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Short communication

A pilot study evaluating the prefeasibility of a behavioral weight loss program in people with multiple sclerosis

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ABSTRACT

Weight loss interventions seldom include individuals with neurologic disease. The aims of the present study were to: 1) develop and assess the prefeasibility of a 6-month telehealth behavioral weight loss program for people with multiple sclerosis (MS) and obesity and 2) examine changes in weight loss (primary outcome), physical activity, and fruit/vegetable consumption at follow-up. Participants with obesity and MS engaged in a 24-week weight loss program. Participants followed established diet, exercise, and self-monitoring guidelines and attended weekly online group meetings. Median percentage weight loss was 10.54 % ($SD = 7.19$). Participants who adhered more closely to the self-monitoring guidelines ($r = 0.81$, $p = .02$), and who averaged higher weekly active minutes ($r = 0.91$, $p = .002$) achieved greater percentage weight loss. Six of the eight pilot participants achieved clinically meaningful weight loss (>5%) after 6-months.

1. Introduction

Multiple Sclerosis (MS) is an autoimmune disease of the central nervous system. Obesity is a modifiable lifestyle factor that is associated with MS onset, severity, and progression (Tettey et al., 2014; Ascherio, 2013). Despite this, the health benefits of weight loss (Van Gaal et al., 1997), remain unexplored in people with MS and obesity. More specifically, no studies have examined a behavioral weight loss intervention for people with MS. The aim of this pilot intervention was to 1) develop and assess the prefeasibility of a 6-month group-based telehealth behavioral weight loss program for people with MS and obesity; and 2) examine changes in participant weight, minutes of physical activity, and daily servings of fruits and vegetables.

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2. Materials & methods

2.1. Participants

This research was approved by the University of Missouri-Kansas City IRB and informed consent was obtained from all participants. Individuals were recruited from the University of Kansas Medical Center MS specialty clinic. A list of the eligibility criteria for the pilot program can be found in Supplementary Material 1.0.

2.2. Weight loss intervention

Diet and exercise guidelines were based on established obesity treatment recommendations and our previous work (Befort et al., 2016; Jensen et al., 2014; Look et al., 2006), in order to aid participants in achieving 1-2lbs of weight loss per week. The intervention utilized weekly group telehealth counseling, self-monitoring, technology, and diet and exercise guidelines.

Participants were provided with a 1-year subscription to the *Lose It!*® phone application, a *FitBit*® activity tracker, a *FitBit Aria Smart Scale*®, and a study binder with MS-specific educational materials for all group sessions (Supplementary Table 1). Participants ate between 1200 and 1800 calories a day and were encouraged to eat five combined 1-cup servings of fruits and vegetables daily. Participants were instructed to log all of the food and beverages they consumed each day in the *LoseIt!*® application. To make self-monitoring easy and increase initial weight loss, participants were encouraged to eat meals that were easy to track (e.g., frozen entrées and meal replacement shakes) and met the recommended guidelines (Befort et al., 2016). Participants were responsible for purchasing their own meals and shakes. Additionally, participants worked up to engaging in 150 min of moderate intensity physical activity per week (Supplementary Table 2). Participants were instructed to wear their *FitBit*® daily and to weigh-in at a minimum of one time per week. Further, group members were invited to attend one-hour weekly group calls and two individual calls over the course of six-months. Calls were conducted by two continuous group facilitators (PhD student psychologists) using the Zoom Protected conferencing system. Group leaders attended weekly supervision with licensed clinical psychologists, with expertise in motivational interviewing and weight management, as well as with a licensed physical therapist. Throughout the program, cognitive behavioral strategies and motivational interviewing techniques were used to help participants achieve weight loss. Group leaders worked with participants to promote goal setting, self-monitoring, problem-solving, relapse prevention, and build social support. To encourage accountability and provide further support, the group leader messaged participants in the *Lose It!*® platform weekly.

2.3. Measures

At baseline and 6-month assessments, anthropometric measurements were recorded, and participants completed self-report questionnaires.

2.3.1. Disease characteristics

Disease duration, MS subtype, and self-report disability status were obtained. The Patient Determined Disease Steps (PDDS) (Learmonth et al., 2013) was used to measure participants' perceived disability status.

2.3.2. Prefeasibility

Recruitment enrollment rates and session attendance were examined as prefeasibility metrics. A satisfaction questionnaire was adapted from our previous work (Godin and Shephard, 1985) and administered to collect qualitative and quantitative feedback from participants to further examine program tolerability.

2.3.3. Anthropometric measurements

Physical measurements were obtained following World Health Organization (WHO) Surveillance Guidelines for Physical Measurements (Organization, 2005). Weight was recorded using a calibrated Health-o-Meter® Model 500KL Eye Level Digital Beam Scale. Height was measured using a Seca® Model 213 Portable Stadiometer. BMI was calculated using the formula provided by the Centers for Disease Control and Prevention (CDC) (CDC, 2014).

2.3.4. Diet quality

The self-report Dietary Screener Questionnaire (DSQ) was administered at both assessments and provided data for comparisons regarding daily frequency of fruit and vegetable consumption (Fitzgerald et al., 2018; Institute, 2018). Average weekly calories logged in *Lose It!*® were used to assess adherence to the diet and self-monitoring guidelines. Completeness and frequency of self-monitoring logs have been used in previous research to examine dietary adherence (Payne et al., 2018).

2.3.5. Physical activity

The Godin Leisure-Time Exercise questionnaire is a sensitive measure for detecting change in physical activity status in MS exercise interventions (Amireault and Godin, 2015; Sikes et al., 2019; Godin and Shephard, 1985). Higher scores on the questionnaire indicate more time spent engaging in physical activity. Average weekly active minutes in *FitBit*® were also used to assess physical activity throughout the intervention. Previous research has found that active minutes, as measured by *FitBit*®, are consistent with validated ActiGraph devices over a 7-day period (Brewer et al., 2017).

Table 1
Paired samples *t*-test results comparing baseline and follow-up anthropometric measurements and self-reported diet quality and physical activity status ($n = 8$).

		Baseline	6-month	M_{diff}	*SD*	95 % CI	*T*	*df*	*p*	*d*
Anthropometric Measurements										
	BMI (kg/m^2)	37.56 (6.56)	33.35 (6.71)	4.21	2.62	2.02, 6.40	4.55	7	0.003	1.61
	Waist Circumference (cm)[a]	110.35 (7.96)	97.65 (12.02)	12.70	9.34	2.90, 22.50	3.33	5	0.02	1.36
	Waist-to-Height Ratio[a]	0.67 (0.07)	0.59 (0.09)	0.08	0.02	0.02, 0.13	3.50	5	0.02	1.43
	Weight (kg)	101.24 (15.36)	90.32 (13.92)	10.92	7.37	4.76, 17.08	4.20	7	0.004	1.48
Physical Activity										
	Godin Scale Score	13.00 (14.98)	43.50 (21.31)	−30.5	25.89	−52.14, −8.86	−3.33	7	0.01	−1.18
Diet Quality										
	DSQ Fruit[b]	0.78 (0.33)	1.33 (0.28)	−0.54	0.59	−1.04, −0.05	−2.61	7	0.04	−0.92
	DSQ Vegetable[b]	1.46 (0.52)	1.73 (0.09)	−0.26	0.73	−0.87, 0.35	−1.01	7	0.35	−0.36
	DSQ Fruit & Vegetable[b]	2.27 (0.72)	3.14 (0.62)	−0.85	1.13	−1.80, 0.09	−2.14	7	0.07	−0.76

Means and standard deviations are reported in *mean (SD)* format. Mean difference (M_{diff}) between baseline to 6-month follow-up values are also reported.
[a] missing n = 2 for follow-up.
[b] 1 cup = 1 serving, $p < 0.05$.

3. Results

3.1. Patient characteristics

Eleven of 24 screened individuals met eligibility criteria (See Fig. 1). Eight Caucasian participants (7 females and 1 male) were consented and enrolled in the 24-week weight loss program (See Supplementary Table 3). Participants ranged in age from 40 to 70 with an average age of 50.0 (SD = 9.3). Participants reported an average of 17.7 years of education (SD = 2.9). Average MS disease duration was 16.7 years (SD = 12.9) and participants reported mild MS-related disability (average PDDS = 1.1). All participants had relapsing-remitting disease course.

3.2. Attrition and attendance

Median number of group sessions attended was 20.50 (SD = 7.15) of the 24 weekly sessions or 85 %. All participants attended both individual calls. No individuals withdrew from the program.

3.3. Weight loss

Two participants weighed in remotely using their *FitBit Aria*® scale due to COVID-19 concerns. Median percent weight loss at 6-months was 10.54 % (SD = 7.19). Six participants achieved clinically meaningful weight loss (≥5%) (Williamson et al., 2015). Table 1 displays results from paired samples t-tests for all outcome variables pre and post-intervention. All analyses involving anthropometric changes were significant at the 0.05 alpha level and had effect sizes greater than 1.00. See Supplementary Fig. 1 for a figure demonstrating the association between percent weight change and key program components.

3.4. Physical activity

Average weekly active minutes recorded in *FitBit*® were significantly associated with percent weight loss (r = 0.905, p =.002). Self-reported change in activity measured via the Godin questionnaire significantly increased at follow-up (95 % CI [-52.1, −8.8], p = 0.01, d = -1.18), but this difference was not associated with weight change (r = 0.17, p =.68).

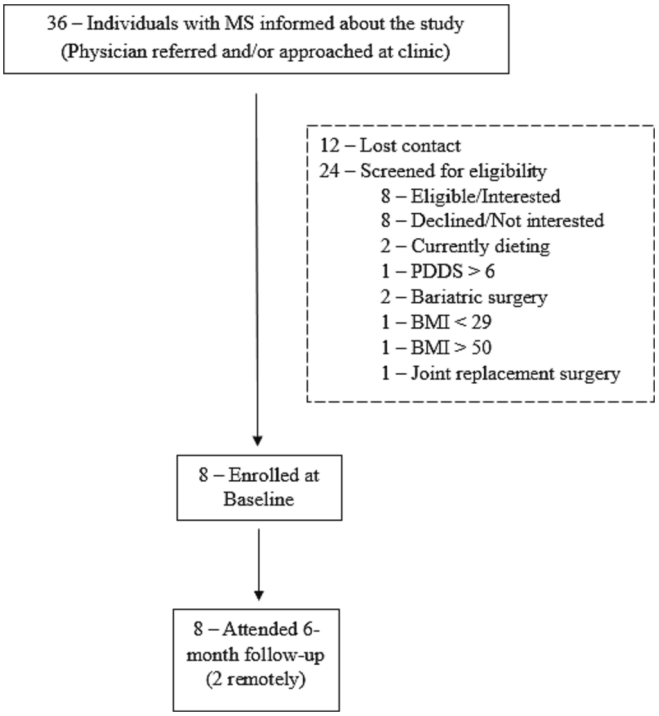

Fig. 1. Flow diagram of pilot screening and enrollment.

3.5. Diet quality

Combined intake of fruits and vegetables did not significantly change at follow-up ($mean_{diff}$ = -0.85, 95 % CI [-1.80, 0.09], p = 0.07, d = -0.76), but a large effect size was found. Average calories logged per week in *LoseIt*!® was significantly related to percent weight loss at 6-months (r = 0.81, p =.02).

3.6. Study satisfaction

Responses from the satisfaction questionnaire were favorable (See Supplementary Table 4). Participants reported that the program provided a source of social support and accountability and improved their self-esteem and sense of physical well-being.

4. Discussion

This pilot study is the first behavioral weight loss intervention delivered to people with MS and obesity. Initial results demonstrate the *preliminary* feasibility and acceptability of the six-month telehealth program, as two-thirds of participants in the group lost clinically meaningful weight loss (>5%).

Our study is limited by the small sample size, as well as the absence of a control group and randomized design. Additionally, long-term outcomes with the addition of a maintenance phase are needed to understand whether weight loss is maintained over time. Larger trials with more diverse cohorts of people with MS are needed to better understand the feasibility and acceptability of the program.

This prefeasibility study provides preliminary evidence of the acceptability of a behavioral weight loss intervention for people with MS and obesity. The present research is the first to show that behavioral weight loss programs have the potential to successfully help people with MS and obesity lose weight. This pilot work lays the groundwork for experimental studies and randomized controlled trials that can be used to more thoroughly address established causal links between obesity and MS.

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CRediT authorship contribution statement

Julia S. Cozart: Conceptualization, Methodology, Investigation, Formal analysis, Writing – original draft, Resources. **Amanda S. Bruce:** Conceptualization, Methodology, Writing – review & editing, Supervision, Resources. **Christie Befort:** Conceptualization, Methodology, Writing – review & editing, Supervision, Resources. **Catherine Siengsukon:** Methodology, Writing – review & editing, Supervision, Resources. **Sharon G. Lynch:** Methodology, Writing – review & editing, Supervision, Resources. **Stephanie Punt:** Investigation, Writing – review & editing. **Stephen Simon:** Formal analysis. **Robin P. Shook:** Conceptualization, Resources. **Joanie Huebner:** Conceptualization, Writing – review & editing. **Taylor Bradish:** Project administration. **Jade Robichaud:** Project administration. **Jared M. Bruce:** Conceptualization, Methodology, Investigation, Funding acquisition, Formal analysis, Supervision, Writing – original draft, Resources.

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Jared Bruce is a part-time employee of the National Hockey League, a

grantee of the National Multiple Sclerosis Society, has received grant funding from Genzyme, and has received consulting fees from Med IQ. Sharon Lynch has participated in multi-center clinical trials in MS funded by Biogen, Genzyme, Teva, Sanofi, Novartis, Opexa, Roche, NIH, NMSS, Acorda, Sun Pharma, Vaccinex, and Actelion. Catherine Siengsukon is the owner and CEO of Sleep Health Education, LLC. All other authors have nothing to disclose relevant to the current manuscript.

Data availability

Data will be made available on request.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.pmedr.2023.102437.

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