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Using social and mobile tools for weight loss in overweight and obese young adults (Project SMART): a 2 year, parallel-group, randomised, controlled trial



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Summary

Background Few weight loss interventions are evaluated for longer than a year, and even fewer employ social and mobile technologies commonly used among young adults. We assessed the efficacy of a 2 year, theory-based, weight loss intervention that was remotely and adaptively delivered via integrated user experiences with Facebook, mobile apps, text messaging, emails, a website, and technology-mediated communication with a health coach (the SMART intervention).

Methods In this parallel-group, randomised, controlled trial, we enrolled overweight or obese college students (aged 18–35 years) from three universities in San Diego, CA, USA. Participants were randomly assigned (1:1) to receive either the intervention (SMART intervention group) or general information about health and wellness (control group). We used computer-based permuted-block randomisation with block sizes of four, stratified by sex, ethnicity, and college. Participants, study staff, and investigators were masked until the intervention was assigned. The primary outcome was objectively measured weight in kg at 24 months. Differences between groups were evaluated using linear mixed-effects regression within an intention-to-treat framework. Objectively measured weight at 6, 12, and 18 months was included as a secondary outcome. The trial is registered with ClinicalTrials.gov, number NCT01200459.

Findings Between May 18, 2011, and May 17, 2012, 404 individuals were randomly assigned to the intervention (n=202) or control (n=202). Participants' mean (SD) age was 22.7 (3.8) years. 284 (70%) participants were female and 125 (31%) were Hispanic. Mean (SD) body-mass index at baseline was 29.0 (2.8) kg/m². At 24 months, weight was assessed in 341 (84%) participants, but all 404 were included in analyses. Weight, adjusted for sex, ethnicity, and college, was not significantly different between the groups at 24 months (−0.79 kg [95% CI −2.02 to 0.43], p=0.204). However, weight was significantly less in the intervention group compared with the control group at 6 months (−1.33 kg [95% CI −2.36 to −0.30], p=0.011) and 12 months (−1.33 kg [−2.30 to −0.35], p=0.008), but not 18 months (−0.67 kg [95% CI −1.69 to 0.35], p=0.200). One serious adverse event in the intervention group (gallstones) could be attributable to rapid and excessive weight loss.

Interpretation Social and mobile technologies did not facilitate sustained reductions in weight among young adults, although these approaches might facilitate limited short-term weight loss.

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Introduction

Overweight and obesity are major public health concerns in the USA.¹ Recent data from the Centers for Disease Control and Prevention indicate that the extent of this problem is great even among young adults, as about 60.3% of those aged 20–39 years are overweight or obese (defined as a body-mass index [BMI] ≥25 kg/m²).² Evidence shows that excess weight gain occurs most rapidly in young adults³ and is associated with future weight gain,⁴ cardiovascular risk factors such as hypertension, dyslipidaemia, and diabetes,⁵ and psychological distress.⁶ Therefore, it has been suggested that treating overweight and obesity in young adults might reduce or even prevent the onset of chronic disease risk factors in middle-age.⁷

The college years are a period of time when students undergoing the transition from adolescence to young adulthood often adopt unhealthy weight-related

behaviours such as decreased physical activity, increased sedentary behaviour, and poor sleep and diet quality.⁸ Consequently, students typically gain a clinically significant amount of weight, and there is a crucial need for behavioural weight loss interventions that target this population.⁹ One potential strategy is to deploy interventions designed to promote weight loss through healthy changes in physical activity and diet via social and mobile technologies that are pervasive among young adults.^{10,11} Instead of relying on regular in-person interactions as weight loss interventions have traditionally done,¹² technology-based interventions can use modalities such as text messaging, mobile apps, and Facebook to interact with students in the virtual spaces they frequently inhabit.^{10,11,13}

A recent systematic review of technology-based behavioural weight loss studies showed that most studies

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Research in context

Evidence before this study

From Sept 1, 2015, to Jan 31, 2016, we searched MEDLINE, PubMed, and Google Scholar since the inception of these databases for any relevant studies of technology-based interventions to promote weight loss in overweight and obese adults. We searched for terms "overweight", "obesity", "systematic review", "eHealth", "mHealth", "social network", and "social media". Two reviews on the effectiveness of technology-based interventions to promote weight loss among overweight and obese adults were published in May, 2015. Therefore, we did not do a new systematic review. Evidence suggests that most interventions have focused on middle-aged and older adults, most interventions were implemented for less than 1 year, and most interventions used just one or two modalities. Furthermore, few studies have tested how online social networks can be used in technology-based interventions and none appears to have leveraged participants' existing online social networks (using social media). The reviews and individual studies also suggest that eHealth modalities are effective in the treatment of overweight and obesity but that weight loss is modest. Interventions that deploy evidence-based behavioural features are associated with greater weight loss.

Added value of this study

Our study adds substantial value to the existing research in that it targeted young adults in a 2 year trial, and tested the delivery of theory-based and evidence-based content across multiple modalities used by the young adult population, including social media. Although we found no significant differences in weight between the treatment and control groups at 2 years we did observe significant differences between groups at 6 months and 12 months.

Implications of all the available evidence

Technology-based weight loss interventions should continue to target overweight and obese young adults given that this population is at risk for long-term weight gain and associated chronic health conditions, and technology-based interventions can meet young adults in virtual spaces they frequently inhabit. Our study is in line with existing evidence that suggests technology-based weight loss interventions are most effective in the first 6 months, and future studies should test which modalities can help young adults sustain weight loss for longer periods of time (>1 year). Future research should also consider how technology-enabled connectivity (eg, online social networks on social media platforms) and commercial app use affect internal validity (ie, contamination).

(76 of 84) exclusively include middle-aged and older adults.¹⁴ Furthermore, although the use of several modalities would allow for greater individual tailoring and exposure to intervention components, 60·4% of interventions used only one type of technology, 33·8% used two, 5·0% three, and only one used five types of technology.¹⁴ Moreover, very few interventions were implemented for longer than 18 months (13·9%). Overall, these interventions resulted in moderate weight loss (between -1·4 kg and -2·7 kg).¹⁴ Thus, there is a need for studies of long-term, multimodal, technology-based weight loss interventions that have the potential for widespread dissemination among young adults.

In the Social Mobile Approaches to Reduce weightT (SMART) study, we assessed the efficacy of a 2 year social and mobile intervention designed to reduce weight by improving weight-related behaviours among college students. To maximise the potential for clinically meaningful weight loss (about 5% of bodyweight), intervention content was grounded in health behaviour theory and used several evidence-based behavioural change techniques.¹⁵⁻¹⁷ Additionally, whereas previous studies have used Facebook to encourage interactions among participants,¹⁸ this was the first to promote social support, accountability, and the formation of healthy social norms about weight-related behaviours via uncontrived interactions with existing social networks. This approach might complement interactions in offline settings and multiply effects through social networks.¹⁹ We hypothesised that compared with providing general

information about health and wellness, the SMART intervention would lead to clinically meaningful weight loss at 24 months. Also, we hypothesised that these changes would be associated with improved body composition and physiological indicators of disease risk.

Methods

Study design and participants

The SMART study was a parallel-group randomised controlled trial done in San Diego, CA, USA. The study methods have been described elsewhere,²⁰ and a detailed research protocol is included in the appendix. This was one of seven trials funded by the National Heart, Lung, and Blood Institute of the National Institutes of Health to evaluate the efficacy of technology-based interventions for weight control in young adults.⁷

Students were recruited at the three college campuses via a combination of print (eg, newspapers, flyers, posters, and magnets) and digital (eg, emails, electronic bulletins, websites, and Facebook) advertisements. Additionally, in-person recruitment was done at student orientations and health fairs and was coordinated with real-time monitoring of online interest form submissions. All recruitment channels directed students to the study website where they could view detailed information and complete an eligibility survey.

Eligible students were adults aged 18-35 years. They had a BMI of between 25·0 kg/m² and 34·9 kg/m², used Facebook or were willing to begin, owned a personal computer, owned a smartphone, used text messaging,

See Online for appendix

and were willing to attend measurement visits in San Diego over 2 years. Exclusion criteria included having a clinically diagnosed eating disorder, orthopaedic disorder, sleep apnoea, pseudotumour cerebri, diabetes, or a psychiatric or medical condition that prohibited compliance with the study protocol. Students were also excluded if they had been recently prescribed dietary or physical activity changes, were enrolled in or expecting to enrol in a weight loss programme within 2 years, were taking medications that alter weight, or were pregnant or expecting to become pregnant within 2 years. Study staff reassessed the inclusion and exclusion criteria in person before the start of the baseline measurement visit, and all eligible participants provided written informed consent.

The study procedures were approved by the University of California, San Diego Institutional Review Board (approval number 091040) in cooperation with the institutional review boards of San Diego State University and California State University, San Marcos.

Randomisation and masking

After completing the baseline measurement visit, a statistician (GJN) allocated participants (1:1) to the intervention or control group using computer-based permuted-block randomisation with block sizes of four that were stratified by sex, ethnicity, and college. Allocation was concealed from the participants, study staff, and investigators until the intervention was assigned. It was not possible to mask participants or the study staff that delivered the intervention. However, study staff who measured participants and investigators who analysed study outcomes remained masked to the allocation throughout the study. Participants received an incentive of US\$40 at baseline and \$50 at 6 months.

Procedures

The SMART intervention was theoretically informed by Michie and colleagues¹⁷ taxonomy of 26 behaviour change techniques. The taxonomy identifies commonly used intervention techniques that are linked to various behaviour change theories, such as social cognitive theory,²¹ control theory,²² and operant conditioning.²³ Meta-analysis of intervention studies that targeted healthy changes in physical activity and diet revealed that the five most effective techniques were self-regulatory and included intention formation, goal setting, self-monitoring, feedback, and goal review.¹⁷ Thus, these self-regulatory techniques were embedded throughout the components of the SMART intervention. They were enhanced by the inclusion of techniques to increase self-efficacy for, understand the benefits of, and remove barriers to, healthy changes in physical activity and diet.¹⁷ Additional theoretical framing came from ecological theory²⁴ and social network theory,²⁵ as intervention content was tailored to participants' physical and social environment.

The SMART intervention was remotely delivered via six modalities: Facebook, three study-designed mobile apps,

text messaging, emails, a website with blog posts, and technology-mediated communication with a health coach (up to ten brief [5–15 min] interactions). Intervention participants were instructed to use at least one or more modalities a minimum of five times per week throughout the 24 months of the intervention. The integration of user experiences across modalities and over time was intended to promote adoption and maintenance of healthy changes in physical activity and diet through convenient, dynamic, and sustained exposure to behaviour change techniques. The intervention was adaptively delivered in that new components were developed and released throughout the study in response to patterns of use and participant feedback. This approach provided participants with a high level of individual choice and allowed for changes in technological preference.

More specifically, intervention participants were able to privately or publicly set individually tailored physical activity and diet goals and then choose how (ie, via their preferred modality) and when to track these behaviours, receive feedback, and participate in goal review. Real-time location-based prompts were sent via text message to reinforce self-regulatory techniques. The health coach initiated challenges and campaigns that were often culturally themed and promoted changes to weight-related behaviours (eg, avoid overeating during Thanksgiving celebrations). Participants were then encouraged to make a pledge to participate and set appropriate goals. They were asked to share these with their existing social networks to promote social support, accountability, and the formation of healthy social norms about weight-related behaviours (additional information about the intervention is shown in table 1).

Engagement with the SMART intervention was defined as the sum of a participant's recorded interactions on the study Facebook page (ie, a post, comment, or like) and mobile apps (eg, entry of the number of steps taken per day), text messages sent and replied to, and communication with the health coach between each study measurement.

Participants allocated to the control group were given access to a different website than intervention participants and were sent quarterly newsletters via email. Both the website and emails contained information on health topics relevant to young adults (eg, smoking cessation, sun protection, stress management, sexual health, alcohol, and drug use). The website also included general weight loss information that was comparable to what would have been received from primary care providers, but it did not include specific behavioural recommendations. Control participants were instructed to interact with the website on at least a weekly basis.

Demographic information on age, sex, ethnicity (Hispanic, non-Hispanic), and race were self-reported through a survey collected at baseline. Study staff took standardised anthropometric blood pressure, and heart

	Description	Example of engagement
Facebook	Used the social networking features of Facebook to connect participants and allow for social support, accountability, and healthy social norms from existing social networks. Delivered 17 challenges and campaigns that were often culturally themed and promoted changes to weight-related behaviours on at least a monthly basis	Health coach challenged participants to not eat candy for 2 weeks before Halloween. Participants publicly accepted the challenge by posting on Facebook for their friends to see. Participants posted methods used to meet the goal. Health coach provided feedback on methods, encouraged self-monitoring, and prompted goal review. Health coach and each participant's social network provided social support and accountability through posts, comments, or likes until campaign has ended
GoalGetter app	Used to set weight-related goals and review progress ad hoc. Information could be shared with others	A participant set the goal to run three times per week before school. The health coach and social network provided social support and accountability through posts, comments, or likes
BeHealthy app	Used to deliver two weight-related challenges per day. Information could be shared with others	A participant accepted the challenge to "Run stairs for a workout!" and posted about it on Facebook
TrendSetter app	Used to self-monitor weight, physical activity, and diet daily. Graphs of trends over time could be viewed and shared with others	A participant recorded the number of daily calories consumed and posted about it on Facebook
Text messaging	Used to deliver reminders, facts, and feedback on self-monitored weight, physical activity, and diet on at least a weekly basis. Participants could set message frequency and timing	Participants were sent a message asking if they were at home or school. If a participant replied affirmatively, the subsequent message was, "You can do strength training at home! Do some squats, lunges, crunches, push-ups, and back extensions tonight!"
Emails	Used to summarise use of the apps, promote reading of blog posts on the website, and provide reminders of ongoing challenges and campaigns on a weekly basis	Participants were sent an email that summarises their weight-loss trend over the past 2 months, notified them that there was an article on the website about the health benefits of eating fruits and vegetables, and asked them to join the "Gobbles Campaign" aimed at avoiding over eating during Thanksgiving celebrations
Website	Used to host knowledge-based blog posts on weight, physical activity, diet, and participant success stories. Also contained "Frequently Asked Questions" with information on how to contact the health coach for support. Participants asked to visit website weekly	Participants read blog post on meeting physical activity recommendations
Health coach	Participants could speak with the health coach up to ten times as needed via instant messenger, telephone call, or video call for no longer than 15 min. The health coach contacted participants directly if they gained 5 pounds (2.27 kg) or more since their baseline measurement or stopped using apps for more than month	Participants who gained 7 pounds (3.18 kg) since baseline spoke with the health coach on the telephone about ways to improve diet

*Five self-regulatory techniques (intention formation, goal setting, self-monitoring, feedback, and goal review) were embedded throughout the modalities of the SMART intervention; they were enhanced by the inclusion of techniques to increase self-efficacy for, understand the benefits of, and remove barriers to, healthy changes in physical activity and diet; intervention content was also tailored to participants' physical and social environment when possible.

Table 1: Intervention content of Project SMART*

rate measurements in person at baseline and every 6 months thereafter, for a total of five measurements. Weight was measured objectively (to the nearest 0.1 kg) using a calibrated digital scale (Seca 703, Seca GmbH & Co KG, Hamburg, Germany). Height was measured objectively (to the nearest 0.1 cm) using a stadiometer (Seca 703, Seca GmbH & Co KG, Hamburg, Germany). Both weight and height were measured with participants wearing lightweight clothes but without shoes, and two separate measurements were averaged. BMI was calculated as weight in kg divided by height in m². Waist circumference was measured from the narrowest area between the base of the ribs and the top of the iliac crest, and arm circumference was measured at the midpoint between the acromion process and the olecranon process. Both waist circumference and arm circumference were measured to the nearest 0.1 cm and two separate measurements were averaged. Blood pressure and heart rate measurements were taken with a calibrated digital monitor (Critikon Dinamap 8100, GE Healthcare, Chalfont, UK). After 5 min of rest, two consecutive measurements were taken at 1 min intervals from the right arm while the participant was seated with their forearm supported on a table. Two measures of blood pressure and corresponding measures of heart rate were averaged.

Outcomes

The primary outcome was the effect of the SMART intervention on objectively measured weight in kg at 24 months. Secondary outcomes reported here are the between-group differences in objectively measured weight in kg at 6, 12, and 18 months, BMI (kg/m²), waist circumference (cm), arm circumference (cm), systolic blood pressure (mm Hg), diastolic blood pressure (mm Hg), heart rate (beats per min), and the level of engagement (ie, amount of use) of the intervention components. The effect of the SMART intervention on the probability of losing 5% of bodyweight and the probability of losing 10% of bodyweight were assessed as a post-hoc exploratory outcome, and the effect of the level of engagement on the primary and secondary outcomes was assessed as a prespecified exploratory outcome. Additional secondary outcomes were measured through self-report. They include physical activity measured with the Paffenbarger Physical Activity Questionnaire and the Global Physical Activity Questionnaire II; sedentary behaviours; total dietary intake measured with the Diet History Questionnaire II and the Automated Self-Administered 24-hour Dietary Recall System; eating behaviours related to weight management; sugar-sweetened beverage consumption; eating away from home; quality of life with the Quality

of Well-Being Scale; depression with the Center for Epidemiologic Studies Depression Scale and the Patient Health Questionnaire for Depression and Anxiety; self-esteem with the Rosenberg Self-Esteem Scale; body image with the Eating Disorder Inventory; psychosocial constructs related to physical activity and diet; and social support and social network composition with Facebook data. The intervention effects on these outcomes will be reported elsewhere.

Statistical analysis

All statistical analyses were done using R version 3.2.0 (The R Foundation, Vienna, Austria) and two-tailed *p* values with the predefined cutoff for statistical significance set at 0.05.

An a-priori power calculation was used to determine the sample size required to detect a difference in the primary outcome, weight in kg at 24 months, between the SMART intervention and control group using a *t* test with 0.80 statistical power. Based on our previous research, we determined that a 3.0 kg (about 3.75% weight loss for an 80 kg individual) would be a minimal clinically meaningful between-group difference in weight.²⁶ Furthermore, given our previous study's SD in baseline weight of 13.5 kg combined with an expected within-person correlation of 0.80 between baseline and 24 month weights, we estimated that the average SD of change in weight would be 8.5 kg.²⁶ This resulted in an effect size estimate of 0.35, which required 127 participants per group. To account for a maximum attrition of 30% between baseline and 24 months and the potential clustering of intervention participants over time due to interactions on Facebook (an estimated design effect of 1.09), we planned to allocate about 200 participants to each group for a total sample size of 400 participants. Descriptive statistics (proportions, means, and SD) described key demographic characteristics. Differences between groups were assessed with linear mixed-effects regression models for continuous outcomes and generalised estimating equations for binary outcomes. All models were adjusted for sex, ethnicity, and college (the factors used in the stratified randomisation), and were specified with a between-subject factor of treatment group, a within-subject factor of time treated categorically, and a treatment group by time interaction. Statistical significance of the treatment group by time interaction effect indicated differential between-group change in the outcome, and estimated marginal means or probabilities and corresponding 95% CIs of outcomes were computed at each timepoint. The primary analysis was a test of a treatment group by time interaction effect on weight in kg at 24 months. All other analyses were considered secondary or exploratory. All analyses were done using an intention-to-treat framework and included all participants. Parameter estimates were based on maximum likelihood estimation or a generalised estimating equation, which allows for the inclusion of participants with missing data.

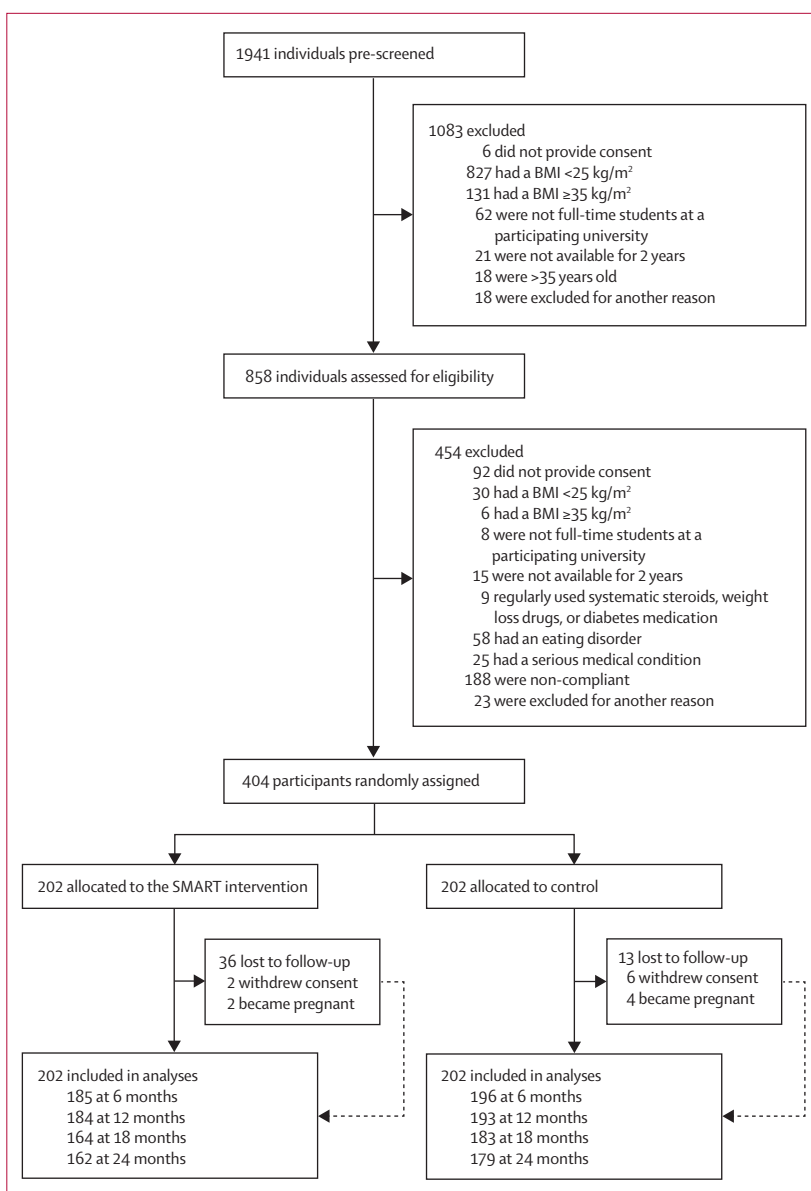


Figure 1: Trial profile

This approach increases power compared with a completers analysis, uses all available data, and is an appropriate method for handling missing data when the extent of missing data is relatively small and missing completely at random.²⁷

To assess the potential effect of missing data on the primary outcome, a sensitivity analysis was done using an inclusive strategy.²⁸ Multivariate imputation by chained equations generated 100 imputed datasets.²⁹ Each dataset was generated by 200 iterations of the Gibbs sampler. The imputation procedure included the following variables: treatment group, time, weight, height, age, sex, race, ethnicity, college, waist circumference, arm circumference, systolic blood

pressure, diastolic blood pressure, and pulse rate. ANCOVA models of weight in kg at month 24 were fit to the imputed data with covariates for baseline weight, treatment group, sex, ethnicity, and college. Results were pooled using Barnard-Rubin adjusted degrees of freedom for small samples.³⁰ Subgroup analyses were also done to determine if age, sex, and ethnicity moderated the intervention effects on weight, by adding a multiplicative interaction term for each separately into the model. An additional pre-planned, exploratory analysis was done to test if level of engagement affected weight loss in the SMART intervention group. This was also analysed by

adding a multiplicative interaction term for engagement (high vs low, based on a median split) to a linear mixed-effects regression. The trial is registered with ClinicalTrials.gov, number NCT01200459.

Role of the funding source

Representatives of the National Heart, Lung, and Blood Institute of the National Institutes of Health participated in the design and conduct of the study, but had no role in the collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Figure 1 shows the flow of participants from recruitment through to the final assessment at 24 months. From May 18, 2011, to May 17, 2012, 1941 individuals completed an interest form on the study website. Of those, 858 (44%) were assessed for eligibility via an online questionnaire. 404 (21%) individuals met all of the inclusion and exclusion criteria after an in-person assessment and were subsequently randomly assigned (202 [50%] were allocated to each study group). The SMART intervention group and control group did not differ according to key demographic characteristics (table 2). Participants had a mean (SD) age of 22.7 (3.8) years and most were female (284 [70%]). All participants were English speaking and had diverse ethnic and racial backgrounds (125 [31%] Hispanic and 169 [42%] white). Most participants were recruited from University of California, San Diego (204 [50%]), followed by San Diego State University (152 [38%]), and California State University, San Marcos (48 [12%]).

Of the randomly assigned participants, 341 (84%) were assessed for the primary outcome (weight at 24 months) and 63 (16%) were lost to follow-up (ie, we were unable to contact participants). All participants were included in the analyses. Figure 2 shows the estimated marginal means and 95% CIs for weight at each study timepoint. There was no difference in weight adjusted for sex, ethnicity, and college in the SMART intervention group compared with the control group at 24 months (−0.79 kg [95% CI −2.02 to 0.43], $p=0.204$). However, adjusted weight was significantly less in the SMART intervention group compared with the control group at 6 months (−1.33 kg [95% CI −2.36 to −0.30], $p=0.011$) and 12 months (−1.33 kg [−2.30 to −0.35], $p=0.008$), but not at 18 months (−0.67 kg [95% CI −1.69 to 0.35], $p=0.200$). The sensitivity analysis did not result in a change to the findings, and there was no evidence that effects were moderated by age, sex, or ethnicity ($p>0.05$ for all interaction terms).

Table 3 shows the estimated marginal means or probabilities, 95% CIs, and p values for the between-group differences for secondary outcomes at each timepoint. Differences in BMI between the SMART

	Intervention group (n=202)	Control group (n=202)
Age (years)		
18–22	124 (61%)	122 (60%)
23–27	56 (28%)	52 (26%)
28–32	15 (7%)	25 (12%)
33–35	7 (3%)	3 (1%)
Sex		
Male	59 (29%)	61 (30%)
Female	143 (71%)	141 (70%)
Ethnicity		
Hispanic	63 (31%)	62 (31%)
Non-Hispanic	139 (69%)	140 (69%)
Race		
White	86 (43%)	83 (41%)
Asian	46 (23%)	50 (25%)
Other	43 (21%)	38 (19%)
Multiple	17 (8%)	20 (10%)
Black or African American	6 (3%)	9 (4%)
American Indian, Alaska Native, Hawaiian Native, or other Pacific Islander	4 (2%)	2 (1%)
College		
UCSD	102 (50%)	102 (50%)
SDSU	77 (38%)	75 (37%)
CSUSM	23 (11%)	25 (12%)
CES-D 10 score (scale 0–30)	8.5 (3.5)	8.3 (3.4)
GPAQ moderate to vigorous recreational activity (min/week)	109.9 (111.1)	117.8 (128.5)
SSB consumption (number per week)	3.5 (5.1)	2.8 (4.4)
Weight (kg)	80.8 (12.7)	81.3 (13.2)
Body-mass index (kg/m ²)	28.9 (2.8)	29.0 (2.7)
Waist circumference (cm)	87.5 (8.8)	88.0 (9.1)
Arm circumference (cm)	33.3 (3.1)	33.4 (3.1)
Systolic blood pressure (mm Hg)	114.9 (10.5)	115.7 (11.4)
Diastolic blood pressure (mm Hg)	71.2 (7.9)	71.8 (7.9)
Heart rate (beats per min)	76.7 (11.6)	76.8 (10.5)

Data are n (%) or mean (SD). UCSD=University of California, San Diego. SDSU=San Diego State University. CSUSM=California State University, San Marcos. CES-D=Center for Epidemiologic Studies Depression Scale.³¹ GPAQ=Global Physical Activity Questionnaire.³² SSB=sugar-sweetened beverage.

Table 2: Baseline characteristics by study group in Project SMART

intervention group and the control group paralleled weight in that differences were only significant at 6 months and 12 months. There were small but statistically significant differences between groups in the proportion of participants who lost 5% of their bodyweight at 6 months, waist circumference at 6 months, and systolic blood pressure at 24 months. There were no statistically significant differences between groups in the percentage of participants who lost 10% of their bodyweight, arm circumference, diastolic blood pressure, or heart rate.

Among those in the SMART intervention group, median (IQR) level of engagement with the intervention declined over time: 98 (9–265) interactions at 6 months, 76 (0–222) at 12 months, 41 (0–198) at 18 months, and 12 (0–161) at 24 months. Participants with high levels of engagement as determined by a median split, did not achieve greater weight loss than participants with low levels of engagement ($p > 0.05$ at all timepoints).

Among those who received the SMART intervention, most (119 [78%] of 153) reported that they were satisfied with the intervention and most (123 [80%] of 153) would recommend it to others. Given its numerous features and capacity to encourage content creation,³³ Facebook emerged as the primary modality through which dynamic content was delivered at the group level.

One serious adverse event possibly related to participation in the study occurred: a participant in the intervention group experienced gallstones that could be attributable to rapid and excessive weight loss. Eight additional serious adverse events unrelated to participation in the study were reported.

Discussion

A theory-based weight loss intervention delivered to overweight or obese college students via social and mobile technologies commonly used among young adults was not associated with significant decreases in weight after 2 years, compared with general health information provided via a website and email. This result was not significantly moderated by age, sex, or ethnicity. However, the intervention did stimulate modest reductions in weight and BMI for at least 1 year, resulting in an increase in the number of college students who achieved a 5% reduction in bodyweight and a reduced average waist circumference during the first 6 months. Although there was little evidence that these short-term changes in weight corresponded with clinically significant improvements in body composition, blood pressure, or heart rate, the principle finding aligns with previous research. Specifically, systematic reviews and meta-analyses have shown that the efficacy of both traditional and technology-based weight loss interventions is greatest during the first 6 months.^{12,14}

In the case of technology-based weight loss interventions, the lack of long-term effects might be due to a well documented decline in engagement with intervention

modalities.¹³ Although the SMART intervention included a large amount of individually tailored interactions that provided convenient, dynamic, and sustained exposure to behaviour change techniques, there was a general decline

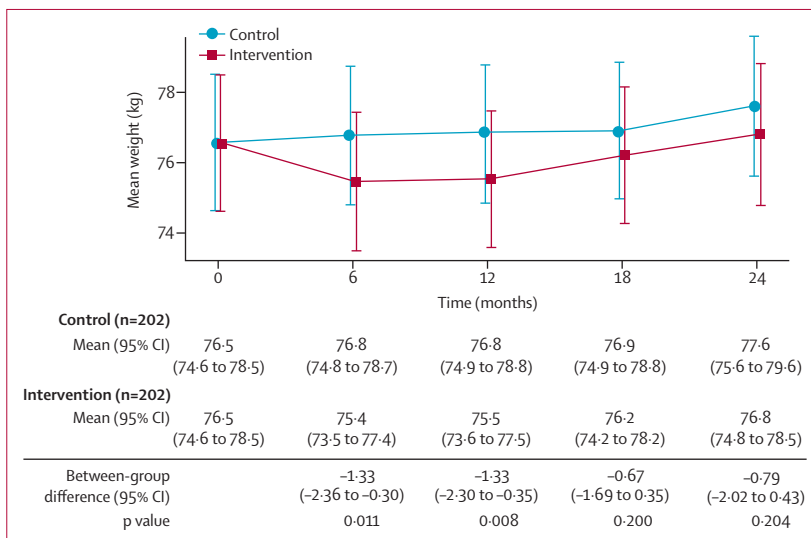


Figure 2: Estimated marginal means and between-group differences for the comparison of weight between the SMART intervention group and control group over 24 months from a linear mixed-effects regression model adjusted for sex, ethnicity, and college

	Intervention group	Control group	Between-group difference (95% CI)	p value
Body-mass index (kg/m²)				
Baseline	28.5 (27.9 to 29.0)	28.5 (27.9 to 29.0)
6 months	28.1 (27.5 to 28.6)	28.6 (28.0 to 29.1)	-0.49 (-0.83 to -0.15)	0.005
12 months	28.1 (27.6 to 28.6)	28.6 (28.1 to 29.1)	-0.49 (-0.81 to -0.16)	0.004
18 months	28.4 (27.8 to 28.9)	28.6 (28.1 to 29.1)	-0.24 (-0.59 to 0.11)	0.185
24 months	28.6 (28.0 to 29.1)	28.9 (28.3 to 29.0)	-0.28 (-0.71 to 0.15)	0.201
Probability of losing 5% of bodyweight				
Baseline
6 months	0.09 (0.06 to 0.11)	0.06 (0.04 to 0.08)	0.031 (-0.001 to 0.620)	0.047
12 months	0.11 (0.09 to 0.14)	0.08 (0.06 to 0.11)	0.031 (-0.005 to 0.068)	0.093
18 months	0.14 (0.11 to 0.18)	0.12 (0.09 to 0.15)	0.027 (-0.020 to 0.074)	0.255
24 months	0.19 (0.14 to 0.24)	0.17 (0.13 to 0.22)	0.016 (-0.047 to 0.081)	0.612
Probability of losing 10% of bodyweight				
Baseline
6 months	0.01 (0.01 to 0.02)	0.02 (0.01 to 0.03)	-0.003 (-0.017 to 0.111)	0.696
12 months	0.02 (0.01 to 0.04)	0.03 (0.01 to 0.04)	-0.001 (-0.020 to 0.018)	0.917
18 months	0.04 (0.02 to 0.06)	0.04 (0.02 to 0.06)	0.004 (-0.023 to 0.031)	0.765
24 months	0.07 (0.04 to 0.10)	0.06 (0.03 to 0.09)	0.016 (-0.025 to 0.056)	0.452
Waist circumference (cm)				
Baseline	84.5 (83.1 to 85.9)	84.5 (83.1 to 85.9)
6 months	82.9 (81.5 to 84.4)	84.0 (82.5 to 85.4)	-1.02 (-1.89 to -0.16)	0.021
12 months	83.3 (81.8 to 84.7)	84.0 (82.6 to 85.4)	-0.73 (-1.56 to 0.09)	0.082
18 months	83.5 (82.1 to 85.0)	84.0 (82.6 to 85.4)	-0.46 (-1.41 to 0.49)	0.338
24 months	83.9 (82.3 to 85.4)	84.8 (83.3 to 86.3)	-0.98 (-2.06 to 0.96)	0.075

(Table 3 continues on next page)

	Intervention group	Control group	Between-group difference (95% CI)	p value
(Continued from previous page)				
Arm circumference (cm)				
Baseline	32.4 (32.0 to 32.9)	32.4 (32.0 to 32.9)
6 months	32.0 (31.5 to 32.6)	32.3 (31.8 to 32.8)	-0.28 (-0.62 to 0.06)	0.101
12 months	31.8 (31.3 to 32.3)	32.1 (31.6 to 32.6)	-0.27 (-0.61 to 0.07)	0.121
18 months	31.9 (31.3 to 32.4)	31.9 (31.4 to 32.4)	-0.02 (-0.37 to 0.33)	0.909
24 months	31.9 (31.3 to 32.4)	32.1 (31.6 to 32.6)	-0.26 (-0.61 to 0.09)	0.146
Systolic blood pressure (mm Hg)				
Baseline	110 (109 to 112)	110 (109 to 112)
6 months	109 (108 to 111)	110 (108 to 111)	-0.76 (-2.31 to 0.80)	0.340
12 months	109 (107 to 110)	108 (107 to 110)	0.26 (-1.33 to 1.85)	0.749
18 months	107 (105 to 109)	106 (104 to 108)	1.11 (-0.63 to 2.84)	0.212
24 months	109 (107 to 111)	107 (105 to 109)	2.09 (0.21 to 3.97)	0.030
Diastolic blood pressure (mm Hg)				
Baseline	70.5 (69.3 to 71.7)	70.5 (69.3 to 71.7)
6 months	69.3 (68.0 to 70.7)	70.0 (68.6 to 71.3)	-0.63 (-1.83 to 0.57)	0.303
12 months	69.3 (68.0 to 70.6)	69.7 (68.4 to 71.0)	-0.37 (-1.55 to 0.82)	0.546
18 months	69.2 (67.9 to 70.5)	68.9 (67.6 to 70.2)	0.29 (-0.95 to 1.52)	0.649
24 months	70.3 (68.9 to 71.8)	69.5 (68.0 to 70.9)	0.85 (-0.59 to 2.29)	0.246
Heart rate (beats per min)				
Baseline	78.4 (76.8 to 80.0)	78.4 (76.8 to 80.0)
6 months	75.5 (73.6 to 77.3)	76.6 (74.8 to 78.5)	-1.17 (-3.06 to 0.73)	0.227
12 months	75.0 (73.1 to 76.8)	76.4 (74.5 to 78.2)	-1.43 (-3.34 to 0.49)	0.144
18 months	75.6 (73.6 to 77.5)	75.6 (73.7 to 77.5)	-0.05 (-2.06 to 1.95)	0.960
24 months	75.7 (73.8 to 77.6)	76.7 (74.8 to 78.6)	-1.02 (-3.02 to 0.99)	0.321

Data are mean (95% CI) unless otherwise indicated.

Table 3: Estimated marginal means, probabilities, and between-group differences for the comparison of secondary and exploratory outcomes between the SMART intervention group and control group over 24 months from linear mixed-effects regression models for continuous outcomes and generalised estimating equations for binary outcomes, all adjusted for sex, ethnicity, and college

in engagement over time. Different levels of engagement were not associated with changes in weight, but this could be due, at least in part, to how engagement was defined. The measure of engagement encompassed most of the observable interactions (excluding website visits and emails) participants could have had with intervention modalities, but it did not take into account the depth of those interactions. For example, liking a post about healthy eating on the SMART intervention Facebook page was considered the same level of engagement as posting a pledge to reduce consumption of sugar-sweetened beverages. Furthermore, the measure did not quantify the common practice of lurking (ie, passively consuming content but not interacting in a visible way) on the digital intervention modalities.³³ More research is needed to determine the definitions and metrics of engagement most useful in understanding intervention effects.¹⁴ Current understanding of what constitutes engagement in digital health interventions is limited and few studies have attempted to quantify it in ways that are comparable between studies.¹⁴ The heterogeneity of digital health interventions presents a clear barrier to achieving

common metrics of engagement, but standardised qualitative approaches might be particularly well suited to this task.³⁴

The study had limitations. First, two types of contamination could have affected the results. The first, between-group social influence, is suggested by participant Facebook data which revealed that at least 61 (30%) participants in the control group were friends with one or more participants in the SMART intervention group. Depending on individual privacy settings, the control group could have viewed intervention-related posts, comments, or likes. The second, utilisation of non-study-related modalities, is suggested by the use of commercially available apps for weight loss, some of which incorporate evidence-based strategies for weight loss.³⁵ The control group was not prohibited or discouraged from using commercial apps and several participants in both the control and intervention groups anecdotally expressed they were doing so in exit interviews. Further evidence that contamination might have diluted intervention effects comes from the observation that systematic reviews and meta-analyses indicate that students typically gain between 1.31 kg and 1.79 kg while in college,⁹ yet in our study, the unadjusted mean (SD) increase in weight among participants was relatively modest: 0.44 kg (6.4) in the SMART intervention group and 0.92 kg (6.9) in the control group. Future studies of technology-based weight loss interventions should attempt to measure contamination directly (eg, quantify the amount of interaction between the study groups and usage of non-study-designed apps throughout the intervention) to better show how these variables affect internal validity. Addressing this issue through study design alone (eg, increased sample sizes or cluster randomisation) might not be adequate given increasing technological connectivity and commercial health app use, neither of which are geographically confined. Directly measuring contamination might also allow for accurate assessment of the presence of spillover effects and a more complete determination of the impact of interventions. Finally, participants were recruited from three geographically close colleges and were relatively healthy. Thus, our results might not generalise to other settings or groups, such as those not in college or those with greater disease risk and thus potentially more to gain from reducing their weight.

Nevertheless, the study had several important strengths. The sample was large and ethnically diverse. The multiyear intervention was theory based, was delivered via modalities that have the potential for widespread dissemination, and, to our knowledge, was the first to test the value of leveraging existing social networks via Facebook. Those who analysed outcomes were unaware of participants' group allocation and an intention-to-treat framework was used. Finally, participant retention in the trial was high (84%) and did not differ significantly between study groups.

To our knowledge, the SMART intervention is the first to incorporate several theory-based behaviour change techniques previously demonstrated to be effective in improving weight-related behaviours and deliver them in an individually tailored and dynamic manner via Facebook and mobile technologies commonly used among young adults. If future social and mobile interventions are able to stimulate reductions in weight similar to those observed in the first 12 months of this trial but maintained for a longer period of time, a meaningful population-level effect on the weight status and health of young adults could be seen.

Contributors

GJN, SJM, KJC, JSH, CLR, WGG, FR, BJB, TNR, JHF, and KP were responsible for study concept and design. JGG, GM, GJN, MCD, SJM, KJC, JSH, CLR, WGG, AG, FR, TNR, JHF, and KP were responsible for acquisition, analysis, or interpretation of data. JGG, GM, and KP drafted the manuscript. JGG, GM, GJN, MCD, CLR, AG, FR, TNR, JHF, and KP were responsible for critical revision of the manuscript for important intellectual content. JGG, GJN, and MCD did the statistical analysis. GJN, SJM, KJC, JSH, CLR, WGG, FR, BJB, TNR, JHF, and KP obtained the funding. GM, GJN, SJM, AG, FR, and KP provided administrative, technical, or material support. GJN, SJM, AG, FR, and KP supervised the study. JGG and KP had full access to all of the data in the study and take responsibility for the integrity of the data, the data analysis, and the manuscript.

Declaration of interests

We declare no competing interests.

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