

A Randomized Controlled Trial of a Community-based Behavioral Counseling Program

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ABSTRACT

BACKGROUND: The US Preventive Services Task Force (USPSTF) recommends that clinicians refer obese adults for intensive, multicomponent behavioral counseling, yet most obese Americans choose a self-help approach to lose weight. The current study examined weight loss between a community-based, intensive behavioral counseling program (Weight Watchers program) and a self-help condition.

METHODS: A total of 292 participants were randomized to either a Weight Watchers condition (WW) (n = 147) or a self-help condition (n = 145). Participants in the WW condition were provided with 3 ways to access the treatment: weekly meetings; WW mobile application; and WW online tools. Weights were measured at baseline and at 3 and 6 months. Additionally, self-report use of access modes was collected at 3 and 6 months.

RESULTS: Participants in the WW condition significantly decreased their body mass index at 6 months (F = 36.7, P < .001) and were 8.0 and 8.8 times more likely to achieve a 5% and 10% reduction in weight, respectively, compared with those in the self-help condition. In a secondary analysis, high usage of all 3 access modes resulted in the greatest weight loss (P < .001).

CONCLUSION: Use of the WW program yielded significantly greater weight loss than a self-help approach, suggesting it is a viable community-based provider of weight loss treatment, as recommended by the USPSTF. Further, high usage of 3 access modes was associated with greater weight loss results.

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Obesity is a direct and indirect contributor to a plethora of chronic diseases, 1 yet 80% of weight loss attempts are self-directed. 2 Even when people needing treatment for obesity seek medical advice, there is limited evidence to support the effectiveness of primary care physicians in weight management. 3

In 2012, the United States Preventive Services Task Force (USPSTF) recommended that physicians should screen all patients for excess weight and offer or refer

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those identified as obese for intensive, multicomponent behavioral counseling. Commercial and proprietary weight loss programs that can be delivered in the community have been developed. However, most of these programs have limited or no efficacy data. 4

Weight Watchers (WW) has conducted many studies on its efficacy and effectiveness. ⁵⁻¹² Overall, participants randomized to WW conditions have demonstrated significant reductions in weight in the short and long term. ⁵⁻⁸ The amount of weight loss has been shown to be enough to improve cardiovascular function, ^{6,11,13,14} and the program has been shown to be cost-effective when compared with treatment by primary care providers. ^{10,12} In summary, WW provides the intensive, multicomponent behavioral counseling recommended by the USPSTF.

Although the effectiveness of WW has already been established, there are several reasons that this program is in need of continued evaluation.⁴ For example, the modes of

access to help people engage and follow the program have evolved as technology has advanced, even though the core concepts of WW have remained constant. Both online tools and mobile applications are now available to be used in conjunction with traditional group meetings. The overall impact of the WW program using these modes of delivery

and the impact of the different tools used within the program have yet to be evaluated.

The primary purpose of this study was first to examine the efficacy of the WW program that incorporates multiple access points compared with the selfdirected approach that most Americans employ. We hypothesized that participants in the WW condition would have significantly greater reductions in body mass index (BMI) and weight compared with the self-help condition. The secondary purpose of this study was to examine the role of the modes of accessing the program within the treatment group. We hypothesized that participants

within the WW condition would have greater weight loss if all access points were used frequently, compared with those who used these access points infrequently.

METHODS

Participants

A total of 292 overweight and obese individuals met criteria for inclusion in this randomized controlled trial and provided informed consent following an informational session and screening. In order to recruit participants, a market research firm was hired to send e-mails with a description of the study to individuals in the Danbury, Connecticut area. Eligibility criteria included having a BMI between 27 and 40 kg/m² and an age of 18 years and above. Potential participants were excluded if they reported dieting or taking medications affecting appetite or weight. Other exclusionary criteria included untreated thyroid disease, uncontrolled hypertension, history or presence of cancer, presence of implanted cardiac defibrillator or pacemaker, taking oral steroids, chronic gastrointestinal disorders, orthopedic limitations, history of heart problems, and recent and major surgery. Women who were pregnant, nursing, or planning to become pregnant also were excluded.

The majority of the sample reported being female (89.8%), married (71.4%), employed for wages (64%), and having at least some college credit (76.7%) (see **Table 1**). This study was approved by the Institutional Review Board for human subjects at Baylor College of Medicine. **Figure 1** provides a schematic of the study design and participant flow.

Randomization

Once informed consent was obtained and eligibility was confirmed, participants were randomly assigned to either the WW (n=147) or self-help (n=145) condition based on a computer-generated random numbers chart. Participants in the WW group were provided with free access to a

commercially available program, whereas participants in the self-help group were provided with informational materials.

CLINICAL SIGNIFICANCE

- Compared with a control condition, participants in a Weight Watchers condition significantly decreased their weight at 6 months and were more likely to achieve a 5% and 10% reduction in initial weight.
- Those using multiple methods of accessing the program (ie, online, mobile applications, meetings) had the greatest weight loss.
- Meeting attendance accounted for the most variance in predicting successful weight loss.

Intervention

Weight Watchers. The WW program was based on 4 components:

- a food plan, which was based on a balanced diet and healthy eating;
- an activity plan, designed to promote progressive physical activity increase;
- group support; and
- skills to change behavior.

Participants in the WW condition were provided with 3 modes

of accessing this commercial program: weekly meetings, WW mobile application, and WW online Web site. Participants determined their weight goal and were encouraged to utilize all 3 modes of access in order to reach their goal.

The program was delivered in weekly WW meetings that consisted of facilitated group discussions about weight loss skills. The group discussions were led by WW leaders who were Lifetime members that have successfully achieved and maintained a healthy body weight and have successfully completed a leader skills training course. For this intervention, staff were trained to provide the program incorporating 3 modes of access with a focus on integrating eTools into the meeting environment, using training methods consistent with typical WW training procedures.

Participants in the WW condition were given access to WW eTools on their computer and mobile device. The WW eTools provided participants the opportunity to access food, activity, and weight-monitoring systems in addition to a library of meal ideas, recipes, and content on a variety of weight-related topics. Participants also were able to seek group support outside of the weekly meetings by participating in community message and discussion boards. These boards were established as part of the WW program in order to provide participants with the support to continue adherence to the program.

Self-help. Participants in the self-help group were provided with publicly available printed materials explaining basic dietary and exercise guidelines for safe weight loss. Other resources such as public library materials, Web sites, and telephone numbers of health promotion organizations

166.5 (7.8) 92.2 (13.8)

Variable	Overall Sample (n = 292)	Condition		Completion Status	
		Weight Watchers $(n = 147)$	Self-Help (n = 145)	Completers $(n = 257)$	Noncompleters $(n = 35)$
Age (years)	46.5 (10.5)	47.5 (11.7)	45.6 (9.2)	46.7 (10.6)	45.4 (10.3)
Sex (% female)	89.8	89.1	90.3	90.7	82.9
Ethnicity (%)					
Not Hispanic or	90.2	90.8	89.6	91.4	81.2
Latino					
Hispanic or Latino	9.8	9.2	10.4	8.6	18.8
Race (%)*					
American Indian	1.0	0.7	1.4	0.8	3.0
Black	6.2	4.1	8.3	6.2	6.1
Other/mixed	1.4	1.4	1.4	0.4	9.1
Pacific Islander	0.7	1.4	0.0	0.8	0
White	90.7	92.4	88.9	91.8	81.8
BMI (kg/m ²)	33.0 (3.6)	33.1 (3.7)	32.8 (3.6)	32.9 (3.7)	33.1 (3.4)
Weight classification (% obese)	74.0	74.1	73.8	72.8	82.9

164.7 (7.8)

90.2 (14.1)

BMI = body mass index.

Height (cm)

Weight (kg)

offering free weight control information also were made available. Upon completion of the trial, these individuals were provided a free 6-month WW membership.

165.1 (7.5)

90.1 (13.4)

Access modes. In order to determine the role of the individual modes of access for participants in the WW condition, we examined the use of access points (ie, meeting attendance, WW Web site, and mobile device application). Participants were divided into groups based on high and low levels of meeting attendance, Web site usage, and

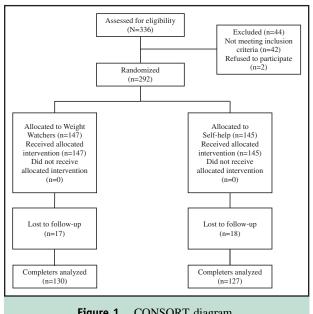


Figure 1 CONSORT diagram.

application usage. High meeting attendance was defined as attending more than 12 of 24 weekly group sessions, whereas low attendance was defined as attending 12 or fewer weekly group sessions. Participants were identified as frequent users of the Web site if they reported using the Web site 2 or more times a week, whereas infrequent users of the Web site reported using the Web site one time a week or less. Similarly, frequent users of the mobile device application were defined as using the application 2 or more times a week, whereas low frequency application users were defined as using the application one time a week or less. Individuals were then classified as using all 3 modes (n = 38), 2 modes (n = 17), one mode (n = 24), or no modes (n = 68). Table 2 provides more detailed information on these groupings.

164.9 (7.5)

89.8 (13.3)

Measures

Heights were measured at baseline in centimeters using a stadiometer (Seca 213, Hamburg, Germany), and weights were collected in kilograms at baseline and at 3 and 6 months using a calibrated Tanita 300 series digital scale (Tanita Corporation of America, Arlington Heights, Ill). Participants were instructed to wear light clothing and no footwear. BMI was calculated using obtained heights and weights (weight [kg]/[height (m)]²).

Statistical Analyses

165.5 (7.3)

90.0 (12.7)

Statistical analyses were performed using SPSS (version 20; SPSS Inc., Chicago, Ill). Differences in baseline characteristics between study conditions and participants who remained in the study and those who dropped out before

^{*}Significant differences were found between racial groups in terms of completion of the intervention.

condition, ricans (3b) or 10										
Variable	Meeting Attendance		Web Site Usage		Application Usage					
	$High\; (n = 44)$	Low (n $= 103$)	$High\; (n = 57)$	Low (n = 90)	High (n = 66)	Low (n = 81)				
Age (years)	49.7 (12.3)	46.5 (11.3)	47.3 (11.4)	47.5 (11.9)	45.8 (11.5)	48.8 (11.6)				
Sex (% female)	90.9	88.3	87.7	89.9	87.9	90.1				
BMI (kg/m ²)	33.2 (3.7)	33.1 (3.7)	33.9 (3.7)	33.3 (3.7)	33.1 (3.7)	33.1 (3.7)				
Weight classification	75.0	73.8	68.4	77.5	74.2	74.1				
(% obese)										
Height (cm)	164.3 (6.9)	164.9 (8.1)	165.2 (7.2)	164.3 (8.1)	165.0 (7.9)	164.4 (7.7)				
Weight (kg)	90.0 (14.5)	90.3 (14.0)	90.1 (14.2)	90.1 (14.1)	90.6 (14.4)	89.8 (13.9)				

Comparison of Baseline Characteristics of High and Low Use of Modes of Access in the Participants in the Weight Watchers Condition, Means (SD) or %

BMI = body mass index.

the end of the 6-month assessment were examined using t tests and chi-squared analyses. No significant differences were found. A 2-group (WW vs self-help) repeatedmeasures analysis of variance was used to evaluate group differences in BMI and weight for baseline, 3-, and 6-month outcomes. As recommended by the consolidated standards of reporting trials guidelines for randomized trials, models were developed for both completers and intention-to-treat using the last-observation-carried-forward method. 15-17

RESULTS

A total of 257 participants (88.0%) completed baseline, 3-, and 6-month measurements. Significant differences were found between racial groups in terms of completion of the intervention ($\chi^2 = 18.0$, P < .01). Although there was not a significant difference in the representation of racial groups between conditions ($\chi^2 = .01$, ns), race was used as a covariate for the following analyses.

Primary Outcomes

Overall, a significant interaction of time and condition was found for both weight (F = 34.5, P < .001) and BMI (F = 36.7, P < .001), indicating that participants in the WW condition significantly decreased their weight and BMI compared with participants in the self-help condition (see Figure 2). Similar results were obtained using an intent-to-treat model for both weight (F = 36.8, P < .001) and BMI (F = 38.9, P < .001). Those in the WW group were 8.0 times (95% confidence interval [CI], 3.9-16.2) and 8.8 times (95% CI, 3.0-25.9) more likely to achieve a 5% and 10% (respectively) reduction in baseline weight at 6 months than self-help participants (Ps < .001). WW subjects lost 4.6 kg (10.1 lbs) and self-help subjects lost 0.6 kg (1.3 lbs) at 6 months.

Treatment Adherence and Weight Loss at 6 Months

A one-way analysis of variance was conducted to determine differences in weight loss between groups using differential numbers of access points to a high degree (0, 1, 2, and all 3 modes). Overall, these 4 groups demonstrated significant differences in the amount of weight loss at 6 months (F = 14.9, P < .0001). Post hoc analyses indicated that those using 3 modes of access to a high degree had significantly more weight loss than all other groups (P < .01). Additionally, those using 1 or 2 access modes to a high degree had significantly more weight loss than those using no access modes to a high degree (P < .05). The difference in weight loss between those using 2 modes of access and one mode of access to a high degree was not statistically significant. These outcomes are presented in Figure 3.

Attendance. Participants randomized to the treatment condition attended an average of 9.1 \pm 7.3 of a possible 24 weekly group meetings. Correlation analysis indicated that the more sessions individuals attended, the more likely they were to lose weight at 6 months (r = 0.60, P < .0001). Additional logistic regression analyses, which divided participants into high and low attendance categories, showed that participants with high attendance records were 11.2 times (95% CI, 4.6-26.9) and 15.5 times (95% CI, 5.6-43.2) more likely to reach 5% and 10% (respectively) weight loss at 6 months compared with those with low attendance (Ps < .01) (see Figure 4).

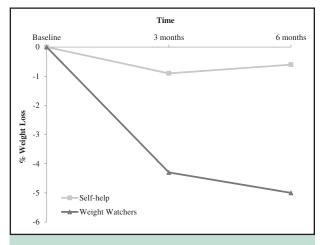


Figure 2 Percent weight loss from baseline to 3 and 6 months by condition.

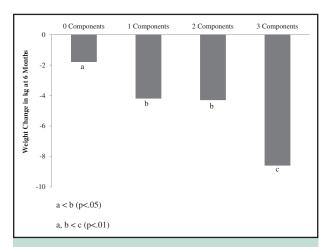


Figure 3 Weight loss at 6 months across participants using the treatment modes of access to a high degree.

Online Web site usage. The majority of participants in the treatment group reported using the WW Web site at least once a week. More frequent usage of the online Web site was correlated with greater weight loss at 6 months (r=0.36, P<.0001). Logistic regression analyses showed that participants with high Web site usage were 3.1 times (95% CI, 1.5-6.5) and 5.4 times (95% CI, 2.1-14.0) more likely to reach 5% and 10% weight loss, respectively, at 6 months compared with those with low Web site usage (Ps<.01).

Mobile device application usage. Most participants in the treatment group reported using the mobile application at least 2 to 6 times a week. Similar to previous analyses, more frequent usage of the mobile application was correlated with greater weight loss at 6 months (r = 0.28, P < .01). Logistic regression analyses indicated that frequent users of the mobile application were 2.0 times (95% CI, 1.0-4.1) and 3.3 times (95% CI, 1.3-8.1) more likely to reach

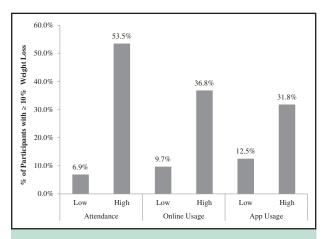


Figure 4 Percentage of participants meeting 10% weight loss and level of meeting attendance, Web site usage, and application usage.

5% and 10% weight loss, respectively, at 6 months compared with infrequent users of the application (Ps < .05).

Intercorrelation of measures. The 3 measures of use of access points were highly correlated. Attendance correlated with online usage (r=0.40, P<.0001) and application usage (r=0.37, P<.0001), and the 2 latter variables also were related (r=0.66, P<.0001). Stepwise multiple regression, which allowed the model to enter the strongest variable first, indicated that meeting attendance accounted for 29.4% of the variance in weight loss at 6 months (F change = 52.8, P<.0001). When including online usage in the model, the amount of variance accounted for significantly increased to 31.7% (F change = 4.2, P<.05). Mobile application usage did not contribute significantly to the predictive capability of this model at 6 months.

Use of Access Points at 3 Months

Because the majority of weight loss occurred at 3 months, we examined the role of these access points at this time. A similar pattern to the 6-month outcomes was found with participants who had high attendance, Web site usage, and mobile application usage having a greater likelihood of reaching 5% weight loss (7.2, 3.8, and 8.3 times more likely, respectively) compared with those who used these access points less frequently (Ps < .0001). Additionally, a stepwise demonstrated that regression meeting attendance (F change = 42.2, P < .0001) accounted for the most variance, and mobile application usage (F change = 9.0, P < .01) significantly increased the variance accounted for in weight loss at 3 months. The overall model predicted 28.9% of the variance.

DISCUSSION

The results of this study demonstrate that participants enrolled in a commercially available, community-based weight loss program using 3 access points (ie, meetings, online Web site, and mobile device application) demonstrated significantly greater weight loss than a self-help condition. In terms of clinical significance, participants in the WW condition were more likely to achieve a weight loss of 5%-10% of their initial body weight. A weight loss of this magnitude is considered to be beneficial in reducing some of the negative effects of obesity, such as high blood pressure and glucose levels. ^{13,14} Moreover, it exemplifies the intensive, multicomponent behavioral counseling approach recommended by the USPSTF.

These findings replicate results from earlier studies that have established the effectiveness of the WW program. One important difference between this study and many randomized trials is that this one was conducted in a community setting, similar to other WW trials, rather than a typical research setting. As a result, the same protocol was used that would be followed when a typical person walks into a WW Center. The only exception was that

there was no fee for service. While results were similar to previous studies in terms of average weight loss, participants attended fewer weekly sessions. It is noteworthy that similar weight loss results were obtained despite lower weekly attendance.

Since the initial studies investigating the effectiveness of the WW program, technological advancements have enhanced the methods by which participants can utilize weight loss interventions and treatment tools. For example, patients can now track their food intake and physical activity online or using a mobile application and seek support through message boards in addition to the traditional mode of group meetings. As a result, it is important to reassess the effectiveness of the WW program using the new modes of access. The findings of this study suggest that participants utilizing all 3 modes of access (ie, meeting attendance, online usage, and mobile application usage) to a high degree were the most successful in achieving a weight loss of 5% and 10% at 6 months. However, it is possible that using all 3 access points to a high degree may be a proxy measurement for participants' overall adherence or level of motivation.¹⁸

Further examination of the impact of the individual modes of access showed that the mobile application and online usage appeared to play a larger role in the initial stages of treatment (ie, first 3 months); however, with regard to longer-term outcomes, meeting attendance accounted for the most variance in predicting successful weight loss. One limitation of this study is that it was not designed to determine the individual impact of the modes of access. As a result, it was not possible to determine the independent efficacy of online use, application use, or meeting attendance. Although the individual impact of these access points cannot be determined, this study demonstrates that when all 3 access points are used in conjunction, the greatest weight losses are achieved. Future dismantling studies are needed to examine the independent efficacy of the individual access points. In addition to dismantling, further investigation of the long-term outcomes (1 and 2 years) is needed to determine weight loss maintenance.

CONCLUSION

In summary, this study found that participants in a community-based, intensive behavioral counseling program demonstrated significantly greater weight loss at 6 months compared with participants in a self-help condition. Participants using all 3 modes of access (ie, meeting attendance, online usage, and mobile application usage) to a high degree were the most successful in achieving 5% and 10% weight loss at 6 months. These findings suggest that the WW program is effective in promoting significant weight loss in

community-based settings and is a viable referral choice for clinicians' patients diagnosed with obesity.

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