD and FTF delivery.

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1. Introduction

Intellectual and developmental disabilities (IDD) are characterized by significant limitations in both intellectual functioning (IQ < 75) and in adaptive behavior including conceptual skills (e.g. language and literacy, self-direction), social skills (e.g. interpersonal skills, ability to follow rules) and practical skills (e.g. personal care, use of money/phone) which originate before the age of 18 [1]. The prevalence of

overweight and obesity (BMI ≥ the 85th %ile) in adolescents with IDD (age 11–18 years) in the United States is ~50% [2][3] which is considerably higher than the prevalence of overweight and obesity in general adolescent population (~35%) [4]. The premature morbidity and mortality in adulthood associated with overweight/obesity in typically developing children and adolescents likely applies to adolescents with IDD [5] although data specific to adolescents with IDD are unavailable.

Adolescents with IDD are an underserved group in need of weight management; however, the limitations associated with IDD, and the altered dynamics of interactions with parents and siblings preclude the extrapolation of weight management strategies shown to be effective in typically developing adolescents to this group. Unfortunately, the quality and quantity of data on which to base recommendations for effective weight management specifically for adolescents with IDD is limited. The most recent systematic review evaluating weight loss interventions in youth/adolescents with IDD identified only 9 trials

Abbreviations: eSLD, enhanced Stop Light Diet; IDD, Intellectual and developmental disabilities; PCMs, Portion controlled meals; RD, Remote delivery; CD, Conventional diet.

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published between 1985 and 2013 [2]. The majority of trials were non-randomized (8/9, ~89%), with interventions recommending increased physical activity with no dietary component (7/9, ~78%), conducted over short durations (<6 months), in small samples with inadequate statistical power ($n < 30$). These interventions were not conducted in accordance with current recommendations for the treatment of child and adolescent overweight and obesity, which comprise 1) a planned negative energy balance achieved through structured diet and physical activity, 2) a structured behavior modification program that includes self-monitoring of both diet and physical activity, and 3) weekly (at least 8–12 weeks in duration) followed by monthly individual or group counseling to change and maintain diet and physical activity behaviors [6]. Not unexpectedly, weight loss reported in these trials was minimal ($\leq 3\%$). A trial published subsequent to the Maiano et al. [2] review compared weight loss in overweight and obese adolescents and young adults with Down syndrome (13–26 years) randomized to a 6-month nutrition and physical activity education intervention ($n = 10$) or a nutrition and physical activity education plus parent-supported behavioral intervention ($n = 11$) with a 6-month no contact follow-up [7]. Both groups included a reduced energy diet and increased physical activity; however, only the parent-supported group included a structured behavioral modification program as suggested by current adolescent weight loss guidelines [6]. Results indicated weight change at both 6 and 12 months was significantly greater in the group with parental support (6 months = -3.4% ; 12 months = -2.4%) compared with the non-parental support groups (6 months = $+0.6\%$; 12 months = $+2.2\%$). However, the magnitude of weight loss at 12 months in the parental support group was not clinically meaningful ($\leq 3\%$) [8].

The limited available literature and the generally small magnitude of reported weight loss suggests that additional innovative weight management strategies for adolescents with IDD need to be developed and evaluated. Our group has conducted preliminary work to evaluate the feasibility and effectiveness of an enhanced version of the Stop Light Diet (eSLD) delivered remotely to adolescents with IDD and a parent, in their homes, via video chat on an iPad (FaceTime™, Apple, Inc., Cupertino, CA) [9]. The Stop Light Diet, originally developed for use in children [10], classifies foods by energy content into 3 categories associated with a traffic light: green (low energy - consume freely), yellow (moderate energy - consume in moderation) and red (high energy - consume sparingly). We enhanced the Stop Light Diet by recommending daily consumption of 2–200 kcal portion-controlled entrées, 2–100 kcal

shakes, 5 servings of fruits/vegetables, and ad-libitum non-caloric beverages. Participants desiring additional food selected food items categorized as low energy (i.e., green) using the SLD system. The eSLD is easy to understand and simplifies meal planning, and food shopping/meal preparation, thus making it potentially effective for use with individuals with IDD. We recently compared 2-month weight loss in 20 overweight/obese adolescents with IDD and his/her parent who were randomized to either an eSLD ($n = 11$) or a conventional meal plan diet (CD, $n = 11$) and increased physical activity [9]. The participant/parent dyads were asked to attend weekly 30–45 minute behavioral sessions conducted by a trained health educator delivered on an iPad using FaceTime™ (Apple Inc. Cupertino, CA). Participants, with assistance from a parent, were asked to self-monitor daily dietary intake using a web-based application (Lose It!, Fitnow Inc., Boston, MA) using the iPad. Physical activity was monitored using a pedometer and by recording daily steps on a paper log ($n = 13$) or using a wireless activity tracker (Fitbit Ultra, Fitbit Inc., San Francisco, CA) which automatically uploaded physical activity data to the iPad ($n = 7$). Results indicated participants attended 84% of scheduled weekly behavioral sessions; 80% using FaceTime™, and 4% by phone when away from home where internet access was unavailable. Dietary intake using the Lose It! app on the iPad was recorded on 83% of study days. Self-monitoring of physical activity in the 7 participants who used the Fitbit was completed on 72% of study days compared with 60% of study days in the 13 participants who recorded pedometer steps using paper logs. Clinically meaningful weight loss was observed in both the eSLD and CD groups (-4.6% vs. -3.1% , $p = 0.12$) at 2 months. These encouraging preliminary results led to the development of the current randomized trial designed to compare the effectiveness of two diets (eSLD vs. CD), and two delivery strategies (face-to-face (FTF)) vs. remote delivery (RD) using FaceTime™ for both weight loss and maintenance in adolescents with IDD.

2. Methods and materials

2.1. Overview of study design (Table 1)

One hundred twenty-three overweight/obese adolescents (ages 13–21) with mild to moderate IDD along with a parent will be randomized to one of three groups for an 18-month trial (6 month weight loss, 12 month maintenance): RD/CD, RD/eSLD or FTF/CD. The adolescent/

Table 1
Intervention overview.

	Intervention groups		
	RD/CD	RD/eSLD	FTF/CD
Behavioral sessions			
Delivery method	FaceTime™ (iPad)	FaceTime™ (iPad)	Home visits
Delivery target	Adolescent + Parent	Adolescent + Parent	Adolescent + Parent
Session duration	30–45 min	30–45 min	30–45 min
Session frequency			
0–6 months	2× per month	2× per month	2× per month
7–12 months	2× per month	2× per month	2× per month
13–18 months	1× per month	1× per month	1× per month
Diet			
Type	Conventional meal plan diet	eSLD (portion controlled entree's + low kcal shakes)	Conventional meal plan diet
Energy intake (0–6 months)	500–700 kcal/day below estimated energy expenditure	500–700 kcal/day below estimated energy expenditure	500–700 kcal/day below estimated energy expenditure
Energy intake (7–18 months)	kcal/day to reflect estimated energy expenditure × 1.4 to account for PA	kcal/day to reflect estimated energy expenditure × 1.4 to account for PA	kcal/day to reflect estimated energy expenditure × 1.4 to account for PA
Physical activity	300 min/week	300 min/week	300 min/week
Self-monitoring (diet)	Lose It! with iPad	Lose It! with iPad	Pencil/paper logs
Self-monitoring (PA)	Fitbit with iPad	Fitbit with iPad	Pedometer–Pencil/paper logs
Self-monitoring (weight)	Wi-Fi enabled scale	Wi-Fi enabled scale	Portable scale

RD = remote delivery, CD = conventional diet, eSLD = enhanced Stop Light Diet, FTF = face-to-face, PA = physical activity.

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