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Efficacy of a Commercial Weight Management Program Compared With a Do-It-Yourself Approach

A Randomized Clinical Trial

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Abstract

IMPORTANCE Given the prevalence of obesity, accessible and effective treatment options are needed to manage obesity and its comorbid conditions. Commercial weight management programs are a potential solution to the lack of available treatment, providing greater access at lower cost than clinic-based approaches, but few commercial programs have been rigorously evaluated.

OBJECTIVE To compare the differences in weight change between individuals randomly assigned to a commercial weight management program and those randomly assigned to a do-it-yourself (DIY) approach.

DESIGN, SETTING, AND PARTICIPANTS This 1-year, randomized clinical trial conducted in the United States, Canada, and United Kingdom between June 19, 2018, and November 30, 2019, enrolled 373 adults aged 18 to 75 years with a body mass index (BMI; calculated as weight in kilograms divided by height in meters squared) of 25 to 45. Assessors were blinded to treatment conditions.

INTERVENTIONS A widely available commercial weight management program that included reduced requirements for dietary self-monitoring and recommendations for a variety of DIY approaches to weight loss.

MAIN OUTCOMES AND MEASURES The primary outcomes were the difference in weight change between the 2 groups at 3 and 12 months. The a priori hypothesis was that the commercial program would result in greater weight loss than the DIY approach at 3 and 12 months. Analyses were performed on an intention-to-treat basis.

RESULTS The study include 373 participants (272 women [72.9%]; mean [SD] BMI, 33.8 [5.2]; 77 [20.6%] aged 18-34 years, 74 [19.8%] aged 35-43 years, 82 [22.0%] aged 44-52 years, and 140 [37.5%] aged 53-75 years). At 12 months, retention rates were 88.8% (166 of 187) for the commercial weight management program group and 95.7% (178 of 186) for the DIY group. At 3 months, participants in the commercial program had a mean (SD) weight loss of −3.8 (4.1) kg vs −1.8 (3.7) kg among those in the DIY group. At 12 months, participants in the commercial program had a mean (SD) weight loss of −4.4 (7.3) kg vs −1.7 (7.3) kg among those in the DIY group. The mean difference between groups was −2.0 kg (97.5% CI, −2.9 to −1.1 kg) at 3 months ($P < .001$) and −2.6 kg (97.5% CI, −4.3 to −0.8 kg) at 12 months ($P < .001$). A greater percentage of participants in the commercial program group than participants in the DIY group achieved loss of 5% of body weight at both 3 months (40.7% [72 of 177] vs 18.6% [34 of 183]) and 12 months (42.8% [71 of 166] vs 24.7% [44 of 178]).

(continued)

Key Points

Question What is the efficacy at 3 and 12 months of a widely available commercial weight management program compared with a do-it-yourself approach?

Findings In this 3-country randomized clinical trial that included 373 adults, reductions in weight were significantly greater at both 3 and 12 months for participants in the commercial weight management program, which included reduced requirements for dietary self-monitoring, than for participants using the do-it-yourself approach.

Meaning This randomized clinical trial found that a commercial weight management program with reduced dietary self-monitoring produced clinically significant weight loss and may partially address the need for evidence-based approaches beyond the clinic setting.

+ Visual Abstract

+ Supplemental content

Author affiliations and article information are listed at the end of this article.

Abstract (continued)

CONCLUSIONS AND RELEVANCE Adults randomly assigned to a commercial weight management program with reduced requirements for dietary self-monitoring lost more weight and were more likely to achieve weight loss of 5% at 3 and 12 months than adults following a DIY approach. This study contributes data on the efficacy of commercial weight management programs and DIY weight management approaches.

TRIAL REGISTRATION ClinicalTrials.gov Identifier: NCT03571893

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Introduction

Given the widespread prevalence of obesity, accessible and effective treatment options are needed to manage obesity and its multiple comorbid conditions.[1] The US Preventive Services Task Force (USPSTF) guidelines recommend that, for patients with obesity, physicians should provide intensive behavioral treatment or refer for such treatment.[2] Similarly, guidelines from professional societies underscore the need for behavioral treatment as the basis for any obesity therapy.[3,4] Clinic-based treatments in tertiary care centers are the most studied,[5] but they have limited reach given their availability and constraints of time, training, and reimbursement for physicians and other health care professionals.

Commercial weight management programs are a potential solution to the lack of available treatment, given their greater accessibility and lower cost than clinic-based approaches.[6] Although there are numerous commercial weight management programs, to our knowledge, few have been rigorously evaluated, making it difficult for practitioners to refer patients to evidence-based programs. For example, Gudzune et al[7] found that among 141 commercial programs, 32 had both behavioral and nutritional components (with or without physical activity), 11 had data from randomized clinical trials of 12 weeks or more, and only 6 met USPSTF criteria.

One internationally available weight management program (WW, formerly Weight Watchers) that meets USPSTF criteria and has clear evidence to support its efficacy in safely achieving sustained, modest weight losses[7-9] also has the most randomized clinical trials evaluating its efficacy[7] and the most cost-effective nonsurgical treatment for obesity.[10,11] Despite a body of published research, most studies of this commercial program were conducted in a single country,[12-15] used usual care or active treatments as controls,[13,14,16] and were conducted more than 10 years ago.[12,14-16] Single-country studies limit generalization, and although active treatments are reasonable controls, many people trying to lose weight do it on their own without joining formal programs (a do-it-yourself [DIY] approach).[17] Moreover, because the components and methods of commercial weight management programs change over time, it is important to continue to evaluate new iterations. A major shift in the approach of the commercial weight management program in this study has been the inclusion of hundreds of foods that do not need to be self-monitored. Partial recording of food intake was designed to reduce the well-documented burden of self-monitoring[18-20] and is consistent with expert recommendations to modify the self-monitoring paradigm for behavioral weight management.[21] Dietary self-monitoring is strongly associated with weight loss outcomes, and monitoring in greater detail may lead to greater success.[22-24] A single-group 6-month pilot trial demonstrated the feasibility of reduced monitoring for weight loss[25]; however, a randomized clinical trial is needed to evaluate the effects of reducing monitoring requirements on weight loss.

The purpose of this 3-country randomized clinical trial was to compare the differences in weight change between individuals randomly assigned to a commercial weight management program with reduced requirements for dietary self-monitoring and individuals randomly assigned to follow a DIY

approach. We hypothesized that the commercial program would result in greater weight loss compared with the DIY approach at 3- and 12-month follow-up.

Methods

Study Design

This study was a randomized, parallel-group, 1-year clinical trial conducted from June 19, 2018, to November 30, 2019, at the University of North Carolina (UNC) at Chapel Hill in the US; the University of British Columbia in Kelowna, British Columiba, Canada; and the University of Leeds in Leeds, West Yorkshire, England, in the United Kingdom. The primary outcome was weight change at 3 and 12 months. The study was approved by the University of North Carolina at Chapel Hill Biomedical Institutional Review Board, the North West–Preston Research Ethics Committee, and The University of British Columbia Okanagan Research Services Behavioural Research Ethics Board. Written informed consent was provided by participants. The trial protocol is included in Supplement 1.

Recruitment and Screening

Participants were recruited using methods that had previously been successful in trials within each country, with special efforts to increase recruitment of underrepresented groups. Interested individuals were directed to a universal recruitment website that included study details with links to site-specific web screeners. Research staff contacted web-eligible participants to confirm eligibility and to schedule baseline in-person consent and screening. Final eligibility was determined after the in-person visit. This report follows the Consolidated Standards of Reporting Trials (CONSORT) reporting guideline for randomized studies (**Figure 1**).

Participant Eligibility

Major inclusion criteria were being 18 to 75 years of age, body mass index (BMI) of 25 to 45 (calculated as weight in kilograms divided by height in meters squared), access to a smartphone, and residence within 48.3 km of a location of this commercial weight management program. Major exclusion criteria were recent, current, or planned pregnancy; recent weight loss of 5 kg or more; health conditions or medications known to affect weight or make weight loss or unsupervised exercise unsafe; and prior or planned bariatric surgery. Full inclusion and exclusion criteria are detailed in the eMethods in Supplement 2.

Randomization and Blinding

The Data and Analysis Coordinating Unit at UNC provided randomization assignments, using a random numbers generator, with a 1:1 allocation to either the commercial program or the DIY method, stratified by clinical site, race and ethnicity status, and sex (Figure 1). After randomization, study staff who needed to be unblinded owing to study oversight requirements were not involved in follow-up assessments.

Interventions

DIY Group

Participants underwent a 15- to 30-minute meeting reviewing common DIY strategies for weight loss that are available in the public domain. Participants engaged in a short discussion of prior weight loss attempts and successes and were provided with a brief resource guide with information about a variety of strategies (diet tracking or self-monitoring apps, meal plans, meal replacements, and physical activity) and dietary approaches to reduce energy intake healthfully (low fat, low carbohydrate, vegan, and Mediterranean diet). Emphasis was placed on strategies that used dietary self-monitoring to achieve a weight loss energy deficit, and referral to free digital dietary self-monitoring resources was given. Participants were informed that 50% of people in the National Weight Control Registry, a research-based registry of individuals who had lost weight and kept it off

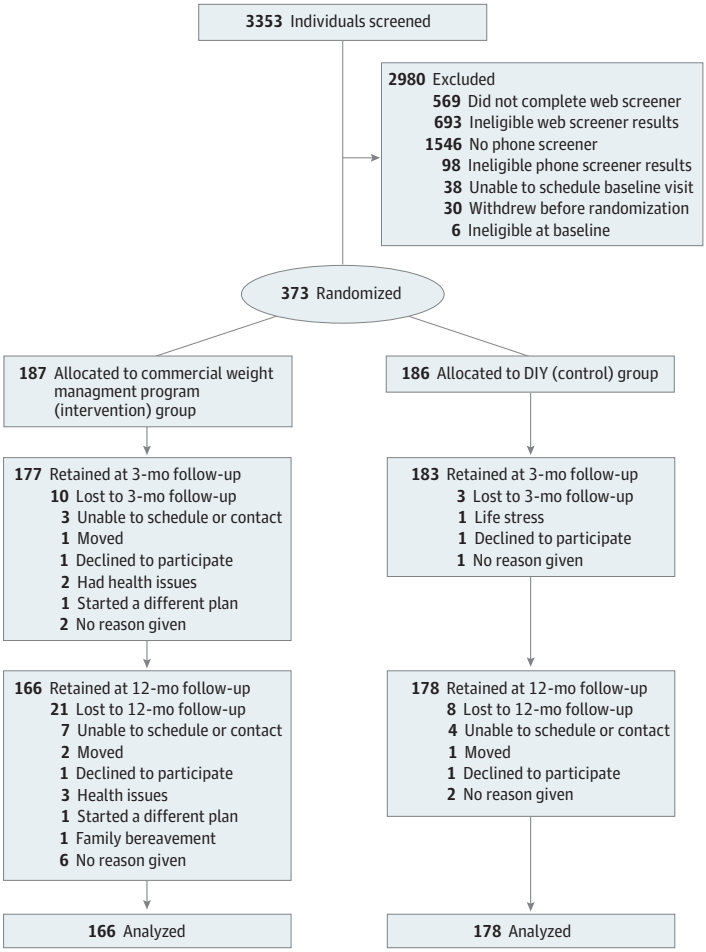
successfully, followed a DIY approach.[26] Participants were encouraged to select a DIY strategy that best fit with their preferences, adopt that strategy for at least 8 weeks, then reevaluate, and, if needed, try another strategy. Participants in the DIY group were provided a free voucher for 12 months of the commercial program at the completion of 12-month assessment. Information on the DIY approaches suggested is available in eTable 3 in Supplement 2.

Commercial Program

Similar to the the DIY group, the commercial program group had a 15- to 30-minute session directly after randomization and were provided with a code to enroll in the program at no charge for 12 months. They were guided to download the commercial program's smartphone app and were given a list of locations of the commercial program in their community. To enable the actual enrollment in the commercial program, study staff were not involved in the delivery of the commercial program intervention, nor were any commercial program staff or locations alerted to study enrollment.

Treatment Format | Participants were encouraged to attend weekly commercial weight management program workshops (30 to 45 minutes in person) in the community. Workshops included a private weight assessment, celebrating successes and problem-solving challenges, and a discussion and handout of featured topics and skills related to weight loss and behavior change. Participants also had access to the commercial program's app, which included self-monitoring of intake, activity, and weight; informational articles; support from coaches through 1-on-1 online chats

Figure 1. Participant Flow Diagram



DIY indicates do-it-yourself.

available 24 hours a day; and an online social media peer community limited to members of the commercial program.

Dietary Approach | The commercial program assigns each food and beverage a points value per portion, based on calories, sugar, saturated fat, and protein. A unique new feature of this program was that more than 200 foods were assigned a points value of 0 and did not have to be weighed, measured, or tracked (eg, plant-based proteins, skinless chicken and turkey breast, eggs, nonfat yogurt, seafood, fruits, and most vegetables). These foods were chosen as the cornerstone of a healthy pattern based on dietary guidelines (the US Department of Agriculture and the World Health Organization) and were qualitatively assessed as having low risk of overconsumption. Participants were encouraged to track only foods that had point values greater than 0 to decrease the burden of tracking everything that was consumed. Based on the Mifflin St-Jeor formula[27] to estimate resting energy expenditure, participants were given an adjusted personalized daily points budget—to account for foods consumed but not monitored—to result in a 750-kcal/d (3138-kJ/d) energy deficit.

Other Components | Participants received a personalized weekly activity goal based on their current level of activity and were encouraged to track their activity. The program also promoted the adoption of skills and techniques to shift participants' thinking. Mindset topics were based on cognitive behavioral, acceptance-based, and positive psychology. Examples included gratitude, self-compassion, dealing with setbacks, unhelpful thinking styles, and responding to weight stigma.

Data Collection

Research staff at the clinical sites were centrally trained and certified on the study protocol and conducted measurements at baseline, 3 months, and 12 months. Participants were instructed to refrain from revealing their treatment assignment at assessment visits to try to retain blinding of staff. Assessments were conducted at the research staff offices, except in the UK, where they occurred in general practitioner practices. Data across countries were collected using a centralized REDCap[28] system with deidentified data stored centrally at UNC. All participants were provided the equivalent of $175 US dollars total compensation for completing the 3 study assessments.

Primary Outcome

This trial had 2 a priori outcomes: the difference in weight loss in kilograms between groups at 3 and 12 months. Measurement protocols for body weight and height followed the National Health and Nutrition Examination survey anthropometry procedures.[29]

Prespecified Secondary Outcome Measures

Secondary outcomes included BMI, percentage weight change, percentage of participants achieving loss of 5% of body weight, waist circumference, blood pressure, heart rate, and flexibility as measured by the Sit and Reach Test.[30] Aerobic stamina was measured using the 1-minute Sit to Stand Test across all sites and the 6-minute walk test[31] in the US and Canada (not possible in the UK owing to space limitations in general practitioner practices). Other secondary outcomes were happiness, assessed with the Oxford Happiness Questionnaire[32]; sleep quality, assessed using the Pittsburgh Sleep Quality Index[33,34]; and quality of life, assessed using the Impact of Weight on Quality of Life–Lite.[35] Engagement was assessed by the number of commercial program workshops attended and the number of days of commercial program app logins. In the DIY group, the methods used for weight loss were obtained via self-report.

Sample Size

Given 2 primary outcomes, α was set at .02 (Bonferonni correction). Using a 2-sided power analysis with 80% power and assuming a within-group SD of 5.0 kg, we found that a sample size of 360 individuals was sufficient to detect an effect size of 0.35 or more for weight loss (between-group

difference of −1.75 kg) at 12 months, with 30% attrition. The study was planned with equal recruitment goals in each country and powered for the overall pooled effect.

Statistical Analysis

For the primary outcomes, general linear regression models were used to compare the differences in weight change (in kilograms) between the 2 groups at 3 and 12 months. These models were adjusted for country (US, Canada, or UK), race and ethnicity (White or underrepresented race and ethnicity [self-reported in the UK and categorized as racial and ethnic minority group in the US and Canada if reported as anything other than White and not Hispanic or Latino]), and sex (male or female) and included a random effect for the commercial program workshop locations to control for potential clustering. Missing weight data were imputed using a multiple (n = 100) imputation model that included site, age, race and ethnicity status, sex, educational level, height, and all available information on body weight, waist circumference, and BMI. Age was categorized into 6 groups, and educational level was categorized into 5 categories (**Table 1**).

Secondary outcomes were analyzed using the same approach as for the primary outcomes, with the exception that imputation of missing data was not applied. The primary outcome variables were also analyzed without imputation as secondary outcomes (completers). The study was not powered for country-specific analyses; thus, no statistical tests were conducted at the country level. All analyses were conducted in SAS, version 9.4 (SAS Institute Inc) by investigators (K.P.T. and J.S.) who were not involved in the study intervention or assessments. All *P* values were from 2-sided tests, and results were deemed statistically significant at $P < .03$.

Results

Sample Characteristics

Among 3353 adults who demonstrated initial interest in participation, 373 were randomized (186 to the DIY group, and 187 to the commercial weight management program; 272 women [72.9%]; mean [SD] BMI, 33.8 [5.2]; 106 [28.4%] from underrepresented racial and ethnic groups; 77 [20.6%] aged 18-34 years, 74 [19.8%] aged 35-43 years, 82 [22.0%] aged 44-52 years, and 140 [37.5%] aged 53-75 years) (Table 1). There were no significant differences between randomized groups on any baseline characteristic. The retention rate for the commercial program group was 94.7% (177 of 187) at 3 months and 88.8% (166 of 187) at 12 months, and the retention rate for the DIY group was 98.4% (183 of 186) at 3 months and 95.7% (178 of 186) at 12 months (Figure 1). The retention rate in the DIY group was significantly higher at both time points ($P = .05$ at 3 months and $P = .01$ at 12 months, determined by the χ^2 test).

Primary Outcomes

Figure 2 shows the adjusted 97.5% CIs around the differences in weight change between the groups at 3 and 12 months. Intention-to-treat analyses with multiple imputation showed that participants in the commercial program group had a mean (SD) weight loss at 3 months of −3.8 (4.1) kg vs −1.8 (3.7) kg in the DIY group and a mean (SD) weight loss at 12 months of −4.4 (7.3) kg vs −1.7 (7.3) kg in the DIY group. As hypothesized, commercial program participants had significantly greater weight loss at 3 months (mean difference, −2.0 kg [97.5% CI, −2.9 to −1.1 kg]) and 12 months (mean difference, −2.6 kg [97.5% CI, −4.3 to −0.8 kg]) (Figure 2). Results by completers and multiple imputation showed identical patterns of significance (eTable 1 in Supplement 2).

Secondary Outcomes

Differences in weight change between the groups persisted when examining only completers (**Table 2**). At 3 and 12 months, participants in the commercial program group experienced a significantly larger percentage weight loss than those in the DIY group (difference: 3 months, −2.3% [97.5% CI, −3.2% to −1.4%]; 12 months, −2.8% [97.5% CI, −4.5% to −1.1%]) and reductions in waist

Table 1. Baseline Measures by Treatment Group

Measure	All participants (N = 373)	DIY (n = 186)	Commercial weight management program (n = 187)
Age, No. (%), y			
18-34	77 (20.6)	36 (19.4)	41 (21.9)
35-43	74 (19.8)	33 (17.7)	41 (21.9)
44-52	82 (22.0)	42 (22.6)	40 (21.4)
53-75	140 (37.5)	75 (40.3)	65 (34.8)
Race and ethnicity, No. (%)			
White	267 (71.6)	132 (71.0)	135 (72.2)
Racial and ethnic minority group[a]	106 (28.4)	54 (29.0)	52 (27.8)
Sex, No. (%)			
Female	272 (72.9)	136 (73.1)	136 (72.7)
Male	101 (27.1)	50 (26.9)	51 (27.3)
Educational level, No. (%)[b]			
<High school graduate	6 (1.6)	1 (0.5)	5/186 (2.7)
High school graduate, GED, or GCSE	51 (13.7)	25 (13.4)	26 (13.9)
Vocational school or some college or A levels	105 (28.2)	56 (30.1)	49 (26.2)
Undergraduate degree	129 (34.6)	58 (31.2)	71 (38.0)
Graduate degree	81 (21.8)	46 (24.7)	35 (18.7)
BMI status, No. (%)			
Overweight	98 (26.3)	48 (25.8)	50 (26.7)
Obese	275 (73.7)	138 (74.2)	137 (73.3)
Weight, mean (SD), kg	95.2 (18.7)	95.3 (18.7)	95.1 (18.7)
Height, mean (SD), cm	167.4 (9.1)	167.1 (8.8)	167.6 (9.3)
Waist circumference, mean (SD), cm	109.6 (13.7)	110.1 (13.6)	109.0 (13.8)
BMI, mean (SD)	33.8 (5.2)	34.0 (5.3)	33.7 (5.1)
Blood pressure, mean (SD), mm Hg			
Systolic	121.1 (14.9)	121.1 (14.3)	121.2 (15.5)
Diastolic	75.5 (11.0)	74.9 (10.8)	76.2 (11.2)
Heart rate, mean (SD), beats/min	70.6 (10.7)	70.5 (10.1)	70.8 (11.3)
Flexibility, mean (SD), cm			
Sit and reach[c]	−3.3 (9.4)	−3.9 (9.4)	−2.6 (9.5)
Aerobic stamina, mean (SD)			
1-Minute sit to stand, No. of stands	27.5 (7.9)	27.8 (8.0)	27.3 (7.7)
6-Minute walk, m[d]	528.1 (67.1)	526.1 (61.5)	530.2 (72.5)
Oxford Happiness Questionnaire total score, mean (SD)[e]	4.2 (0.7)	4.2 (0.7)	4.2 (0.7)
Impact of Weight on Quality of Life-Lite score, mean (SD)[f]			
Total	73.0 (19.3)	73.7 (20.2)	72.4 (18.2)
Physical function	50.8 (27.3)	52.0 (27.6)	49.6 (27.1)
Self-esteem	71.8 (27.6)	72.5 (28.2)	71.1 (27.0)
Sexual life	84.9 (19.7)	83.9 (21.0)	85.9 (18.4)
Public distress	82.7 (19.2)	81.7 (20.8)	83.7 (17.5)
Work	71.0 (17.8)	71.3 (18.5)	70.7 (17.1)
Pittsburg Sleep Quality Index score, mean (SD)[g]			
Total	6.4 (3.2)	6.3 (3.3)	6.6 (3.2)
Duration of sleep	0.7 (0.8)	0.7 (0.8)	0.7 (0.8)
Sleep disturbance	1.3 (0.5)	1.3 (0.5)	1.3 (0.6)
Sleep latency	1.1 (1.0)	1.0 (0.9)	1.2 (1.0)
Day dysfunction due to sleepiness	1.0 (0.7)	1.0 (0.7)	1.1 (0.8)
Sleep efficiency	0.8 (1.0)	0.8 (1.0)	0.8 (1.0)
Overall sleep quality	1.2 (0.7)	1.2 (0.7)	1.3 (0.7)
Need medication to sleep	0.3 (0.7)	0.3 (0.8)	0.2 (0.7)

Abbreviations: A level, General Certificate of Education Advanced Level; BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); DIY, do-it-yourself; GCSE, General Certificate of Secondary Education; GED, General Educational Development Certification.

[a] Racial and ethnic minority group was self-reported in the UK and categorized as racial and ethnic minority group in the US and Canada if reported as anything other than White and not Hispanic or Latino.

[b] Data were missing for 1 patient in the commercial weight loss program group.

[c] Flexibility was measured using the Sit and Reach Test. A measurement of 0 cm means the participant was able to touch their toes.

[d] The 6-minute walk was not measured among the UK participants (62 in the commercial weight management program and 63 in the DIY group) because of a lack of space to conduct the measurement in the clinic.

[e] Oxford Happiness Questionnaire is a 29-item instrument that is self-administered and uses a 6-point response format. Scores range from 1 (strongly disagree) to 6 (strongly agree). The overall happiness score is the mean.

[f] Impact of Weight on Quality of Life–Lite is a 31-item instrument. The overall score and the 5 subscale scores are calculated as the mean scores from the 5-point response format, where 1 indicates never true and 5 indicates always true.

[g] Pittsburgh Sleep Quality Index assesses participant's usual sleep habits during the past month. Participants receive scores between 0 and 3 (where 0 is better) for 7 sleep categories. Total score ranges from 0 (better) to 21 (worse); a score of less than 5 is associated with good sleep quality, and a score of 5 or more is associated with poor sleep quality.

circumference (difference: 3 months, −2.0 cm [97.5% CI, −3.7 to −0.4 cm]; 12 months, −3.1 cm [97.5% CI, −5.2 to −1.0 cm]) than participants in the DIY group. At 3 months, more participants in the commercial program group than in the DIY group lost 5% of body weight (40.7% [72 of 177] vs 18.6% [34 of 183]; relative risk, 2.13 [97.5% CI, 1.44-3.17]), and that difference persisted at 12 months (42.8% [71 of 166] in the commercial program group vs 24.7% [44 of 178] in the DIY group; relative risk, 1.73 [97.5% CI, 1.22-2.47]).

Although both groups experienced improvements in blood pressure, aerobic stamina, flexibility, and happiness at 3 and 12 months, there were no significant differences between groups. At 3 months, participants in the commercial program group had significantly greater improvements than those in the DIY group in quality of life (total score, 2.49 [97.5% CI, 0.03-4.95]; *P* = .02; and physical function subscale, 4.10 [97.5% CI, 1.08-7.13]; *P* = .02). At 12 months, only the difference in improvements on the self-esteem subscale was significant (5.14 [97.5% CI, 0.37-9.91]; *P* = .02).

Commercial Weight Management Program Engagement

During the first 3 months, 75.4% of those randomly assigned to the commercial program (141 of 187) used the app and attended workshops, 19.8% (37 of 187) used only the app, no participants attended only workshops, and 4.8% (9 of 187) did not engage in the workshops or use the app (eTable 2 in Supplement 2). The mean (SD) number of meetings attended during the first 3 months was 5.5 (4.5) (approximately 2 per month), and participants used the app a mean (SD) of 50.8 (29.5) days (approximately 4 logins per week). Although participation decreased between months 3 and 12, 81.3% (152 of 187) continued engaging in the program at some level (with mean [SD] attendance of approximately 1.0 [1.5] meeting per month and 2.4 [2.6] logins per week).

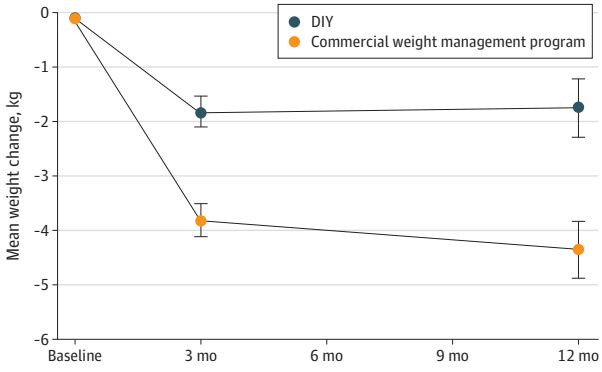
DIY Engagement

The DIY group reported limited use of commercial programs (1.7% [3 of 178]) and limited use of other formal weight loss support groups (3.4% [6 of 178]) (eTable 3 in Supplement 2). The most popular strategies were using their own approach without following any published diet (71.4% [127 of 178]), using a weight loss app on a smartphone (38.2% [68 of 178]), losing weight with a friend or family member (24.7% [44 of 178]), and using structured exercise classes or a personal trainer (19.7% [35 of 178]).

Response to Treatment

Among commercial weight management program participants, attendance at workshops (r = −0.565; P < .001) and number of days of app use (r = −0.622; P < .001) were significantly correlated with 12-month weight loss (**Table 3**). In models adjusted for sex, race and ethnicity, and site, each workshop attended was associated with 0.24 kg (97.5% CI, 0.18-0.31 kg) greater weight

Figure 2. Weight Losses by Study Group at 3 and 12 Months



Error bars indicate 97.5% CIs. DIY indicates do-it-yourself.

Table 2. Mean Difference Between Study Groups in Predefined Secondary Outcomes Among Completers

Outcome	Change, mean (SD)[a]		Difference (97.5% CI)[b]	*P* value
	DIY group	Commercial weight management program group		
3-Month secondary outcomes				
Weight change, %	−1.81 (3.89)	−4.12 (4.13)	−2.29 (−3.20 to −1.37)	<.001
Waist circumference, cm	−2.10 (6.55)	−4.12 (7.55)	−2.03 (−3.70 to −0.36)	.007
Blood pressure, mm Hg				
Systolic	0.60 (8.50)	−0.80 (9.04)	−1.07 (−3.66 to 1.52)	.36
Diastolic	0.07 (10.85)	−1.07 (11.25)	−1.34 (−3.41 to 0.73)	.15
Heart rate, beats/min	−0.54 (8.45)	−1.71 (8.86)	−1.13 (−3.19 to 0.93)	.22
Flexibility				
Sit and reach distance, cm	2.40 (4.19)	2.64 (4.38)	0.24 (−0.78 to 1.26)	.59
Aerobic stamina				
1-Minute sit to stand, No. of stands	2.07 (5.98)	3.11 (5.51)	1.07 (−0.29 to 2.42)	.08
6-Minute walk, m	6.76 (41.74)	13.14 (43.10)	6.34 (−6.09 to 18.78)	.25
Oxford Happiness Questionnaire score	−0.03 (0.51)	0.05 (0.50)	0.08 (−0.04 to 0.19)	.15
Pittsburgh Sleep Quality Index score				
Total	−0.09 (2.69)	−0.49 (2.59)	−0.39 (−1.02 to 0.23)	.16
Duration of sleep	−0.03 (0.76)	−0.03 (0.79)	0.01 (−0.18 to 0.19)	.93
Sleep disturbance	0.03 (0.55)	−0.06 (0.52)	−0.09 (−0.22 to 0.04)	.11
Sleep latency	0.03 (0.81)	−0.14 (0.83)	−0.17 (−0.37 to 0.02)	.05
Day dysfunction due to sleepiness	−0.04 (0.70)	−0.15 (0.63)	−0.10 (−0.26 to 0.06)	.15
Sleep efficiency	−0.02 (1.11)	0.06 (1.08)	0.07 (−0.19 to 0.34)	.52
Overall sleep quality	−0.09 (0.67)	−0.20 (0.71)	−0.11 (−0.28 to 0.05)	.12
Need medication to sleep	0.04 (0.63)	0.04 (0.62)	0.00 (−0.15 to 0.15)	.99
Impact of Weight on Quality of Life score				
Total	5.11 (10.32)	7.58 (10.62)	2.49 (0.03 to 4.95)	.02
Physical function	5.17 (12.57)	9.28 (13.01)	4.10 (1.08 to 7.13)	.002
Self-esteem	7.49 (17.98)	10.84 (16.50)	3.46 (−0.57 to 7.48)	.05
Sexual life	4.32 (19.39)	6.39 (20.81)	1.97 (−2.83 to 6.78)	.36
Public distress	2.76 (12.12)	3.53 (12.39)	0.79 (−2.13 to 3.70)	.55
Work	4.61 11.90)	3.64 (12.22)	−0.97 (−3.84 to 1.90)	.83
12-Month secondary outcomes				
Weight change, %	−1.93 (7.21)	−4.68 (7.33)	−2.80 (−4.54 to −1.05)	<.001
Waist circumference, cm	−2.70 (8.70)	−5.70 (8.85)	−3.10 (−5.23 to −0.97)	.001
Blood pressure, mm Hg				
Systolic	−0.68 (8.39)	−1.39 (9.45)	0.19 (−2.57 to 2.95)	.88
Diastolic	−1.70 (11.01)	−1.57 (11.39)	−0.72 (−2.93 to 1.49)	.46
Heart rate, beats/min	0.47 (9.07)	−0.32 (8.81)	−0.73 (−2.94 to 1.47)	.46
Flexibility				
Sit and reach distance, cm	1.97 (5.56)	2.99 (5.66)	1.06 (−0.35 to 2.48)	.09
Aerobic stamina				
1-Minute sit to stand, No. of stands	3.39 (6.98)	3.49 (6.24)	0.16 (−1.47 to 1.80)	.82
6-Minute walk test, m	−4.97 (58.04)	−2.04 (79.61)	2.88 (−17.01 to 22.76)	.74
Oxford Happiness Questionnaire score	0.05 (0.61)	0.09 (0.57)	0.04 (−0.10 to 0.18)	.52

(continued)

Table 2. Mean Difference Between Study Groups in Predefined Secondary Outcomes Among Completers (continued)

Outcome	Change, mean (SD)[a]		Difference (97.5% CI)[b]	*P* value
	DIY group	Commercial weight management program group		
Pittsburgh Sleep Quality Index score				
Total	0.21 (2.98)	−0.31 (2.61)	−0.55 (−1.23 to 0.14)	.07
Duration of sleep	0.04 (0.81)	−0.07 (0.79)	−0.11 (−0.30 to 0.09)	.22
Sleep disturbance	0.02 (0.55)	0.02 (0.55)	0.00 (−0.13 to 0.14)	.94
Sleep latency	−0.02 (0.77)	−0.12 (0.82)	−0.10 (−0.29 to 0.09)	.25
Day dysfunction due to sleepiness	−0.07 (0.78)	−0.12 (0.76)	−0.05 (−0.24 to 0.14)	.55
Sleep efficiency	0.23 (1.22)	0.02 (1.18)	−0.21 (−0.50 to 0.08)	.10
Overall sleep quality	−0.04 (0.70)	−0.10 (0.65)	−0.06 (−0.22 to 0.11)	.43
Need medication to sleep	0.07 (0.76)	0.04 (0.71)	−0.02 (−0.20 to 0.15)	.76
Impact of Weight on Quality of Life score				
Total	5.96 (12.28)	8.43 (11.83)	2.54 (−0.38 to 5.45)	.05
Physical function	5.76 (14.00)	8.72 (14.17)	3.04 (−0.37 to 6.46)	.05
Self-esteem	8.23 (19.29)	13.23 (20.36)	5.14 (0.37 to 9.91)	.02
Sexual life	5.70 (22.73)	8.56 (21.53)	2.88 (−2.54 to 8.30)	.23
Public distress	3.26 (12.80)	3.34 (13.95)	0.10 (−3.15 to 3.36)	.73
Work	5.90 (15.01)	5.53 (12.81)	−0.38 (−3.78 to 3.02)	.80

Abbreviation: DIY, do-it-yourself.

[a] Unadjusted mean values.

[b] Model-estimated difference (commercial program − DIY) adjusted for site, sex, and minority status. Differences were significant at $P < .03$.

Table 3. Weight Change by Participation in Commercial Weight Management Program[a]

Absolute weight change	Mean weight change per 1 in-person session or app login (97.5% CI)				Correlations between weight change and intervention dose			
	Weight change per 1 in-person session attended, kg	*P* value	Weight change per app login (day), kg	*P* value	Correlation with in-person sessions attended	*P* value	Correlation with app login (day)	*P* value
At 0-3 mo	−0.5 (−0.6 to −0.3)	<.001	−0.1 (−0.1 to −0.06)	<.001	−0.477	<.001	−0.540	<.001
At 0-12 mo	−0.2 (−0.3 to −0.2)	<.001	−0.04 (−0.04 to −0.03)	<.001	−0.565	<.001	−0.622	<.001

[a] Model adjusted for site, sex, and minority status.

loss at 12 months, and each app login day was associated with an additional 0.04 kg (97.5% CI, 0.03-0.04 kg) greater weight loss at 12 months. In other words, every 4 meetings attended and/or every 25 days of app use were associated with an additional kilogram of weight loss.

Discussion

This 3-country randomized clinical trial revealed that at 3 and 12 months, compared with individuals randomly assigned to a DIY weight loss method, those randomly assigned to the commercial weight management program had greater reductions in weight and waist circumference and a greater percentage achieved a 5% weight loss. These changes are clinically meaningful, having been consistently associated with improvements in multiple health conditions.[3,36-38] Although many secondary outcomes improved among participants in both groups (blood pressure, heart rate, aerobic stamina, flexibility, and sleep), those changes were not significantly different between the groups at 3 or 12 months. Failure to detect changes in some of these physiological measures, such as blood pressure, despite the level of weight loss achieved, is consistent with other studies[39] and may be related to the fact that the sample was relatively healthy at baseline (eg, blood pressure of 121/76 mm Hg; Table 1).

One of the key features of the commercial program evaluated in this study was that self-monitoring was simplified to be less burdensome. Participants did not need to weigh, measure, or track more than 200 foods. This larger randomized clinical trial across 3 countries yielded results similar to those found in a single-group pilot study[25] of this approach and suggests that programs with lower demands for self-monitoring can produce clinically significant weight loss. Future studies should compare partial self-monitoring approaches with traditional monitoring of all foods and their effect on weight loss to isolate the mechanisms of action as well as other methods of partial self-monitoring.

Participation in the commercial program intervention, both in app use and in-person sessions, was associated with weight loss, as previously shown in both community[15,40] and clinical settings.[41-43] Consistent with other studies, attendance at in-person sessions and login rates decreased during months 3 to 12 compared with the initial period,[2,44-46] but this decrease was not associated with weight regain, and a greater proportion of the overall sample achieved a loss of 5% of body weight at 12 vs 3 months. Few participants in the DIY group used commercial programs, and the most common DIY method was their own approach (71.4%), followed by the use of a weight loss app on a smartphone (38.2%) and losing weight with a friend or family member (24.7%). Thus, the comparison between the commercial program and the DIY group seems consistent with the intended design.

Strengths and Limitations

This study has several strengths that contribute to internal validity, including the randomized clinical trial design, blinded assessors, separate intervention and assessment staff, initial and longer-term outcomes, objective measures of commercial program app engagement, and strong retention rates over 12 months. Study strengths that contribute to external validity included a more diverse population than typical in commercial weight management program evaluations, inclusion of participants in multiple countries, and a realistic comparator (DIY approach). Differences between groups may have been larger if a no-treatment control had been used, but the DIY comparator has strong relevance because it is feasible and often used in community and health settings. In addition, the commercial program intervention is publicly available in the 3 countries studied and is a program implemented by staff who were not part of this research.

The study also has some limitations. Sample sizes within each country did not permit a statistically powerful analysis by country, participants in the DIY group may have postponed weight loss efforts until receipt of the commercial program at 12 months, and we had no outcome data beyond 1 year to assess longer-term efficacy. Secondary outcomes were considered exploratory, and additional corrections for multiplicity were not applied. Finally, despite strong retention rates, more DIY participants attended the 3- and 12-month follow-up.

Conclusions

In this randomized clinical trial, adults randomly assigned to a widely available commercial weight management program had greater reductions in weight and were more likely to achieve a 5% weight loss than those randomly assigned to a DIY approach. The results suggest that health care professionals might discuss the potential merits of commercial programs compared with efforts patients might undertake to lose weight on their own for greater likelihood of clinical benefit. The results of this trial also offer initial insights into ways in which dietary monitoring, a key behavior change tool, can be simplified while retaining efficacy.

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