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Design and Implementation of a Randomized Controlled Social and Mobile Weight Loss Trial for Young Adults (project SMART)

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Abstract

Purpose—To describe the theoretical rationale, intervention design, and clinical trial of a two-year weight control intervention for young adults deployed via social and mobile media.

Methods—A total of 404 overweight or obese college students from three Southern California universities (M_{age} = 22($\pm$4) years; M_{BMI}=29($\pm$2.8); 70% female) were randomized to participate in the intervention or to receive an informational web-based weight loss program. The intervention is based on behavioral theory and integrates intervention elements across multiple touch points, including Facebook, SMS, smartphone applications, blogs, and e-mail. Participants are encouraged to seek social support among their friends, self-monitor their weight weekly, post their health behaviors on Facebook, and e-mail their weight loss questions/concerns to a health coach.

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The intervention is adaptive because new theory-driven and iteratively tailored intervention elements are developed and released over the course of the two-year intervention in response to patterns of use and user feedback. Measures of body mass index, waist circumference, physical activity (PA), sedentary behavior (SED), diet, weight management practices, smoking, alcohol, sleep, body image, self-esteem, and depression occur at 6, 12, 18, and 24 months. Currently, all participants have been recruited, and all are in the final year of the trial.

Conclusion—Theory-driven, evidence-based strategies for PA, SED, and dietary intake can be embedded in an intervention using social and mobile technologies to promote healthy weight-related behaviors in young adults.

Keywords

weight loss; social support; young adult; Internet; health promotion; obesity

Introduction

College students in transition from adolescence into early adulthood may face new stresses that can lead to unhealthy weight-related behaviors and weight gain. A recent study of 80,000 college students from 106 United States academic institutions revealed that 32% of students were overweight or obese. Studies also have shown that college students gain weight at a higher rate than the national average [1,2]. Thus, strategies for promoting healthy weight in this population are imperative. One potential strategy is to deploy weight control interventions via social and mobile media given their popularity among college students.

Social and mobile media include technologies such as online social networks, mobile phones, text messaging (SMS), and blogs. Nationwide surveys conducted in 2013 found that among young adults (age 18-29), 89% use online social networks [3], 79% own a smartphone [4], 97% use SMS [5], 87% access the Internet on their phone [5], 77% download applications [5], and 32% read and/or post to blogs [6]. Use of these technologies in the United States varies little by education, race/ethnicity, income, or place of residence [3-5]. Of these technologies, online social networking is the most widely used and its popularity is increasing rapidly. The numbers of users since 2005 has increased more than 65% [3]. The popularity of online social networks has been largely attributed to Facebook, which in May 2013 reached more than 1.11 billion users [7]. Research with college students showed users spend approximately 30 minutes per day on Facebook [8,9].

The popularity of Facebook has led to interest in its use for improving health behavior. Facebook has the potential to change behavior because an individual's social environment plays an important role in health outcomes, including those related to weight loss. Research has shown that a greater number of overweight or obese friends and family is associated with being overweight [10,11], and more social contacts is associated with greater intention to lose weight [11]. One factor within an individual's social environment that may play an important role in health and behavior change is social support. In both cross sectional and longitudinal studies, social support is associated with improved lifestyle changes and weight loss [12-16], but less is known about how social and mobile media can be used to promote weight loss via social support. There is some evidence that online support groups [17] and web chats [18] improve weight-related outcomes, and studies that compared weight loss between an Internet-based intervention group and a therapist-led group found that weight loss was similar between the two groups [19,20]. Because Facebook has shown to increase social support [21,22] and has been shown to provide both informational and emotional social support to those trying to lose weight [23], investigating if Facebook can be a platform for weight loss interventions among young adults is warranted. College students

particularly may benefit from this social support because they probably recently moved out of the family home and have limited instrumental support to maintain a healthy lifestyle. In addition, students can easily integrate social network technology easily into their social environments. However, few studies have used this technology for weight loss purposes among young adults, particularly in combination with other media.

The purpose of this report is to describe the theoretical rationale and intervention design of the **S**ocial **M**obile **A**pproaches to **R**educe weigh**T** (SMART) Study. The SMART intervention is a two-year clinical trial deployed via Facebook, mobile apps, SMS, and the Internet to provide an engaging weight-loss program for overweight and obese college students who want to lose weight. Currently, all participants have been recruited, and all are in the final year of the trial.

Methods

Theoretical Framework

The SMART intervention was informed by several behavior change theories. Social cognitive theory (SCT) [24] posits that behavior is reciprocally influenced by intrapersonal factors (i.e., cognitive processes, affective processes, and biological events) and the physical and social environment. One cognitive process in particular, self-efficacy, is hypothesized to mediate the influence of intrapersonal factors on learning and subsequent behavior change. To increase self-efficacy, strategies to improve goal achievement are embedded throughout the intervention. These strategies include self-monitoring, intention formation, goal setting, goal review, feedback on performance, self-efficacy, benefits, barriers, problem-solving, social support, and tailoring. Expanding on SCT, control theory [25] proposes that setting goals, monitoring behavior, receiving feedback, and reviewing relevant goals after obtaining feedback are central to self-management and behavioral control. Ecological theory [26] proposes a more comprehensive model of health behavior by suggesting that behaviors are embedded in four nested environments (i.e., a micro-, meso-, exo-, and macro-system) each containing roles, norms, and rules that shape our behavior. In addition to health-behavior theories, the SMART intervention also was informed by social network theory [27]. Social network theory posits that relationships and connections formed by individuals are important for understanding individuals and their behaviors. The SMART intervention integrates these theoretical approaches with evidence-based behavioral strategies for improving PA and diet [28]. Table 1 lists the theory-based behavioral strategies supported in the SMART intervention.

These behavioral and social network-based strategies also inform additional intervention activities aimed at maximizing the potency of the intervention. For example, at regular intervals study staff initiates *challenges and campaigns* that operate similar to a theme-based contest. Participants are encouraged to make a pledge to participate (intention formation) in the challenge, set goals, and identify action plans to reach these goals. Participants are encouraged to share pledges and goals with friends in their Facebook network with the aim of receiving feedback and positive reinforcement from their friends as well as the health coach. Sharing of information and useful tips for reaching goals is encouraged because social support is a critical factor. To make challenges more culturally and socially relevant, many of them are held during calendar events (e.g., Halloween, New Years, Spring Break). Figure 1 shows an example of how a challenge is supported by theory and behavioral strategies.

Intervention Components

The SMART intervention comprises six core intervention modalities: (i) Facebook, (ii) mobile apps, (iii) a website with blogs, (iv) e-mail, (v) SMS, and (vi) occasional 'lifeline' contact with a health coach. Integrating multiple intervention channels is intended to promote adoption and maintenance of improved health behaviors for several reasons. First is convenience, as participants can choose how to interact with the intervention among a variety of modalities and integrate it into their daily routines. Second, incorporating multiple channels provides several ways in which theoretical constructs can be embedded into the intervention. For example, SMS provide cues to action, the Facebook component offers social support, and mobile apps can be used for goal setting. It is hypothesized that incorporating a variety of theory-based health behavior change techniques will increase intervention effectiveness of SMART, as more extensive use of theory in Internet-based interventions is associated with increases in effect size [29]. Third, integrating multiple elements improves exposure outcomes because different types of channels are suited for certain types of exposures. For instance, peer support is associated with a longer stay on websites, whereas e-mail or phone contact is related to more log-ins on websites [30]. Fourth, integrating multiple channels also has been shown to improve adherence [30], an important concern because technology-based programs for health promotion tend to have low engagement and retention [31]. Although participants may not use all intervention components, they are reminded of the available options via campaigns (see campaign description under the Facebook section), e-mails, and SMS. Please see Figure 2 to view how the multiple intervention elements link.

Facebook

Facebook is the primary modality for delivering 'dynamic' (i.e., iterative) intervention content at the group level. Content is intended to be shared within participants' respective social networks, as the intent is not to create a new social network of study participants. Rather, the intent is to leverage the value of participants' existing Facebook network. At study onset, those randomized to the SMART intervention were asked to 'like' the SMART Facebook page, which would allow them to receive intervention content unique to the treatment group and share their intervention-related activities with their existing network (as determined by their privacy settings in Facebook). Facebook content, generated by the SMART research team, includes posts that encourage intervention participants to interact (i.e., 'liking,' sharing, and commenting on the posts) as well as general posts sharing weight-loss tips and experiences. Theme-based weight management 'campaigns' are conducted through Facebook, promoting changes to one or more weight-related behaviors. For example, Halloween-based campaigns ask participants to eliminate or decrease consumption of candy before Halloween. During these campaigns, participants are asked to change their behavior by making a 'pledge' to change (intention formation), planning how they will execute the changes (goal setting), and sharing their experiences with the SMART Facebook page and their own network. The SMART Facebook health coach provides participants timely feedback on their Facebook interactions and behavior change efforts. Participants are encouraged to visit the Facebook page at least weekly.

Mobile Apps

Mobile apps designed to run on smartphones or Facebook are created specifically for the SMART study. Apps allow participants to self-monitor behavior, set goals, and receive feedback on their progress. An example of an app created for SMART is 'Goal Getter' (Figure 3). The Goal Getter app invites participants to develop behavioral goals related to that week's corresponding health topic, which appears on the Facebook page or is sent over e-mail. Goals are encouraged to be specific, measurable, achievable, realistic, time-based, enjoyable, and relevant, as dictated by goal setting theory [32]. Participants' friends are

invited to embed clues of hidden rewards that are unlocked after milestones toward goal achievement had been accomplished. For example, a friend can hide a locked reward (e.g., "I'll buy you a healthy lunch!") in the participant's goal timeline that is revealed after the participant attains 50% of his or her goal.

The SMART app intervention modality is enhanced through an open source SMART Application Programming Interface (API), a protocol that permits different 'SMART-enabled' apps to communicate with each other. The SMART API consists of a library that specifies routines, data structures, object classes, and variables through which data are aggregated and shared across apps. Moreover, development of a SMART API enables programmers outside the SMART study to create new apps that can generate and share data with the existing suite of SMART apps (which also can be used by others). Software development to create and unify these intervention modalities across a common database lasted approximately 10 months. During this time, the software architecture and mobile user interface was refined, an initial set of apps for SMART based upon formative work were developed, and the system was tested.

Website with Blogs

A website was created for SMART study participants randomized to the intervention arm. This website contains diet and PA information, weight loss recommendations, and a section titled "blogs" where threads related to weight management tips are initiated and saved so participants can read and comment on those of interest. Participants are encouraged to visit the website weekly for updates on new content. The website also contains metrics for measuring participant compliance as well as a section titled "Frequently Asked Questions" that contains information on how to contact research staff for support.

SMS

In the first year of the intervention, SMS (i.e., sent once per week) was used to prompt participation in intervention activities, such as self-monitoring of weight. As the intervention progresses into the second year, SMS is used more frequently and begins to be incorporated to reinforce behavior change principles offered via other intervention channels. The enhanced SMS component is deployed in year two as a means of offering something novel to participants to keep them engaged, as the ease of use and ubiquity of SMS is something that may be appealing to participants.

E-mail and Health Coach 'Lifeline Calls'

E-mails are used to notify participants about study updates and to prompt participation in *challenges and campaigns* or other study activities. Participants also are encouraged to e-mail their health coach or the study staff with questions or concerns. In addition, up to 10 'lifelines' are offered to intervention study participants to use during the two-year intervention. The participants can use these lifelines when they require additional support from their health coach. Each lifeline is limited to 15 minutes and is implemented via telephone calls, Skype, or instant chat as one-on-one conversations between the participants and their health coach.

An Adaptive Intervention

The SMART intervention is adaptive in that the set of intervention elements, and the ways in which participants are expected to use them, was not pre-determined at the outset of the trial. Changes are made to the intervention based on usage patterns and user feedback. Existing intervention tools are updated, or new ones are developed, in response to usage patterns and user feedback. Thus, not all participants are receiving the same intervention in a

fixed way. Rather, they can tailor their use of the intervention across modality in ways that suit their needs. For example, the mobile apps released at the beginning of the intervention were used by some and not by others, and two new apps were rolled out during the study. Similarly, the Facebook campaigns are tailored to such things as time of year, feedback from participants, cultural trends at the time (e.g. a Gangnam Style video related to weight management), and health coaches' perceptions of participants' interests. However, as described above, the underlying theoretical basis of the intervention as well as how the software and database was developed, support consistency of theoretical principles, intervention delivery, tracking, and feedback to participants.

Comparison Condition

Participants assigned to the comparison condition group have access to a website without social networking components that contains general health information relevant to 18-35-year-old college students. Topics include smoking cessation, sun protection, stress management, relationships, sexual health, alcohol, and drugs. This website also includes weight loss information comparable to what participants would receive from primary care providers. Participants assigned to the comparison condition are instructed to interact with at least one intervention modality weekly. Participants in the comparison condition cannot access the SMART Facebook page, as this page requires a login password.

Design of the Randomized Controlled Trial

The SMART intervention is being evaluated in a two-year randomized controlled trial (RCT). Participants were randomized into the SMART intervention or the comparison condition. Institutional review boards from all three universities from which participants were recruited approved study protocols.

Sample

College students have been recruited from the following three universities in San Diego, California: 1) San Diego State University (SDSU) (student population of approximately 36,000 students: 58% female, 44% non-Hispanic white, 16% Hispanic, 6% Asian, 3% African American, 3% Filipino); 2) California State University, San Marcos (CSUSM) (student population of approximately 9,000 students: 49% non-Hispanic white, 22% Hispanic, 12% Asian/Pacific Islander, 3% African American); and 3) University of California, San Diego (UCSD) (student population of approximately 28,000 students: 53% female, 41% Asian, 28% non-Hispanic white, 9% Mexican American, 1% African American). Participants were recruited from May 2011 to May 2013 through following channels: 1) print advertisements in college newspapers, 2) flyers posted around the campuses, 3) advertising on the campus electronic bulletins, 4) online ads, 5) intervention website, and 6) e-mails sent by student health services via electronic distribution lists.

To be eligible to participate in the RCT, students had to meet the following criteria: a) age 18 to 35 years, b) Facebook user or willingness to begin, c) owns a personal computer, d) owns a mobile phone and uses text-messaging, e) willing to attend required research measurement visits in San Diego over the two-year RCT, and f) body mass index (BMI) >25 and <34.9 kg/m^2. Students were excluded for the following reasons: a) comorbidities of obesity that would have required clinical referral, including eating disorders, pseudotumor cerebri, sleep apnea/hypoventilation syndrome, orthopedic problems, and meeting American Diabetes Association criteria for diabetes; b) psychiatric or medical conditions that prohibited compliance with the study protocol, prescribed dietary changes, or moderate PA; c) taking medications that alter weight; d) pregnant or intending to get pregnant over the next two years; or e) enrolled in or planning to enroll in another weight loss program. Eligible participants were invited to attend the baseline measurement visit at a university. At

the baseline measurement visit, potential participants were re-screened for inclusion and exclusion criteria and underwent written informed consent. Participants received a $40 incentive at baseline and $50 at six-months.

Randomization and Blinding

A four-block randomization scheme stratified by college, sex, and ethnicity was used to randomize the participants into the treatment or comparison group. Randomization was automated in the database system, but the database manager monitored participant allocation to conditions. Investigators are blinded to intervention randomization throughout the study period, and role allocation restrictions in the database control study staff access to participant treatment condition.

Measures

Measurements occur at baseline, 6, 12, 18, and 24 months. The primary aim of the intervention is 5-10% weight loss at 24 months. The secondary aims are to assess the impact of the intervention on self-reported diet measured with the Diet History Questionnaire II [33,34] and the Automated Self-administered 24-hour Dietary Recall [35,36], PA measured with the Paffenbarger Physical Activity Questionnaire[37,38] and the Global Physical Activity Questionnaire (version II) [39,40], sedentary behavior measured with a questionnaire that assesses sedentary behaviors during a typical weekday and weekend day [41,42], quality of life measured with the Quality of Well-Being Scale [43,44], and depression measured with the Center for Epidemiologic Studies Depression short form [45]. Mediators of intervention effects (e.g., psychosocial constructs, eating, PA, and sedentary behaviors) will be examined in addition to moderators (e.g. gender, age, education, and baseline levels of self-esteem, body image, and depression). At 24 months, satisfaction with the SMART intervention will be assessed using a Likert scale that asks about level of satisfaction with the program as well as program features.

Internal Validity

In adaptive multimodal interventions, it is important to have a systematic approach to the delivery of intervention content to increase the internal validity of the study. Three strategies are being used to accomplish this. First, to avoid differential access to intervention content as a function of participants' preferred modality use, much of the content is delivered cross-modality. For example, e-mails are sent to alert participants of updates or strategies embedded in the apps. In addition, apps are programmed using HTML5, a method of software development that allows apps to run on a web-based platform as well as all smartphones with web access. Second, new content within modalities (e.g., a new app or a new Facebook campaign) is required to have one or more of the core behavioral strategies embedded within it (e.g., self-monitoring, feedback, goal setting). Finally, with the exception of the emergency 'lifeline call' with the health coach, intervention content is delivered via a technology-mediated channel. This supports automated tracking and standardization and avoids the inevitable variability involved in human interactions, such as counseling style or empathy.

Data Collection and Management

Data collection occurs at Moore's Cancer Center at UCSD and the Student Health Services at SDSU and CSUSM by trained measurement staff blind to intervention randomization. Participants directly enter data into a secure web-based survey system with an easy-to-use "point and click" interface. Incoming data are checked first by measurement staff, and they are instructed to contact participants immediately to recover missing data. Necessary firewall and password protections are implemented, and backup files are made nightly.

Statistical Analyses

The primary test of the treatment effect on body weight will be the treatment condition by time interaction. Other study endpoints are considered secondary or exploratory and will be evaluated using linear mixed models. Differences between groups will be evaluated with a mixed-effects regression analysis with a factor for treatment condition (SMART, control), a continuous linear term for time (baseline, 6, 12, 18, and 24 months), and random effects for subject, campus, and friend network defined according to Facebook. These analyses use observed data with missing data assumed missing at random. Participants were enrolled in the intervention with the assumption that they are independent observations. However, this assumption can be tested by mapping the structure of the social network through Facebook. Friend links will be assessed among participants at baseline and over the course of the intervention. Networks of friends will be categorized, and their effect on dependent variables will be assessed with intra-class correlations.

Statistical Power

The sample size was estimated from an effect size of 0.653 kg/year, an attrition rate of 30% over a two-year period, an ICC of .01 for campus and friend group, and an average friend group size of 10. A sample of 400 students, an alpha set at 0.05, and assuming the standard deviation of change is 3.3 kg, provides 80% power to detect a between-group difference in weight loss of 0.653 kg/year (or 0.653 kg/year × 3 years = 1.96 kg equivalent to 2.45% weight loss for a 80 kg individual). The effect size of 1.96 kg is comparable to that observed in our prior text-messaging RCT [46], which resulted in a 1.72 ±3.3 kg difference in change in body weight at four months between the intervention and control group.

Discussion

The SMART study aims to address obesity in young adults by using social and mobile media to educate, motivate, and change behaviors that support weight loss and healthy weight control. Findings from this study will add to the growing research literature on how technology and social networks can be used to increase PA and healthy eating, two behaviors important for weight control. Furthermore, this study may yield further insights into the relationships between Facebook use, social support, and health behaviors. Facebook is a promising venue for health promotion given its ubiquity and that users can share their experiences in real-time [21,47]. Although this social networking platform has been shown to increase self-esteem [8,48,49] and life satisfaction [8,50], there is limited evidence about its impact on health behaviors [51], in particular from prospective studies.

The study also is expected to contribute to our understanding of the strengths and limitations of using Facebook in health promotion research more broadly. For example, users of Facebook who enroll in a weight loss intervention may be inherently different from those who do not use Facebook, or use it less than others. Some evidence suggests that individuals with larger social networks are more extroverted and have a more positive self-image than individuals with small social networks [52]. This may create a sampling bias that confounds treatment effects because weight-related cognition, affect, and behavior may co-vary with psychosocial factors. In this study, size of friend networks, frequency of activity, and other baseline measures of Facebook use, along with other baseline participant characteristics will be evaluated as potential moderators of intervention effects, identifying those groups of students who benefit most or least from these types of interventions.

Finally, evaluation of interventions capable of adapting to changes is important because mobile and social technologies are rooted in an ever-changing landscape of devices, apps,

and services. This study is an attempt to accomplish this evaluation, and the outcomes may inform this new area of behavioral research.

Acknowledgments

Abbreviations

PA	physical activity
SED	sedentary behavior
SCT	Social Cognitive Theory
RCT	randomized controlled trial
API	application programming interface

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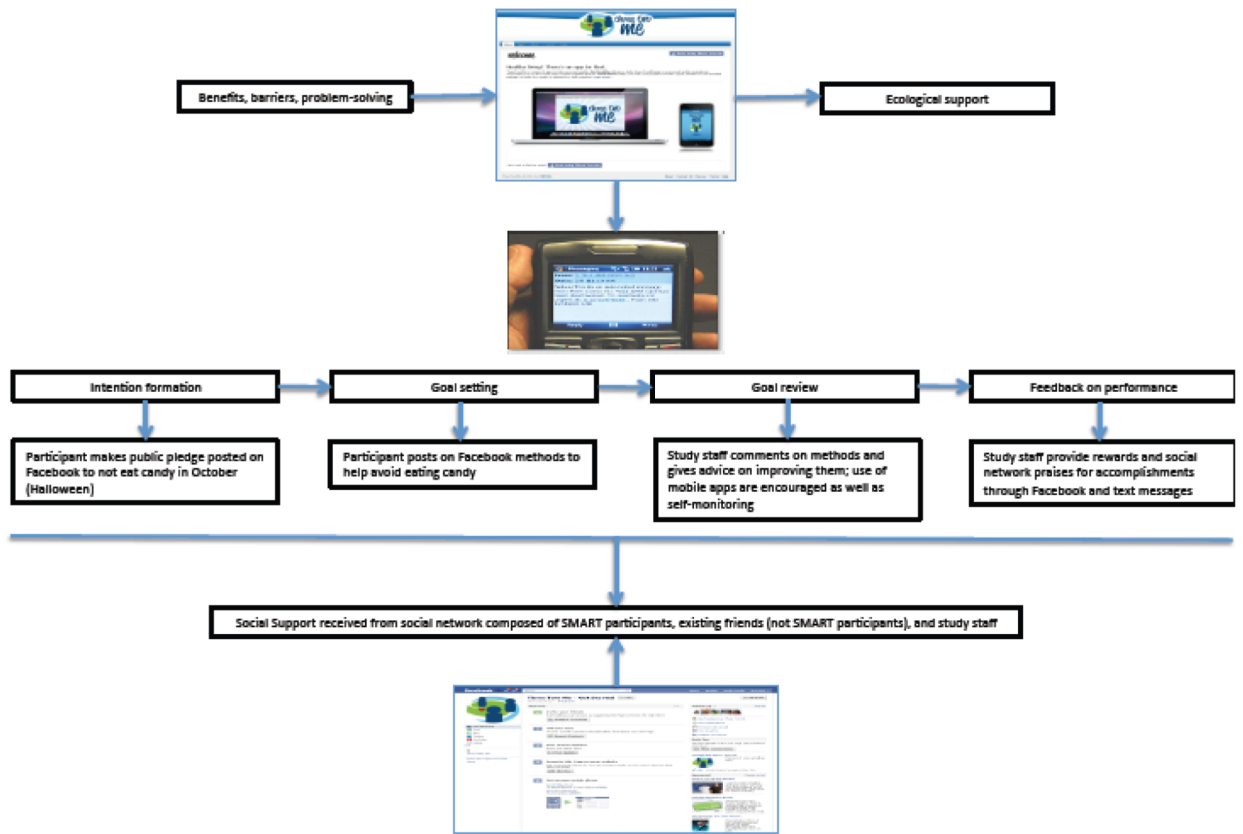
Figure 1.
Example of challenges supported by theoretical behavioral strategies in SMART
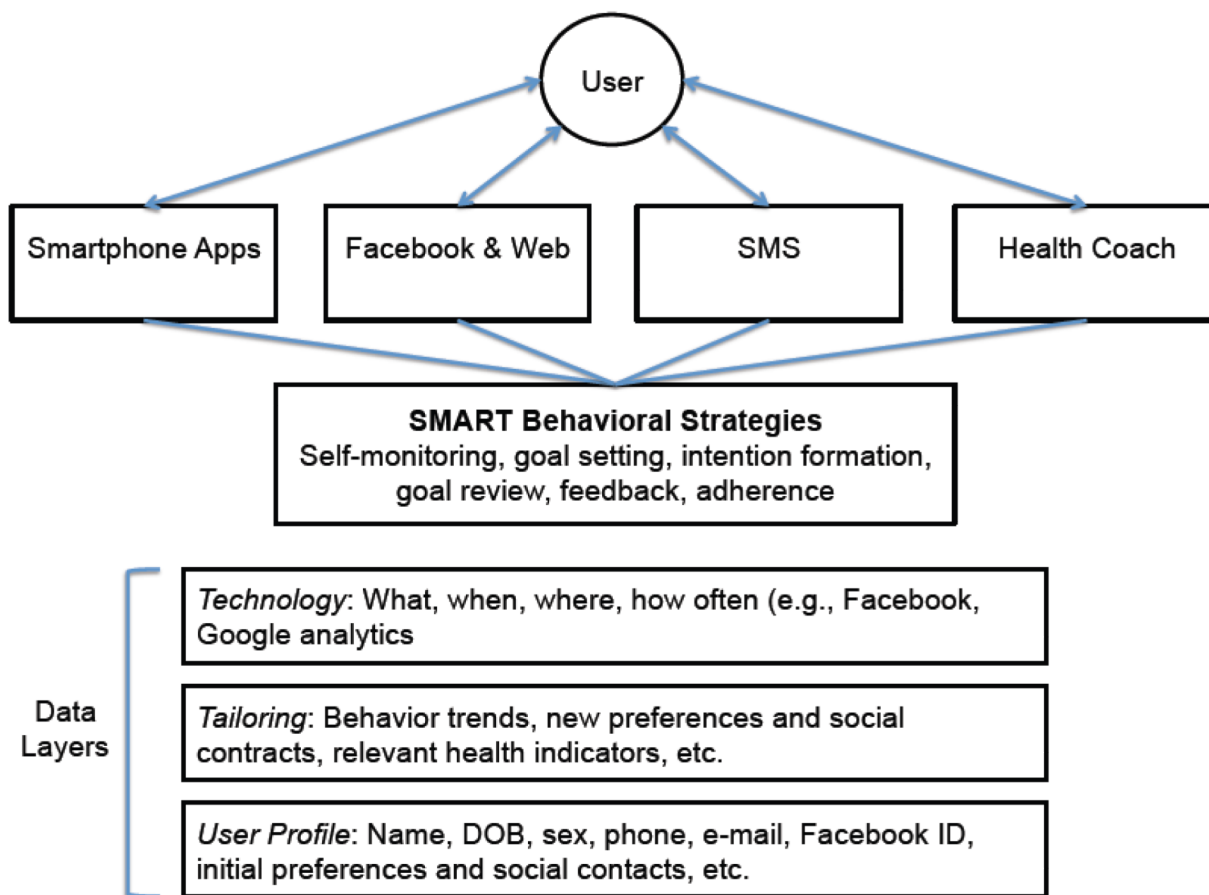
Figure 2.
Depiction of how the multiple SMART intervention elements link

Figure 3.
An example theory-driven app (Goal Getter) used in the SMART intervention

Table 1

Theory-based behavioral strategies supported by SMART intervention technologies/component

		SMART Technology	
Behavioral Construct	**SMART Website**	**Facebook Page & Apps**	**Mobile Phone**
Self-monitoring	Tracks trends	Promotes data input, tracking, and visualization	Tracks trends on-the-go either volitionally or prompted via SMS
Intention formation	Provides diet and PA information	Presents "willingness to try" challenges and goals	Provides on-the-go expert-system driven delivery of intention-based goals
Goal setting & goal review	Encourages goal setting and evaluates goal appropriateness	"Captures" goals and prompts SMART goal setting, and keeps them relevant	Provides on-the-go expert-system driven delivery of goals with updates
Feedback on performance	Tracks trends in evaluative feedback	Gives evaluative feedback and visualizations based on self-monitored data	Gives on-the-go evaluative feedback, either volitionally or prompted via SMS
Self-efficacy	Helps set realistic goals to increase confidence in outcomes	Helps with encouragement	Helps set realistic goals to increase confidence in outcomes on-the-go
Benefits, barriers & problem-solving	Increases knowledge about benefits	Provides suggestions to overcome barriers	Suggests behavioral alternatives on-the-go
Social support	Suggests/reminds how to find social support	Provides social support via Facebook page/blog	Provides social support via SMS
Ecological support	Suggests/reminds how to find ecological support	Provides real-time location-based prompts for diet and PA	Prompts real-time location-based support for diet and PA on-the-go
Tailoring	Collects tailoring information at baseline	Collects tailoring information	Collects tailoring information and provides location-based or expert-driven tailored SMS/MMS