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Effect of Wearable Technology Combined With a Lifestyle Intervention on Long-term Weight Loss
The IDEA Randomized Clinical Trial

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IMPORTANCE Effective long-term treatments are needed to address the obesity epidemic. Numerous wearable technologies specific to physical activity and diet are available, but it is unclear if these are effective at improving weight loss.

OBJECTIVE To test the hypothesis that, compared with a standard behavioral weight loss intervention (standard intervention), a technology-enhanced weight loss intervention (enhanced intervention) would result in greater weight loss.

DESIGN, SETTING, PARTICIPANTS Randomized clinical trial conducted at the University of Pittsburgh and enrolling 471 adult participants between October 2010 and October 2012, with data collection completed by December 2014.

INTERVENTIONS Participants were placed on a low-calorie diet, prescribed increases in physical activity, and had group counseling sessions. At 6 months, the interventions added telephone counseling sessions, text message prompts, and access to study materials on a website. At 6 months, participants randomized to the standard intervention group initiated self-monitoring of diet and physical activity using a website, and those randomized to the enhanced intervention group were provided with a wearable device and accompanying web interface to monitor diet and physical activity.

MAIN OUTCOMES AND MEASURES The primary outcome of weight was measured over 24 months at 6-month intervals, and the primary hypothesis tested the change in weight between 2 groups at 24 months. Secondary outcomes included body composition, fitness, physical activity, and dietary intake.

RESULTS Among the 471 participants randomized (body mass index [BMI], 25 to <40; age range, 18-35 years; 28.9% nonwhite; 77.2% women), 470 (233 in the standard intervention group, 237 in the enhanced intervention group) initiated the interventions as randomized, and 74.5% completed the study. Weight change at 24 months differed significantly by intervention group (difference, 2.4 kg [95% CI, 1.0-3.7]; P = .002). Both groups had significant improvements in body composition, fitness, physical activity, and diet, with no significant difference between groups.

	Standard Intervention	Enhanced Intervention
Weight, mean (95% CI), kg		
Baseline	95.2 (93.0-97.3)	96.3 (94.2-98.5)
24 mo	92.8 (90.6-95.0)	89.3 (87.1-91.5)
Estimated weight loss, mean (95% CI), kg	5.9 (5.0-6.8)	3.5 (2.6-4.5)

CONCLUSIONS AND RELEVANCE Among young adults with a BMI between 25 and less than 40, the addition of a wearable technology device to a standard behavioral intervention resulted in less weight loss over 24 months. Devices that monitor and provide feedback on physical activity may not offer an advantage over standard behavioral weight loss approaches.

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Author Video Interview and JAMA Report Video

Supplemental content

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Overweight and obesity have high prevalence[1] and are associated with numerous health conditions.[2] Interventions emphasizing both diet and physical activity are effective for weight loss, resulting in 6-month weight loss of 8% to 10% of initial weight.[3] However, challenges remain to sustaining weight loss long-term.[3]

There is wide availability of commercial technologies for physical activity and diet.[4] These technologies include wearable devices to monitor physical activity, with many also including an interface to monitor diet. Short-term studies have shown these technologies to result in modest improvements in weight loss when added to a behavioral intervention.[5,6] These technologies may provide a method to improve longer-term weight loss; however, there are limited data on the effectiveness of such technologies for modifying health behaviors long term.[4]

This randomized trial examined whether adding wearable technology to a behavioral intervention would improve weight loss across 24 months among young adults aged 18 to 35 years. Additional outcomes included body composition, fitness, physical activity, and dietary intake.

Key Points

Question Is the addition of a wearable device to monitor and provide feedback on physical activity effective for improving weight loss within the context of a behavioral weight loss intervention?

Findings In this randomized trial that included 470 young adults, weight loss was significantly less (by 2.4 kg) in response to a behavioral intervention when a wearable device that monitored and provided feedback on physical activity was included within the intervention.

Meaning Devices that monitor and provide feedback on physical activity may not offer an advantage over standard behavioral weight loss approaches.

Methods

Design

IDEA (Innovative Approaches to Diet, Exercise and Activity) was a randomized clinical trial conducted at the University of Pittsburgh and was one of the studies within the EARLY (Early Adult Reduction of Weight Through Lifestyle Intervention) Trials consortium, with each study implementing a unique intervention in young adults.[7] The IDEA study protocol is available in Supplement 1. Participants were randomized to 1 of 2 groups. Both groups received a behavioral weight loss intervention for 6 months; at 6 months, both interventions added telephone counseling sessions, text message prompts, and access to study materials on a website. However, after the initial 6 months, participants randomized to the standard behavioral weight loss intervention (standard intervention) group initiated self-monitoring of diet and physical activity behaviors, and those in the technology-enhanced weight loss intervention (enhanced intervention) group used the study website to access education materials only, and wearable technology was provided along with a web-based interface to monitor physical activity and diet. Randomization was stratified by sex and race (white or nonwhite) using a computer program that applied randomly selected block sizes of 2 and 4 with the sequence of randomization kept confidential to the other investigators. The primary outcome was weight change at 24 months.

Participants

Recruitment occurred across 10 recruitment periods that took place between October 2010 and October 2012 at the University of Pittsburgh using direct mail, mass media advertisements, or referral from clinical research registries. Eligibility was assessed based on self-reported medical history, and clearance from the participant's physician was also obtained. Procedures were approved by the University of Pittsburgh institutional review board, and all participants provided informed consent.

Eligibility criteria included age between 18 to 35 years, body mass index (BMI) of 25.0 to less than 40.0 (calculated as weight in kilograms divided by height in meters squared), access to a cellular telephone that could receive text messages, and a computer with internet access. Exclusion criteria have been published.[8]

Intervention

Intervention Contact

Both the standard intervention group and the enhanced intervention group received regular intervention contact. Group-based sessions were scheduled weekly for the initial 6 months and monthly between months 7 to 24. If a participant was unable to attend a scheduled group session, attempts were made to engage the participant in a makeup session. Theory-based strategies were used to promote adherence to weight loss behaviors.[9-13] At each session, participants were given feedback on weight change and were provided materials to complement the topic of the session. Beginning with month 7, these materials were posted on the study website, along with a weekly behavioral tip.

During months 7 to 24, participants were also scheduled to receive a brief (≤10 minutes) individual telephone contact once per month and weekly text messages. The telephone contacts were conducted by intervention staff and followed a standard script. Text messages were provided once or twice per week and were used to prompt engagement in weight loss behaviors or to remind participants of upcoming intervention sessions. Participants were compensated $5 per month to offset the cost of receiving text messages.

Dietary Intervention

Calorie intake in both intervention groups was prescribed based on baseline weight at 1200 kcal/d for individuals who weighed less than 90.7 kg, 1500 kcal/d for those who weighed 90.7 to less than 113.4 kg, and 1800 kcal/d for those who weighed 113.4 kg or more. If weight loss exceeded 6% during each 4-week period or if BMI was 22 or less, prescribed individual calorie intake was increased. Dietary fat was prescribed at 20% to 30% of total calorie intake, and sample meal plans were provided to facilitate adoption of the prescribed dietary recommendations. During months 1 to 6, participants were instructed to

self-monitor dietary intake in a diary that was returned to the interventionists at the conclusion of each week, and the intervention staff provided feedback prior to returning diaries to the participants. During months 7 to 24, participants in the standard intervention group self-reported their daily intake using a website designed for this study, and this information was available to the staff during the intervention telephone contacts. Participants in the enhanced intervention group self-monitored their dietary patterns using the technology described below.

Physical Activity

Nonsupervised moderate-to-vigorous physical activity (MVPA) in both intervention groups was initially prescribed at 100 minutes per week and increased at 4-week intervals until a prescription of 300 minutes per week was achieved. Participants were instructed to engage in structured forms of MVPA that were 10 minutes or longer in duration. During months 1 to 6, participants were instructed to self-monitor their MVPA in a diary returned to the interventionists at the conclusion of each week. The intervention staff provided feedback on these diaries. During months 7 to 24, participants in the standard intervention group self-reported their daily MVPA using a website designed for this study, and this information was available to the staff during the intervention telephone contacts. Participants in the enhanced intervention group self-monitored their MVPA using the technology described below.

Technology Used by the Enhanced Intervention Group

The enhanced intervention group was provided and encouraged to use a commercially available wearable technology that included a web-based interface (FIT Core; BodyMedia). This system included a multisensor device worn on the upper arm that provided feedback to the participant on energy expenditure and physical activity through a small display or through web-based software developed by the manufacturer. While the display provided information about total MVPA, the web-based software also provided feedback on MVPA performed in durations of 10 minutes or longer. The web-based software also allowed for self-monitoring of dietary intake. Intervention staff had access to this information during the scheduled telephone contacts.

Outcome Assessments

Measures occurred at 0, 6, 12, 18, and 24 months. Participants received $100 for completing each of the 4 postbaseline assessments. Assessment staff were masked to prior data at each assessment to minimize potential bias.

Weight was assessed to the nearest 0.1 kg with the participant clothed in a hospital gown or lightweight clothing. Height was measured only at baseline to the nearest 0.1 cm with shoes removed.

Body composition was assessed using dual-energy x-ray absorptiometry from a total body scan. Prior to this scan, women had a urine pregnancy test; a positive result excluded the participant from further study participation.

Cardiorespiratory fitness was assessed with a submaximal graded exercise test performed on a motorized treadmill.[8] Oxygen consumption was assessed using a metabolic cart.

Physical activity was assessed using a portable device worn for 1 week.[14,15] Data were considered valid if the participant wore the device for 10 or more hours per day for 4 or more days during the observation period.[16,17] Minute-by-minute data were used to identify minutes and metabolic equivalent (MET)–minutes per week of sedentary behavior (awake time, <1.5 METs), light-intensity physical activity (1.5 to <3.0 METs), and MVPA (≥3.0 METs). Percent sedentary time was calculated as sedentary time identified by the activity monitor divided by the monitor wear time.

Diet over the past month was assessed using the web-based version of the Diet History Questionnaire[18,19] and DietCalc software (version 1.5.0).

Percent weight loss was included as a post hoc outcome.

For safety, depressive symptoms were assessed using the 10-item Center for Epidemiology Studies questionnaire.[20] Participants with a score of 13 or greater were referred to their primary care physician and provided a list of community resources to assist in obtaining treatment. Resting blood pressure was assessed following a 5-minute seated resting period using an automated system; participants with systolic blood pressure of 140 mm Hg or greater or diastolic blood pressure of 90 mm Hg or greater were referred to their primary care physician. Participants were queried regarding the occurrence of overnight hospitalizations and conditions to assess for adverse and serious adverse events.

Sex, education, income, employment status, smoking status, alcohol consumption, and depressive symptoms[20] were assessed by self-report using questionnaires. Race and ethnicity, measures included in the early trials consortium, were assessed by self-report using questionnaires with fixed categories.

Statistical Methods

Sample Size

The mean weight loss from baseline to month 24 in the standard intervention group was projected to be approximately 3.4 kg at 24 months, with these estimates based on data from prior weight loss studies that included young adults.[21-23] We specified 2.3-kg or more mean weight loss for the enhanced intervention compared with the standard intervention, so that the mean weight loss in the enhanced intervention group was expected to be 5.7 kg at the end of month 24. This would allow participants in the enhanced intervention group to maintain a clinically meaningful weight loss of at least 5%.[3] Using a standard deviation of 6.8 kg for both groups, a 2-sided *t* test at 5% level of significance had 90% power to detect a mean difference of 2.3 kg (effect size, 0.33) between the enhanced intervention and standard intervention groups if 24-month data were available for at least 191 patients in each group. Based on an expected attrition rate of 20%, the recruitment goal was 238 participants per group.

Analysis Plan

Descriptive statistics were used to describe the participants in the 2 groups. Statistical significance of group differences in distributions was tested using Wilcoxon test for continuous variables and Pearson χ^2 test or exact tests for categorical variables, as appropriate.

It was expected that the likelihood of missingness could be predicted by the observed data, so missing data were assumed to be at random and a likelihood-based analysis was used. Thus, the primary hypothesis of participants in the enhanced intervention group achieving weight loss different from those in the standard intervention group was tested by fitting a linear mixed-effects model via maximum likelihood with weight over time as the outcome, including race, sex, time (assessment, treated as discrete, at baseline and at 6, 12, 18, and 24 months), intervention (enhanced intervention vs standard intervention), and intervention × time interaction as fixed effects and participants and recruitment periods as random effects. Weights measured during or after pregnancy were excluded from the analyses. Significance of the difference in distributions of weight was tested with a likelihood ratio test of the null hypothesis H_0: $\beta = 0$, with β as the coefficient of the intervention by 24-month visit interaction in the linear mixed-effects model.

For all of the models, if the intervention × time interaction was statistically significant ($P < .05$), the equality of mean changes in the 2 intervention groups at each intermediate time point was tested. The mean change at each time point, estimated using the least-square means, are presented by intervention along with the corresponding 95% confidence intervals. *P* values were adjusted by the Holm method for multiplicity when the differences were tested at multiple time points.[24] No adjustments for multiple comparisons were made for the primary outcome. *P* values for all other secondary outcome analyses were adjusted for multiplicity using the Holm method.

Multiple imputation was used for sensitivity analysis. Specifically, 10 Monte Carlo Markov Chain imputations based on the observed variables (intervention group, sex, race, ethnicity, education, income, employment status, waist circumference, smoking status, alcohol consumption, depression, and weight) at previous assessments were used to impute the missing weights for the sensitivity analysis. The estimates from the imputed data sets were averaged to see if they were similar to the likelihood-based estimates from the primary analysis. A similar approach was used for the secondary outcomes.

Fisher exact test conducted separately for each time interval was used for comparing adverse events and other alerts. All tests were 2-sided, and $P < .05$ was used as the cutoff for statistical significance. All analyses were conducted using SAS version 9.3 (SAS Institute Inc).

Results

This study randomized 471 participants (BMI, 25 to <40; age range, 18-35 years; 28.9% nonwhite; 77.2% women), with specific exclusion criteria by participant shown in the **Figure**. However, prior to the start of the intervention, 1 participant was discovered to be ineligible and was removed from the study. Thus, 470 participants received the intervention and are included in the analysis. Descriptive characteristics for the standard intervention and enhanced intervention groups are shown in **Table 1**. Weight data at 24 months was available for 74.5% of the sample (72.5% in the standard intervention group, 76.4% in the enhanced intervention group [Figure]). The 20 women in the standard intervention group and 9 in the enhanced intervention group who became pregnant after randomization discontinued participation in the study for safety. When these women are excluded, 79.3% of those in the standard intervention group and 79.4% in the enhanced intervention group had weight measured at 24 months.

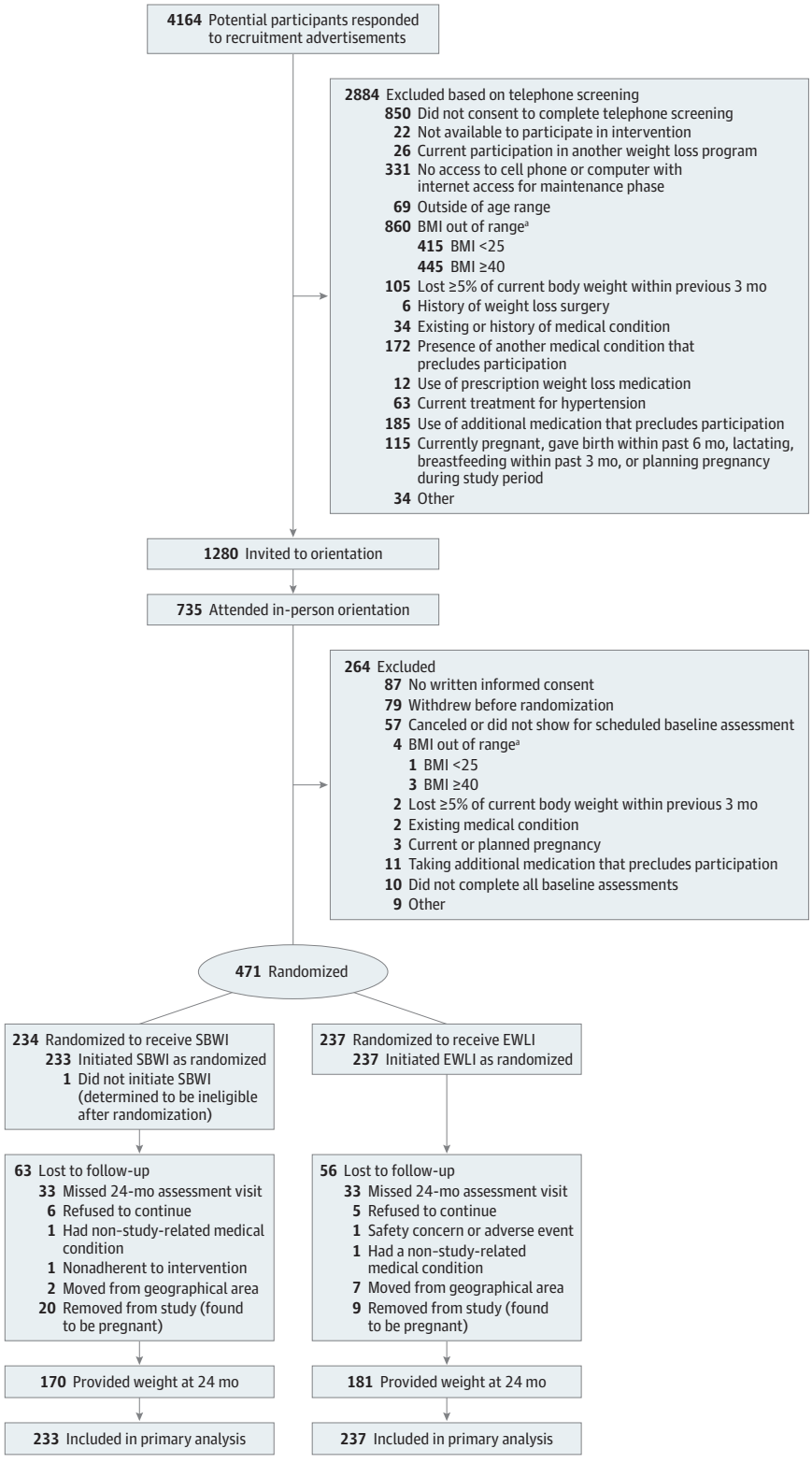
There was significant change in weight over time ($P < .001$ for time), and the change differed significantly between the enhanced intervention and standard intervention groups ($P = .003$ for group × time interaction), with less weight loss in the enhanced intervention group (**Table 2**). Estimated mean weights for the enhanced intervention group were 96.3 kg (95% CI, 94.2 to 98.5) at baseline and 92.8 kg (95% CI, 90.6 to 95.0) at 24 months, resulting in a mean weight loss of 3.5 kg (95% CI, 2.6 to 4.5). Corresponding values for the standard intervention group were 95.2 kg (95% CI, 93.0 to 97.3) at baseline and 89.3 kg (95% CI, 87.1 to 91.5) at 24 months, for a mean loss of 5.9 kg (95% CI, 5.0 to 6.8). At 24 months, weight loss was 2.4 kg (95% CI, 1.0 to 3.7) lower in the enhanced intervention group compared with the standard intervention group ($P = .002$). Results from the sensitivity analysis using multiple imputation were similar, with weight loss at 24 months of 3.3 kg (95% CI, 2.5 to 4.0) in the enhanced intervention group and 5.3 kg (95% CI, 4.5 to 6.2) in the standard intervention group.

In post hoc analysis, percent weight loss differed significantly between the standard intervention and enhanced intervention groups ($P < .001$) (Table 2). Although there was no significant difference between groups at 6 months (estimated means, 9.4% for standard intervention vs 8.4% for enhanced intervention; $P = .15$), percent weight loss was significantly greater in the standard intervention group compared with the enhanced intervention group at 12 months (estimated means, 8.9% vs 7.0%; $P = .01$), 18 months (estimated means, 7.9% vs 5.6%; $P = .002$), and 24 months (estimated means, 6.4% vs 3.6%; $P < .001$).

Participants in the standard intervention and enhanced intervention groups did not differ significantly for fat mass, lean mass, percent body fat, bone mineral content, bone mineral density, or cardiorespiratory fitness ($P \geq .05$ for all), although there were significant changes across time among all participants ($P < .01$ for all for time). (Table 2).

Differences between intervention groups for physical activity and dietary intake were not significant (**Table 3**). Regardless of the intervention conditions, there was a significant change in percent sedentary time, sedentary time, and light-intensity physical activity across time ($P < .001$ for all). Although total MVPA (minutes per week or MET-minutes per week) did not change significantly over time, MVPA performed in bouts of 10 minutes or longer significantly changed across the intervention ($P < .001$ for minutes per week and MET-minutes per week). Approximately 95% of participants providing weight data also provided valid physical activity data across the assessment periods (eTable 1 in Supplement 2).

Figure. Flow of Participants Through the IDEA Study



BMI indicates body mass index; EWLI, technology-enhanced weight loss intervention; IDEA, Innovative Approaches to Diet, Exercise, and Activity; SBWI, standard behavioral weight loss intervention.

[a] Calculated as weight in kilograms divided by height in meters squared.

Total calorie intake and the percent of energy intake consumed as dietary fat, carbohydrates, and protein changed significantly over time ($P < .001$ for all).

Of the 237 participants randomized to enhanced intervention, 191 participants received the wearable device that was a component of the intervention starting after month 6 and wore

Table 1. Baseline Characteristics of Participants by Intervention Condition

Characteristic	Total (n = 470)	SBWI (n = 233)	EWLI (n = 237)
Age, y			
Median (25th-75th percentile)	30.9 (27.8-33.7)	30.9 (28.0-33.9)	31.0 (27.4-33.3)
Range	18.4-35.9	18.4-35.9	19.3-35.9
Sex			
Men	136 (28.9)	67 (28.8)	69 (29.1)
Women	334 (71.1)	166 (71.2)	168 (70.9)
Race/ethnicity			
White	363 (77.2)	180 (77.3)	183 (77.2)
Nonwhite	107 (22.8)	53 (22.8)	54 (22.8)
Hispanic/Latino			
Yes	20 (4.3)	11 (4.7)	9 (3.8)
No	450 (95.7)	222 (95.3)	228 (96.2)
Weight, kg			
Median (25th-75th percentile)	90.0 (79.6-101.7)	88.5 (79.2-101.2)	90.6 (80.8-101.9)
Range	60.1-146.1	62.8-129.6	60.1-146.1
Body mass index[a]			
Median (25th-75th percentile)	31.2 (28.4-34.3)	30.9 (28.7-34.2)	31.5 (28.2-34.3)
Range[b]	24.4-39.9	35.0-39.8	24.4-39.9
Waist circumference, cm			
Iliac crest[c]			
Median (25th-75th percentile)	101.5 (93.5-109.9)	100.7 (92.6-110.3)	102.7 (94.3-109.6)
Range	76.4-134.8	76.7-134.8	76.4-132.7
Umbilicus[d]			
Median (25th-75th percentile)	104.8 (96.8-114.1)	104.3 (96.8-114.4)	105.7 (97.0-113.9)
Range	78.4-136.3	79.2-136.3	78.4-132.2
Education, No. (%)			
High school graduate or GED	117 (24.9)	57 (24.5)	60 (25.3)
College graduate or higher	323 (75.1)	176 (75.5)	177 (74.7)
Relationship status, No. (%)			
Married/like married[e]	233 (49.6)	118 (50.6)	115 (48.5)
Other	237 (50.4)	115 (49.4)	122 (51.5)
Student status, No. (%)			
Not student	349 (74.3)	169 (72.5)	180 (76.0)
Currently a student (part-time or full-time)	121 (25.7)	64 (27.5)	57 (24.1)
Employment status, No. (%)			
No.	468	232	236
Full-time for pay	359 (76.4)	174 (74.7)	185 (78.1)
Part-time for pay	65 (13.8)	34 (14.6)	31 (13.1)
Other	44 (9.4)	24 (10.3)	20 (8.4)
Household income in $, No. (%)			
No.	466	231	35
<25 000	58 (12.4)	27 (11.6)	31 (13.1)
≥25 000	408 (86.8)	204 (87.6)	204 (86.1)
Smoking status, No. (%)			
Current smoker	42 (8.9)	20 (8.6)	22 (9.3)
Depressive symptoms[f]			
Median (25th-75th percentile)	4.5 (2-7)	5 (2-7)	4 (2-7)
Range	0-22	0-19	0-22
Alcohol consumption			
Had ≥1 alcoholic beverage in last 30 d	418 (88.9)	207 (88.8)	211 (89.0)
Days with ≥1 drink, No.	418	207	211
Median (25th-75th percentile)	5 (3-8)	5 (3-8)	5 (3-8)
Range	1-29	1-28	1-29
Average No. of drinks	418	207	211
Median (25th-75th percentile)	2 (1-3)	2 (1-3)	2 (1-3)
Range	1-15	1-12	1-15
No. of times had 4 (women) or 5 (men) drinks	418	207	211
Median (25th-75th percentile)	1 (0-2)	1 (0-2)	1 (0-2)
Range	0-15	0-14	0-15

Abbreviations: EWLI, technology-enhanced weight loss intervention; GED, General Educational Development; SBWI, standard behavioral weight loss intervention.

[a] Calculated as weight in kilograms divided by height in meters squared.

[b] Eligibility based on screening with database on baseline assessment.

[c] Measured horizontally at the level of the iliac crest.

[d] Measured horizontally at the level of the umbilicus.

[e] Self-identified as currently married or in a marriage-like relationship.

[f] Based on Center for Epidemiologic Studies Depression questionnaire score.

Table 2. Change in Weight, Body Mass Index, Body Composition, and Cardiorespiratory Fitness by Intervention Condition

	Least-Squares Mean (95% CI)[a]					*P* Value[b]		
		Change From Baseline, mo						
	Baseline	6	12	18	24	Group	Time	Group × Time
Primary Outcome: Weight, kg						.07	<.001	.003
SBWI	95.2 (93.0 to 97.3)	−8.6 (−9.5 to −7.7)	−8.3 (−9.2 to −7.4)	−7.3 (−8.3 to −6.4)	−5.9 (−6.8 to −5.0)			
EWLI	96.3 (94.2 to 98.5)	−8.0 (−8.8 to −7.1)	−6.7 (−7.6 to −5.8)	−5.4 (−6.3 to −4.4)	−3.5 (−4.5 to −2.6)			
Difference		−0.7 (−1.9 to 0.6)	−1.6 (−2.8 to −0.3)	−2 (−3.3 to −0.6)	−2.4 (−3.7 to −1.0)			
P value[c]		.29	.03	.01	.002			
Weight Change From Baseline, %[d]						.01	<.001	<.001
SBWI		−9.4 (−10.2 to −8.5)	−8.9 (−9.8 to −8.0)	−7.9 (−8.9 to −7.0)	−6.4 (−7.4 to −5.5)			
EBWI		−8.4 (−9.3 to −7.6)	−7 (−7.9 to −6.1)	−5.6 (−6.5 to −4.6)	−3.6 (−4.5 to −2.7)			
Difference		−0.9 (−2.2 to 0.3)	−1.9 (−3.2 to −0.6)	−2.4 (−3.7 to −1)	−2.8 (−4.2 to −1.5)			
P value[c]		.15	.008	.002	<.001			
Body Mass Index[e]						.41	<.001	.63
SBWI	32.4 (31.5 to 33.3)	−2.9 (−3.7 to −2.2)	−2.8 (−3.5 to −2.0)	−2.5 (−3.3 to −1.7)	−1.8 (−2.6 to −1.0)			
EBWI	32.3 (31.4 to 33.2)	−2.7 (−3.4 to −1.9)	−2.1 (−2.9 to −1.4)	−1.9 (−2.7 to −1.1)	−1.1 (−1.9 to −0.3)			
Difference		−0.3 (−1.3 to 0.8)	−0.7 (−1.7 to 0.4)	−0.6 (−1.8 to 0.5)	−0.7 (−1.9 to 0.4)			
Fat Mass, kg						>.99	<.001	.52
SBWI	36.8 (35.4 to 38.3)	−7.0 (−7.8 to −6.3)	−7.0 (−7.7 to −6.2)	−6.0 (−6.8 to −5.2)	−5.1 (−6.0 to −4.3)			
EBWI	37.2 (35.7 to 38.7)	−6.5 (−7.2 to −5.8)	−5.7 (−6.5 to −4.9)	−4.8 (−5.6 to −4.0)	−3.4 (−4.3 to −2.6)			
Difference		−0.6 (−1.6 to 0.5)	−1.3 (−2.4 to −0.2)	−1.2 (−2.3 to −0.1)	−1.7 (−2.9 to −0.6)			
Lean Mass, kg						>.99	<.001	>.99
SBWI	54.9 (53.9 to 55.8)	−1.3 (−1.5 to −1.1)	−1.3 (−1.5 to −1.1)	−1.1 (−1.3 to −0.8)	−0.9 (−1.1 to −0.6)			
EBWI	55.6 (54.7 to 56.6)	−1.2 (−1.5 to −1.0)	−1.1 (−1.4 to −0.9)	−0.7 (−0.9 to −0.4)	−0.6 (−0.8 to −0.3)			
Difference		0 (−0.4 to 0.3)	−0.1 (−0.5 to 0.2)	−0.4 (−0.7 to 0)	−0.3 (−0.7 to 0)			
Body Fat, %						>.99	<.001	.52
SBWI	38.9 (38 to 39.8)	−4.7 (−5.2 to −4.2)	−4.6 (−5.2 to −4.1)	−4.0 (−4.5 to −3.5)	−3.5 (−4.0 to −3.0)			
EBWI	38.8 (37.8 to 39.7)	−4.1 (−4.6 to −3.6)	−3.7 (−4.2 to −3.2)	−3.2 (−3.7 to −2.7)	−2.4 (−3.0 to −1.9)			
Difference		−0.6 (−1.3 to 0.1)	−1.0 (−1.7 to −0.3)	−0.8 (−1.6 to −0.1)	−1.1 (−1.9 to −0.3)			
Tissue Body Fat, %[f]						>.99	<.001	.53
SBWI	40.2 (39.2 to 41.1)	−4.7 (−5.2 to −4.2)	−4.7 (−5.2 to −4.2)	−4.0 (−4.6 to −3.5)	−3.5 (−4.1 to −3.0)			
EBWI	40.0 (39.0 to 40.9)	−4.1 (−4.6 to −3.6)	−3.7 (−4.2 to −3.2)	−3.2 (−3.8 to −2.7)	−2.4 (−3.0 to −1.9)			
Difference		−0.6 (−1.3 to 0.1)	−1.0 (−1.7 to −0.3)	−0.8 (−1.6 to −0.1)	−1.1 (−1.9 to −0.3)			
Bone Mass, kg						>.99	<.001	>.99
SBWI	3008.5 (2957.5 to 3059.6)	−13.4 (−19.0 to −7.8)	−15.5 (−21.4 to −9.6)	−17.4 (−23.5 to −11.3)	−18.7 (−25.0 to −12.4)			
EBWI	3033.2 (2982.6 to 3083.8)	−10.0 (−15.6 to −4.4)	−8.7 (−14.6 to −2.8)	−8.0 (−14.2 to −1.9)	−9.2 (−15.6 to −2.9)			
Difference		−3.4 (−11.3 to 4.6)	−6.8 (−15.1 to 1.5)	−9.4 (−18 to −0.7)	−9.5 (−18.4 to −0.5)			
Total Body Bone Mineral Density, g/cm^2						>.99	<.001	.54
SBWI	1.3 (1.3 to 1.4)	−0.005 (−0.007 to −0.002)	−0.006 (−0.009 to −0.003)	−0.007 (−0.010 to −0.004)	−0.005 (−0.008 to −0.002)			
EBWI	1.3 (1.3 to 1.4)	−0.001 (−0.003 to 0.002)	−0.002 (−0.004 to 0.001)	−0.002 (−0.005 to 0.001)	0.002 (−0.002 to 0.005)			
Difference		−0.004 (−0.008 to −0.000)	−0.004 (−0.008 to −0.000)	−0.005 (−0.009 to −0.001)	−0.006 (−0.011 to −0.002)			

(continued)

Table 2. Change in Weight, Body Mass Index, Body Composition, and Cardiorespiratory Fitness by Intervention Condition (continued)

	Least-Squares Mean (95% CI)[a]							
		Change From Baseline, mo				*P* Value[b]		
	Baseline	6	12	18	24	Group	Time	Group × Time
Cardiorespiratory Fitness, mL/kg/min						>.99	<.001	>.99
SBWI	27.3 (26.4 to 28.1)	3.8 (3.2 to 4.4)	3.1 (2.4 to 3.7)	3.1 (2.4 to 3.7)	2.0 (1.3 to 2.6)			
EBWI	27.3 (26.5 to 28.2)	3.9 (3.3 to 4.5)	2.3 (1.6 to 2.9)	2.6 (1.9 to 3.3)	1.7 (1.0 to 2.4)			
Difference		−0.1 (−0.9 to 0.8)	0.8 (−0.1 to 1.7)	0.5 (−0.4 to 1.4)	0.2 (−0.7 to 1.2)			

Abbreviations: EWLI, technology-enhanced weight loss intervention; SBWI, standard behavioral weight loss intervention.

[a] Model includes group (fixed), recruitment period (random), time (categorical, fixed), race (fixed), sex (fixed), time × group interaction (fixed), time and recruitment period (random).

[b] Adjusted for multiple outcomes using the Holm approach, except for the definitive primary outcome of weight and the exploratory outcome percent change in body weight.

[c] *P* values for comparison at specific time points are adjusted for multiple testing across time points using the Holm method and only provided when there was a significant time × group interaction.

[d] Post hoc analysis of a nonprespecified primary or secondary outcome.

[e] Calculated as weight in kilograms divided by height in meters squared.

[f] Percent body fat excluding bone mass.

the device for 1 day or longer (median days worn, 170.0 [25th-75th percentile: 68.0-347]). On days that the device was worn, the median wear time was 241.1 min/d (25th-75th percentile: 99.3-579.1). User experience with this technology is reported in eTable 2 in Supplement 2.

There were no significant differences between groups in the number of safety alerts, nonserious adverse events, and serious adverse events (**Table 4**).

Discussion

In this study, the addition of wearable technology to a behavioral intervention was less effective for 24-month weight loss. This may be a result of the technology not being as effective for changing diet or physical activity behaviors compared with what was achieved with the standard intervention; however, the study found no significant difference in these measures between the standard intervention and enhanced intervention groups. Thus, the reason for this difference in weight loss between the standard intervention and enhanced intervention groups warrants further investigation.

The few studies that have shown promise for adding wearable technology at the onset of a weight loss intervention have been short in duration and have included relatively small samples of participants.[5,6] However, in one 9-month intervention, combining a group-based weight loss intervention with wearable technology improved weight loss compared with the group-based treatment alone.[25] Furthermore, the group-based treatment resulted in a mean weight loss of approximately 2 kg, whereas our standard intervention resulted in mean weight loss of approximately 8 kg at both 6 and 12 months. Thus, questions remain regarding the effectiveness of wearable technologies over and above a standard intervention and how to best use them to modify physical activity and diet behaviors in adults seeking weight loss.

Although this study showed weight loss across the 24-month intervention in young adults, similar to trials of middle-aged and older-aged adults,[22,23,26,27] the benefits achieved at 6 months were not fully sustained long term. Thus, regardless of age, challenges remain to preventing or minimizing weight regain following initial weight loss in adults. These findings are important because of the lack of data to support the effectiveness of approaches for weight loss in young adults, who have a high prevalence of overweight and obesity.[1] The interventions used in this study resulted in substantially greater weight loss than what was recently reported for young adults in response to a 24-month low-intensity, technology-based intervention.[28] Given that there was not a no-treatment control condition in this study, the degree to which the observed change in weight is a direct result of the intervention vs other factors cannot be determined. However, the importance of examining effective weight loss strategies for young adults is supported by a recent report showing that this age demographic has a prevalence of obesity (32.3%) higher than the prevalence in youth 12 to 19 years of age (20.5%) but lower than that found in middle-aged adults (40.2%).[29] This may suggest that young adulthood is an important transition period for weight gain and the development of obesity.[29]

There were limitations to this study. The study sample was restricted to young adults, so results cannot be generalized to other ages. The multisensor wearable device was worn on the upper arm, which may not reflect the effectiveness of more contemporary devices worn on the wrist. However, the accuracy of wrist-worn devices to monitor physical activity and energy expenditure compared with the arm-worn device has been questioned,[30] which may also limit their effectiveness, and this may not be consequential. Moreover, the use of wearable technology was not initiated at the onset of the intervention, which may have influenced how the participants adopted and used the technology during their weight loss efforts. The device used was also commercially available, and therefore the investigators did not have control over any additional information that may have been provided through the website available for use with

Table 3. Change in Physical Activity and Diet by Intervention Condition[a,b]

	Least-Squares Mean (95% CI)[c]					*P* Value[d]		
		Change From Baseline, mo						
	Baseline	6	12	18	24	Group	Time	Group × Time
Sedentary (% of monitor wear time[e])						>.99	<.001	>.99
SBWI	64.2 (61.9 to 66.5)	−3.8 (−5.8 to −1.8)	−0.3 (−2.4 to 1.8)	−3.4 (−5.6 to −1.2)	−2.0 (−4.3 to 0.3)			
EBWI	64.2 (62 to 66.5)	−0.4 (−2.4 to 1.6)	2.9 (0.8 to 5.0)	−0.9 (−3.1 to 1.4)	−0.5 (−2.8 to 1.8)			
Difference		−3.4 (−6.3 to −0.5)	−3.2 (−6.2 to −0.3)	−2.5 (−5.7 to 0.6)	−1.5 (−4.8 to 1.7)			
Sedentary, h/d						>.99	<.001	>.99
SBWI	8.9 (8.6 to 9.2)	−0.5 (−0.8 to −0.2)	−0.1 (−0.4 to 0.2)	−0.5 (−0.9 to −0.2)	−0.3 (−0.7 to 0.0)			
EBWI	8.9 (8.6 to 9.2)	−0.1 (−0.4 to 0.2)	0.3 (0.0 to 0.6)	−0.2 (−0.5 to 0.2)	0.0 (−0.4 to 0.3)			
Difference		−0.4 (−0.8 to 0.0)	−0.4 (−0.9 to 0.0)	−0.4 (−0.8 to 0.1)	−0.3 (−0.8 to 0.2)			
LPA, min/wk						>.99	<.001	>.99
SBWI	1587.4 (1488.4 to 1686.4)	179.6 (83.9 to 275.3)	14.3 (−84.6 to 113.2)	177.3 (72.7 to 281.9)	82.4 (−25.8 to 190.6)			
EBWI	1566.7 (1467.7 to 1665.6)	60.8 (−34.9 to 156.6)	−76.7 (−175.9 to 22.4)	97.0 (−9.2 to 203.2)	49.5 (−58.3 to 157.4)			
Difference		118.8 (−16.6 to 254.2)	91.0 (−49.0 to 231.1)	80.3 (−68.7 to 229.4)	32.8 (−120.0 to 185.6)			
Total MVPA, min/wk						>.99	.10	.89
SBWI	520.5 (461.2 to 579.7)	68.4 (16.4 to 120.5)	8.8 (−45.0 to 62.5)	31.6 (−25.3 to 88.5)	35.5 (−23.3 to 94.3)			
EBWI	527.6 (468.4 to 586.8)	−30.2 (−82.2 to 21.9)	−78.4 (−132.4 to −24.5)	−24.1 (−81.9 to 33.6)	5.5 (−53.2 to 64.1)			
Difference		98.6 (25.0 to 172.2)	87.2 (11.0 to 163.3)	55.7 (−25.3 to 136.8)	30.0 (−53.1 to 113.1)			
Total MVPA, MET-min/wk						>.99	.10	>.99
SBWI	1959.9 (1728.1 to 2191.6)	221.3 (15.1 to 427.5)	13.4 (−199.7 to 226.4)	106.3 (−119.0 to 331.5)	124.0 (−109.1 to 357.1)			
EBWI	1974.4 (1742.9 to 2206.0)	−133.0 (−339.3 to 73.3)	−306.3 (−520.0 to −92.7)	−100.8 (−329.6 to 128.0)	14.5 (−217.9 to 247.0)			
Difference		354.3 (62.7 to 645.9)	319.7 (18.0 to 621.4)	207.1 (−114.0 to 528.2)	109.5 (−219.7 to 438.6)			
≥10 Minute Sessions of MVPA, min/wk						>.99	<.001	>.99
SBWI	158.9 (117.8 to 199.9)	189.1 (149.9 to 228.4)	126.3 (85.8 to 166.8)	147.1 (104.3 to 189.9)	134.3 (90.0 to 178.6)			
EBWI	174.6 (133.6 to 215.5)	113.1 (73.9 to 152.4)	66.5 (25.9 to 107.1)	105.8 (62.4 to 149.3)	107.6 (63.4 to 151.8)			
Difference		76.0 (20.5 to 131.5)	59.8 (2.5 to 117.2)	41.2 (−19.8 to 102.3)	26.7 (−35.9 to 89.2)			
≥10 Minute Sessions of MVPA, MET-min/wk						>.99	<.001	>.99
SBWI	724.4 (537.5 to 911.4)	790.7 (612.8 to 968.6)	547.3 (363.5 to 731.1)	629.7 (435.4 to 824.0)	572.8 (371.8 to 773.8)			
EBWI	778.6 (591.7 to 965.4)	494.0 (316.0 to 671.9)	280.0 (95.7 to 464.2)	448.5 (251.1 to 645.8)	460.9 (260.4 to 661.3)			
Difference		296.7 (45.1 to 548.3)	267.4 (7.1 to 527.6)	181.2 (−95.7 to 458.1)	111.9 (−171.9 to 395.8)			
Total Calories, kcal/d						>.99	<.001	>.99
SBWI	1987.1 (1872.6 to 2101.6)	−450.6 (−551.8 to −349.4)	−444.9 (−549.3 to −340.5)	−330.6 (−439.6 to −221.5)	−374.4 (−487.8 to −260.9)			
EBWI	2006.3 (1892.8 to 2119.7)	−542.4 (−641.9 to −443.0)	−484.6 (−589.0 to −380.2)	−500.0 (−608.8 to −391.1)	−543.7 (−656.7 to −430.7)			
Difference		91.9 (−50.0 to 233.7)	39.7 (−107.9 to 187.4)	169.4 (15.4 to 323.5)	169.3 (9.2 to 329.4)			
% Calories Carbohydrates						>.99	<.001	>.99
SBWI	47.8 (46.6 to 49.1)	2.8 (1.6 to 3.9)	2.5 (1.3 to 3.6)	0.9 (−0.3 to 2.1)	0.2 (−1.1 to 1.5)			
EBWI	47.9 (46.7 to 49.1)	2.5 (1.4 to 3.6)	1.7 (0.5 to 2.9)	0.4 (−0.9 to 1.6)	−0.4 (−1.7 to 0.8)			
Difference		0.3 (−1.3 to 1.9)	0.8 (−0.9 to 2.4)	0.5 (−1.2 to 2.3)	0.7 (−1.2 to 2.5)			
% Calories Protein						>.99	<.001	>.99
SBWI	15.5 (15.0 to 16.0)	0.7 (0.2 to 1.2)	0.4 (−0.1 to 0.9)	0.3 (−0.2 to 0.9)	0.5 (0.0 to 1)			
EBWI	15.5 (15.0 to 16.0)	0.8 (0.4 to 1.3)	0.5 (0 to 1.0)	0.6 (0.1 to 1.1)	0.9 (0.4 to 1.5)			
Difference		−0.1 (−0.8 to 0.6)	0.0 (−0.7 to 0.7)	−0.3 (−1.0 to 0.5)	−0.4 (−1.2 to 0.3)			

(continued)

Table 3. Change in Physical Activity and Diet by Intervention Condition[a,b] (continued)

	Least-Squares Mean (95% CI)[c]							
		Change From Baseline, mo				*P* Value[d]		
	Baseline	6	12	18	24	Group	Time	Group × Time
% Calories Fat						>.99	<.001	>.99
SBWI	35.7 (34.6 to 36.8)	−3.7 (−4.7 to −2.7)	−2.7 (−3.7 to −1.7)	−1.6 (−2.6 to −0.6)	−0.2 (−1.3 to 0.9)			
EBWI	35.3 (34.2 to 36.4)	−3.1 (−4 to −2.1)	−1.6 (−2.6 to −0.6)	−0.8 (−1.8 to 0.2)	−0.4 (−1.4 to 0.7)			
Difference		−0.6 (−2 to 0.7)	−1.1 (−2.5 to 0.3)	−0.8 (−2.3 to 0.6)	0.2 (−1.4 to 1.7)			

Abbreviations: EWLI, technology-enhanced weight loss intervention; LPA, light-intensity physical activity (1.5 to <3.0 metabolic equivalents); MET, metabolic equivalent; MVPA, moderate-to-vigorous physical activity (≥3.0 METs); SBWI, standard behavioral weight loss intervention.

[a] Physical activity based on data from objective assessment of physical activity for a 1-week period.

[b] Diet based on data from the Diet History Questionnaire.

[c] Model includes group (fixed), recruitment period (random), time (categorical, fixed), race (fixed), sex (fixed), time × group interaction (fixed), time and recruitment period (random).

[d] Adjusted for multiple outcomes using the Holm approach.

[e] Monitor wear time defined as the time that the device was worn per day.

Table 4. Safety Alerts, Nonserious Adverse Events, and Serious Adverse Events by Intervention Condition (N = 470)

	Assessment, No.[a]				
	From Signing Informed Consent Through Baseline	Following Baseline and Through 6 Months	Following 6 Months, Through 12 Months	Following 12 Months, Through 18 Months	Following 18 Months, Through 24 Months
Resting Blood Pressure Alert[b]					
SBWI	4	3	2	2	0
EBWI	5	3	3	4	3
Depression Alert (CES-D Score ≥13)[c]					
SBWI	11	8	4	3	4
EBWI	7	10	7	7	8
Rapid Weight Loss Alert[d]					
SBWI	NA	22	2	0	1
EBWI	NA	18	0	0	0
Nonserious Adverse Events					
SBWI	10	36	38	20	27
EBWI	5	47	34	32	34
Serious Adverse Events[e]					
SBWI	0	1	2	2	1
EBWI	0	1	3	5	2

Abbreviations: CES-D, Center for Epidemiologic Studies Depression questionnaire; EWLI, technology-enhanced weight loss intervention; NA, not applicable; SBWI, standard behavioral weight loss intervention.

[a] Data presented as number of participants.

[b] Resting systolic blood pressure 140 mm Hg or greater or resting diastolic blood pressure 90 mm Hg or greater.

[c] Score of 13 or greater on the CES-D questionnaire.

[d] Greater than 6% weight loss during a 4-week period of the intervention, with the alert based on weight assessed during an intervention visit.

[e] All serious adverse events were a result of an overnight hospitalization or surgery.

this device. Dietary intake was assessed using self-report, which may have affected the accuracy of this measure and therefore influenced the understanding of how the intervention influenced this aspect of energy balance. Additional investigation is also needed to examine for whom wearable devices and other technologies may be effective within the context of weight loss efforts and how these technologies influence other components of weight loss, namely, eating behavior and dietary intake.

Approximately 75% of the participants provided outcome data at the 24-month assessment. Of the 120 participants missing 24-month weight, approximately one-third (n = 38) had missing weight due to either being excluded for pregnancy (n = 29) or moving out of the area (n = 9), which are unlikely to bias the results. Linear mixed models used all available data from participants with missing data (ie, from earlier time points) to gain efficiency. Although multiple imputation was used to account for missing data in a sensitivity analysis, the loss of outcome data most likely resulted in reduced precision for the parameter estimates. Moreover, it is possible that the results could be biased in the event that the data lost to follow-up were not missing at random. Assessment staff were also aware that individuals were engaged in a weight loss trial, which may have introduced additional bias.

Conclusions

Among young adults with a BMI between 25 and less than 40, the addition of a wearable technology device to a standard behavioral intervention resulted in less weight loss over 24 months. Devices that monitor and provide feedback on physical activity may not offer an advantage over standard behavioral weight loss approaches.

ARTICLE INFORMATION

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Author Contributions: Dr Jakicic had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
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