SMART 2.0: Social Mobile Approaches to Reducing weighT in Young Adults

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Study Protocol and Statistical Analysis Plan

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RESEARCH PLAN

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1. PROJECT TITLE

SMART 2.0: Social Mobile Approaches to Reducing weighT in Young Adults

2. PRINCIPAL INVESTIGATOR

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3. FACILITIES

The Center for Wireless and Population Health Systems (CWPHS) and the Exercise and Physical Activity Resource Center (EPARC), located within the California Institute for Telecommunications and Information Technology (Calit2) at UCSD.

4. DURATION OF THE STUDY

The estimated duration of this study is February 1, 2019 – February 1, 2024.

5. LAY LANGUAGE SUMMARY OR SYNOPSIS (no more than one paragraph)

Weight gain and the retention of gained weight is an important issue for young adults. Throughout the transition from adolescence to early adulthood, young adults encounter multiple stressors and influences that can contribute to weight gain. In turn, weight gain leads to increased risk of cardiovascular disease, diabetes, and other health issues. Thus, there is a critical need to advance our understanding of how to develop and deploy multimodal, technology-based weight-loss interventions that have the potential for long-term effects and widespread dissemination among young adults. In the present study, we will test the impact of an intervention, SMART 2.0, designed to promote weight loss through increased energy expenditure, decreased energy intake, and adequate sleep among young adults in a university setting. Evidence and theory-based content in SMART 2.0 will be delivered using a consumer-level wearable and scale, text messaging, social media, and technology-based health coaching over the course of two years.

6. SPECIFIC AIMS

The primary aim of the study is to determine the efficacy of SMART 2.0 with technology and personal health coaching or with technology alone to improve objectively measured weight in kg over 24 months (96 weeks) compared to a control group.

Secondary aims will be to evaluate the following:

1. Anthropometric and physiological outcomes, physical activity, diet, sleep, self-esteem, body image, anxiety, depression, and the frequency and composition of participants' online communication about weight-related behaviors between groups at 6, 12, 18, and 24 months
2. The dose response (i.e., quantified engagement with technological modalities) of the intervention
3. The usability and acceptability of the intervention
4. Potential mediators and moderators of the intervention effects (e.g., social network connectivity, contamination, etc.)
5. Patterns of change in physical activity, diet, and sleep

Given that SMART 2.0 has been greatly enhanced by what we have learned from previous research, we hypothesize that both interventions will significantly improve weight compared to the control group, and the group receiving personal health coaching will experience the greatest improvement. We further hypothesize

that differences in secondary outcomes will favor the SMART 2.0 intervention groups. There is a critical need to advance our understanding of how to develop and deploy multimodal, technology-based weight-loss interventions that have the potential for long-term effects and widespread dissemination among young adults. SMART 2.0 is designed to maximize efficacy in a scalable manner. By measuring usability and acceptability, this study will inform intervention dissemination to campus wellness programs should the findings warrant it.

7. BACKGROUND AND SIGNIFICANCE

Overweight and obesity are major public health concerns in the United States[1,2]. Recent data from the Centers for Disease Control and Prevention indicate that the extent of this problem is great even among young adults, as approximately 60.3% of those 20 to 39 years old are overweight or obese (defined as a body mass index (BMI) ≥25 kg/m2).[3] Evidence shows that excess weight gain occurs most rapidly in young adults and is associated with future weight gain;[4-6] cardiovascular risk factors such as hypertension, dyslipidemia, and diabetes;[7] and psychological distress.[8] Additionally, more than half of young adults in the United States are enrolled in tertiary education,[9,10] and an estimated 40% of students are overweight or obese.[11] This represents a period of time when students undergoing the transition from adolescence to young adulthood often adopt unhealthy weight-related behaviors, such as decreased physical activity (PA),[12,13] poor diet quality (e.g., increased fast food consumption and decreased fruit and vegetable consumption),[13-15] and poor sleep hygiene.[13,16] Consequently, students typically gain a significant amount of weight while in school (meta-analyses estimate it is between 1.31 and 1.79 kg),[17-19] and there is a critical need for behavioral weight loss interventions that target this population.[17-19]

One potential strategy is to deploy interventions designed to promote weight loss through healthy changes in PA, diet, and sleep (an important behavior that is often overlooked in the study of weight loss)[20-23] via mobile and social technologies that are highly pervasive in the US. For example, approximately 86% of young adults own a smart phone and 75% of them use it to get information about their health.[24,25] Furthermore, ownership of activity trackers and smart watches that monitor health-related outcomes has more than doubled among all adults since 2014 (currently 49% own at least one device), and it is likely to continue increasing.[26] Social media use among young adults is also ubiquitous, with an estimated 90% using at least one platform regularly and no differences in use by sex or race and ethnicity.[27,28] Facebook remains the most popular platform and overall engagement is increasing, with approximately 70% using it daily.[28] Thus, instead of relying on regular in person interactions as weight loss interventions have traditionally done,[29-33] interventions can utilize the aforementioned technology-based modalities to meet students in the virtual spaces they frequently inhabit.[34,35] Given the highly variable schedules and time constraints associated with being a student, this approach may be more acceptable to college students than in-person approaches with limited flexibility and scalability.[36]

A recent systematic review shows that the vast majority of technology-based behavioral weight loss studies (76 out of 84) have been conducted exclusively among middle-aged and older adults.[37] Additionally, although the use of several modalities would allow for greater individual tailoring and exposure to intervention content, and would more accurately reflect the norm of using multiple technologies in daily life, 60.4% of interventions identified used only one modality, 33.8% two, 5.0% three, and only one used five.[37] Moreover, technology based behavioral interventions targeting weight loss were often lacking substantial theory- and evidence-based content,[35,38] and very few were implemented for longer than 18 months (13.9%).[37] Despite these shortcomings, on average, interventions achieved moderate weight loss (between -1.4 and -2.7 kg).[37] Thus, there remains a very clear need for studies that inform and implement long-term, multimodal, technology-based weight loss interventions that have the potential for enhanced effect sizes and widespread dissemination among college students.

Additionally, our multidisciplinary investigative team has extensive experience studying the efficacy of interventions that rely on ubiquitous technologies to meet young adults in the virtual spaces they frequently inhabit and use these venues to promote weight loss. The original SMART study was one of seven randomized controlled trials (RCT) comprising the Early Adult Reduction of weight through LifestYle intervention

(EARLY) trials, a consortium funded by the NHLBI (U01 HL096715; Principal Investigator (PI): Patrick; Co-Investigators (Co-Is): Godino, Calfas, Rock, and Weibel).[39-42] It was the only RCT in the consortium to integrate mobile and social technologies within the intervention.[39] In SMART, 404 overweight or obese college students (aged 18 to 35 years) from three universities in San Diego, CA were randomized to receive either the intervention (n=202) or general information about health and wellness (control group, n=202). The 2-year intervention was innovative primarily because it 1) was remotely delivered via 6 technological modalities (i.e., mobile apps, text messaging (SMS), Facebook, emails, a website, and brief ad-hoc technology mediated communication with a health coach) and 2) leveraged participants' existing as well as study engineered social networks to remotely deliver theory-based BCTs and evidence-based strategies for weight management (SWMs). The primary outcome was objectively measured weight in kg at 24 months, and differences between groups were evaluated using linear mixed-effects regression. Participants' mean (standard deviation [SD]) age was 22.7 (3.8) years. They were 70% female and 31% Hispanic. Mean (SD) body mass index 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 significantly less in the intervention group compared to the control group at 6 months (1.51%; -1.33 kg difference, 95% confidence interval (CI) = -2.36 to -0.30, p = 0.011) and 12 months (1.57%; -1.33 kg difference, 95% CI =-2.30 to -0.35, p = 0.008). However, differences between groups at 18 months (-0.67 kg difference, 95% CI = -1.69 to 0.35, p = 0.200) and 24 months (-0.79 kg difference, 95% CI = -2.02 to 0.43, p = 0.204) were not significant.[41]

Although the intervention was well-received (80.4% would recommend it to others), modalities were not fully integrated and engagement declined over time.[41,43] To better understand why engagement may have declined, we interviewed 38 participants (n=20 intervention; n=18 control) throughout the final months of the study.[43] Participants in both study groups reported using non-study designed, consumer-level devices and apps to help them meet their weight-loss goals (e.g., Fitbit and MyFitnessPal). Additionally, although Facebook emerged as the primary modality through which dynamic content was delivered at the group level and over half (56%) of participants had at least one Facebook friend in the study,[41,43] intervention participants expressed a desire for greater online interaction with other participants.[43] This finding aligns with our preliminary quantitative analysis of online communication about weight-related behaviors.[44] Specifically, intervention participants spoke more about PA and diet with their existing online social networks than did control participants. Furthermore, a 20% increase in social support for talking about PA and diet on Facebook (defined as likes and comments) was associated with a weight loss of 4.1 kg from baseline to 6 months among female participants. Taken together, these findings suggest that an intervention that incorporates popular consumer-level devices and apps, while also capitalizing on existing and study-engineered social networks, may be highly engaging to young adults.

The ConTxt study was an RCT that assessed the efficacy of a weight loss intervention delivered almost exclusively via SMS (NCI R01 CA138730; PI: Patrick; Co-Is: Godino and Rock).[45] The study built upon the success of an earlier 4-month trial of interactive SMS on weight outcomes,[46,47] and 298 overweight adults (aged 21-60 years) were allocated to one of three conditions: 1) a control condition; 2) SMS only; or 3) SMS+Health Coach (brief monthly phone calls). The SMS interventions offered 1-4 messages/day which were personalized and tailored using baseline SWMs and then reiteratively and interactively using ecological momentary assessment of PA and diet, goal setting and performance, and "like" or "unlike" messaging controls.[48] The primary outcome was objectively measured weight at 12 months, and differences between groups were evaluated using linear mixed-effects regression. Participants were 77% female and 41% Hispanic. At 12 months, weight was assessed in 253 (85%) participants, but all 298 were included in analyses. Compared to the control group, and controlling for baseline body mass index, the SMS only group lost 1.20% more weight (p = 0.214); and the SMS+Health Coach group lost 2.99% more weight (p = 0.003). Importantly, both SMS interventions were well received, and the results indicate that a weight loss intervention delivered via daily

individualized, dynamic, and interactive SMS was most efficacious when messages were combined with brief monthly communication with a health coach.[45]

Given that 1) the interventions in the SMART and ConTxt studies have evidence of short-term efficacy and can be merged because of their similar theory- and evidence-based content (i.e., BCTs and SWMs); and 2) there is evidence that the incorporation of consumer-level devices and apps along with increased social media and social network connectivity will enhance engagement, we believe that the proposed research is a logical, innovative, and important extension of our previous work.

8. RESEARCH DESIGN AND METHODS

Overview

The SMART 2.0 study is a 24-month (96 week) parallel-group randomized control trial designed to evaluate the efficacy of the intervention with technology and personal health coaching or with technology alone to improve objectively measured weight in kg over 24 months compared to a control group. We will recruit 642 overweight/obese young adults aged 18-35 at the University of California, San Diego (UCSD), San Diego State University (SDSU) and California State University, San Marcos (CSUSM) in San Diego. Participants will be assigned to one of three groups for a 24-month study period. The three groups include:

1. SMART 2.0 with technology, social media, and personal health coaching (T1)
2. SMART 2.0 with technology and social media alone (T2)
3. Control group

SMART 2.0 improves upon its predecessor by using a fully integrated system of modalities that includes 1) a popular consumer-level wearable activity tracker (Fitbit Charge 3), wireless scale (Aria Scale), and apps (Fitbit); 2) a highly tailored and interactive text messaging system (described in detail below) [45, 23]; 3) multiple social media streams including Facebook, Facebook Messenger, Instagram and Twitter, and 4) enhanced social network mechanisms of influence. Consumer-level devices and apps will be used to self-monitor behavior, and their data will be passively acquired in real-time. Algorithms will be used to automatically deliver interactive text messages to support individually tailored goal setting, performance feedback, and goal review in a highly dynamic style that reflects participants' behavioral progress towards achieving a minimum goal of 5% weight loss. Participants will be encouraged to share their data and behavioral progress with others via social networking tools built into the apps. Social network mechanisms of influence will be used both within the study-space, to elicit participant-to-participant and health coach-to-participant support, as well as outside the study-space, to invoke social support and accountability from strong ties known to be important for long-term behavior change.[49-52] Additionally, one group will receive monthly technology-mediated, real-time personal health coaching that is theory- and evidence-based.[53–56]

Subjects assigned to the SMART 2.0 with technology and personal health coaching treatment group (T1) will receive the following during the 24-month (96 week) intervention period: 1) Fitbit Charge 3 activity tracker and Aria scale, 2) daily text messages related to physical activity, diet, sleep and weight loss/maintenance, 3) access to SMART 2.0 social media pages and content through an online group with 6 to12 participants total, and 4) technology-mediated, real-time individual health coaching. Subjects will receive 1 to 2 text messages on a daily basis, be asked to use their Fitbit on a daily basis and self-weigh using the Aria at least once per week, be asked to interact with their online group via social media as frequently as possible, and speak with their health coach at a predetermined session schedule.

Subjects assigned to the SMART 2.0 technology alone treatment group (T2) will receive the following activities during the 24-month (96 week) intervention period: 1) Fitbit Charge 3 activity tracker and Aria scale, 2) daily text messages related to physical activity, diet, sleep, resilience and weight loss/maintenance, and 3) access to SMART 2.0 social media pages and content through an online group with 12 participants total.

Subjects will receive 1 to 2 text messages on a daily basis, be asked to use their Fitbit on a daily basis and self-weigh using the Aria at least once per week, and be asked to interact with their online group via social media as frequently as possible.

Subjects assigned to the control group will simply receive a Fitbit Charge 3 and Aria scale to use at their discretion.

Theoretical Framework and Rationale

Unlike many technology-based interventions wherein theory has only been used superficially,[35] the SMART 2.0 intervention content is mapped directly onto theory-based behavioral change techniques (BCTs). Specifically, the intervention is informed by Abraham and Michie's taxonomy of 93 distinct BCTs clustered into 16 domains.[57] Meta-analysis of 122 evaluations of interventions that targeted healthy changes in PA and diet revealed that the most effective BCTs were self-regulatory and included intention formation, goal setting, self-monitoring, feedback, and goal review.[58] Therefore, content supporting these will be delivered via all modalities, along with content supporting BCTs that target social network mechanisms of influence (e.g., social support, comparison of behavior, restructuring the social environmental, etc.). All BCTs included in the intervention will be classified prior to delivery and the specific features of a given modality will determine which are best delivered via a given modality. We acknowledge that participants will vary in the frequency and depth of their utilization of BCTs across modalities. Our ability to measure this variation is a strength. Table 1 provides examples of how these will optimally be delivered.

Intervention content will also be derived from the strategies for weight management (SWMs), which comprise 35 of the most common evidence-based approaches to achieve weight loss (e.g., reduce portion sizes, avoid processed foods, eliminate sugar sweetened beverages, etc.). The SWMs were successfully integrated into previous studies showing efficacy, and our team has published two papers on the psychometric characteristics of the SWM questionnaire.[59,60] Additional intervention content is drawn from comprehensive lifestyle interventions that teach stimulus control, problem solving, time management, stress management, etc.[61,62] Overall, our approach to the delivery of theory- and evidence based content in SMART 2.0 is flexible and lends itself well to complex and adaptive technology-based interventions that are responsive to an individual's behavioral progress and ever-changing context.[62-65] We do not have a single overarching theoretical framework, rather the intervention content reflects numerous theoretical orientations (e.g., operant conditioning,[66] theories of social comparison,[67] theories of social support,[68] ecological theory,[69] etc.). This represents a strength of our approach.[62-65]

Table 1. Examples of how intervention content will be delivered in SMART 2.0

Content	Modalities	Description of Delivery
Intention formation and goal setting	Health coaching/ email, SMS, social media/ online groups	- Health coach will facilitate long- and short-term goal setting with participant during each session followed by an email summary of goals made. - Activity, dietary, and weight data collected by Fitbit and Aria scale will prompt tailored weekly goals disseminated via SMS. - Health coach will moderate online group discussion so that each group develops and works toward goals. In turn, the health coach will post social media content tailored toward each groups' goals.
Self-monitoring	Fitbit, Aria scale, SMS, social media	- Participant monitors physical activity, sleep, and diet with Fitbit and Fitbit app and weight with Aria scale. Ongoing self-monitoring is supported by prompts and reminders via SMS and social media.
Feedback	Health coaching, Fitbit/ Fitbit app, Aria scale, SMS,	- Health coach will provide feedback on participant's progress toward reaching his/her individual goals. - Feedback is provided in real time on devices and in Fitbit app.

	social media/ online groups	- A data driven automated SMS containing a summary of individual progress toward reaching tailored weekly goals is sent along with a message of encouragement or positive reinforcement. - Participant posts about progress and/or challenges on social media and in online group and receives feedback from their social network, other participants and health coach.
Goal review	Health coaching, SMS	- During health coaching sessions, participants will discuss goals and barriers and facilitators for achieving them. - Automated SMS will be sent suggesting a new goal and providing feedback.
Social support and comparison of behavior	Health coaching, SMS, social media/ online groups	- Health coach will provide social support during sessions and suggest ways in which participant can seek out support. - General SMS content will contain ways in which participants can leverage social support in order to reach activity and weight goals. - Participant is directly connected to other participants in structured online groups that will provide positive reinforcement and encouragement in response to participant's posts about weight loss progress.
Restructuring the social environment	Social media/ online groups	- Social media and online groups are used to encourage participants to plan exercise dates or go grocery shopping together
Restructuring the physical environment	Social media/ online groups	- Information about where to exercise, eat well and seek mental health resources on campus sent via social media and online groups

Description of the Weight Loss Intervention

In the SMART 2.0 study, participants of both treatment groups (T1 and T2) will be encouraged to set a minimum weight loss goal of 5-10% of their baseline weight. Additionally, participants will be encouraged to lose 1-2 lbs/wk[70] until they reach a BMI at or below 25 kg/m. Once a participant reaches a BMI ≤ 25 kg/m^2 the goal will be to maintain their weight loss.

The primary behavioral goals of the weight loss program relate to physical activity, diet, and sleep:

1. Physical activity goals: Consistent with recent evidence-based recommendations for physical activity for weight loss[71], participants will be prescribed stepped physical activity goals per week starting at their baseline exercise minutes building to 225 active min/wk, as measured by the Fitbit activity tracker. Consistent accumulation of 225-420 min/wk of moderate and vigorous physical activity (MVPA) is associated with 5-7.5kg weight loss[71]. To calculate baseline physical activity minutes, participants will be instructed to wear their Fitbit for the first week of the intervention with no physical activity goal. The amount of MVPA for each participant during their first week of the intervention will be calculated and used as their individual baseline. Weekly physical activity goals will be stepped from each participant's baseline levels using a conservative progression of 20 minutes per week from the previous week's minutes of MVPA. This progression will continue until a participant reaches an average of >=225 min/wk of MVPA and 5% weight loss. Once a participant reaches both MVPA and weight loss goals, the physical activity goal will be to maintain at least 225 min/wk of MVPA to prevent weight regain. The weekly progression was chosen to maximize adherence and reduce the risk of discomfort and musculoskeletal injury. Physical activity accumulation will be encouraged across multiple domains (leisure, transportation, lifestyle, etc.) and in bouts lasting at least 10 minutes.
2. Dietary recommendations: Consistent with the 2015-2020 Dietary Guidelines for Americans and evidence-based recommendations for weight loss[72], participants will be prescribed to reduce energy intake by at least 500 kcal per day, consume a variety of nutrient-dense foods, and to limit caloric consumption from added sugars and saturated fats. Energy restriction of 500 kcal/d is associated with weight loss of approximately 0.5-0.9 kg/wk (1 pound/wk)[72].Once a participant reaches a BMI ≤ 25 kg/m^2 the goal will be for their caloric consumption to match their caloric expenditure to support weight maintenance.

3. Sleep recommendations: Consistent with the NHLBI recommendations of sleep duration for adults[73], participants will be prescribed stepped sleep duration goals per week starting at their baseline sleep duration building to a minimum of 7 hours of sleep per night, as measure by the Fitbit activity tracker. Sleep is an important behavior that is often overlooked in the study of weight loss [20-23]. Additionally, less sleep is associated with a greater likelihood of overweight/obesity and the consumption of high-caloric foods. To calculate baseline sleep duration, participants will be instructed to wear their Fitbit for the first week of the intervention to bed at least four nights each week. The average nightly sleep duration for the week will be calculated and used as their individual baseline. Weekly sleep duration goals will be stepped from each participant's baseline levels using a progression of 20 min/wk from the average of the previous week's nightly sleep duration. This progression will continue until the participant reaches an average of ≥ 7 hours of sleep per night where then the sleep duration goal will be to maintain an average of at least 7 hrs of sleep per night.

Intervention Components

The intervention will be delivered using our four principal intervention modalities: (1) consumer-level wearable and scale (Fitbit Charge 3 and Aria Scale), (2) mobile text messages, (3) online social media pages and groups, and (4) individual health coaching (T1 only). Modalities will incorporate the theory-based behavioral change techniques (BCTs) and strategies for weight management (SWMs) mentioned in Table 1.

Consumer-level wearable and scale: Fitbit Charge 3 and Aria Scale

Figure 1. Fitbit Charge 3

A Fitbit Charge 3 (https://www.fitbit.com/charge3) and Fitbit Aria 2 scale (https://www.fitbit.com/aria2) will be provided to all participants in the study. The Fitbit Charge 3 is not considered to be a medical device or a significant risk device. It is made of flexible, durable elastomer material similar to that used in many sport watches, and it has a surgical grade stainless steel buckle. It is lightweight (1.06 oz), 0.5 inches wide, and fits wrists that are 5.4 to 8.7 inches in diameter. It contains a triaxial accelerometer, an optical heart rate monitor, an altimeter, and a vibration motor.

All participants will have the ability to monitor physical activity, sleep and diet with the Fitbit Charge 3 and weight with the Aria scale. Additionally, participants in both intervention groups (T1 and T2) will receive feedback on physical activity, sleep, diet activity, and weight collected through these devices via SMS messaging, as described in the following section.

Data from the devices will be passively and securely streamed to the Fitbit website. It will then be retrieved using software developed by Small Step Labs, LLC and Fitabase Inc (https://www.fitabase.com) and stored securely on their servers. All data that is subsequently downloaded from Fitabase Inc. servers for analytic purposes will remain de-identified and will be stored on secure, password-protected CWPHS/EPARC servers. There are two instances when researchers will contact Fitabase Inc. in order to delete data associated with participants in this study: 1) anytime that a participant chooses to withdraw from the study and 2) at the completion of the study (when all data analysis has been completed). Researchers will contact Aaron Coleman, CEO of Small Step Labs, LLC and creator of Fitabase (aaron@fitabase.com) and he will initiate a deletion of the data from live servers and all data will be phased out of offline backups within 90 days. After 90 days Small Step Labs will have no data associated with the study on their servers.

SMS Component

Participants of both treatment groups (T1 and T2) will receive a behavioral weight loss messages through 1 to 2 tailored SMS daily. The messages will follow the same four-week format, detailed in Table 3, but will incorporate more advanced content and goals as the intervention progresses. This will be dependent on participants weight loss progress and progress in meeting weekly physical activity, dietary and sleep behavior goals. Tailored SMS messages will require participants to use all five core self-regulation strategies: self-monitoring, feedback on performance, behavioral intention formation, goal setting, and goal review.

Table 3. Four-week schedule of text messages to be delivered in SMART 2.0 Intervention

Week #	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
1	Sleep Feedback & Sleep Tip	Exercise Feedback	Monthly Diet Feedback & Diet Tip	Weight Feedback & Weight Tip	Diet Tip	Mid-week Exercise Feedback & Exercise Tip	Resilience Tip
2	Sleep Feedback & Sleep Tip	Exercise Feedback	Diet Tips (2)	Weight Feedback & Weight Tip	Diet Tip	Mid-week Exercise Feedback & Exercise Tip	Resilience Tip
3	Sleep Feedback & Sleep Tip	Exercise Feedback	Mid-month Diet Feedback & Diet Tip	Weight Feedback & Weight Tip	Diet Tip	Mid-week Exercise Feedback & Exercise Tip	Resilience Tip
4	Sleep Feedback & Sleep Tip	Exercise Feedback	Diet Tips (2)	Weight Feedback & Weight Tip	Diet Tip	Mid-week Exercise Feedback & Exercise Tip	Resilience Tip

We will deliver SMS messaging using our previously developed text message system for weight loss and weight management. Based on data collected from a participant's use of Fitbit and Aria Scale, we will push tailored text messages from our SMS library (> 3000 messages). Messages will be time-based (e.g., occur at convenient time for participant every day) or data-based (e.g., in response to data collected from Fitbit and Aria). Most messages will be directly related to the participant's weekly weight, physical activity, caloric intake and sleep goals (tailored messages) and some will be general behavioral change strategies, depending on weekly behavioral goals. Messages based on weight, physical activity, caloric intake and sleep will be in response to data received from participants' use of Fitbit and Aria. For example, after weighing themselves, a message will be sent praising the participant for losing 2 pounds. Additionally, after a participant reaches a BMI < 25 kg/m^2 goals related to weight, caloric intake and physical activity will be automatically adjusted to reflect weight maintenance. For example, if a participant records a caloric intake that is equal to their caloric expenditure, their diet feedback will praise the participant and suggest continued caloric intake to maintain their healthy weight.

A sample of a week of text messages to the user are in Table 4. Participants will receive 1-2 messages each day and will be able to choose the timing of messages (e.g., mornings and evenings).

Table 4. Example of weekly text messages to be used in SMART 2.0 intervention

Day of the Week	Timestamp	Message Type	Message
Sunday	12pm	Sleep Feedback	You reached your weekly sleep goal by getting an average of 6 hrs 30 min a night. Keep it up and try to get in 6 hrs 50 min per night. Make sure to

			wear your Fitbit for at least 4 nights to get a better picture of your sleep patterns this week.
Sunday	7pm	Sleep Tip	Sleep tip: Try reading from a book or using a blue light filter on your laptop/phone when studying or reading before bedtime.
Monday	12pm	Exercise Feedback	Good work getting in 110 active minutes last week. But, your goal was to complete 140 minutes. Try to set a new goal of 130 minutes for this week. You can do it!
Tuesday	12pm	Diet Feedback	Terrific job tracking your calories this month. On average, you are eating as much as you burn. To lose 1 lb, you should be in a deficit of 500 calories per day. Continue to make progress by tracking consecutively for 3 days this month!
Tuesday	7pm	Diet Tip	When you're at the grocery store, make the healthiest choice by reading food labels and comparing calories per serving size. When in doubt, choose the option with less calories.
Wednesday	12pm	Weigh Reminder	Wednesday Weigh-day reminder! Time to step on the scale and see what progress you've made.
Wednesday	1pm	Weight Feedback	Great work! This week, you lost 1.5 lb(s). You got this! This week, your goal is to lose another 1-2 lbs.
Wednesday	7pm	Weight Loss Tip	A good way to stay away from food temptations is to be active. Next time you're craving something, go for a run or swim!
Thursday	12pm	Diet Tip	Eventually aim towards having only healthy items stored in your pantry and fridge! Do this by slowly getting rid of unhealthier items and replacing them with better-for-you alternatives.
Friday	12pm	Exercise Feedback	You're more than half way there! Good job getting to 90 active minutes so far. Your goal is to get 130 minutes by Monday, keep on going!
Friday	7pm	Fitness Tip	Do whatever makes exercise most enjoyable for you. Music? A podcast? You are much more likely to exercise consistently if you enjoy it.
Saturday	12pm	Resilience Tip	It's Saturday and time to release some stress! Press two fingers in the center of your other palm and hold for ten seconds.

Online Group/ Social Media

After randomization, participants in T1 and T2 intervention-arms will be sorted by physical activity preference and placed in groups of 6 to 12 total participants through Facebook messenger. Current literature suggests that small, mixed-gender groups constructed based on a common characteristic (e.g. physical activity preference) result in improved outcomes in health interventions[74,75].

Each participant will "friend" the study health coach on Facebook, who will then add participants to their respective, private groups on Facebook Messenger. Content shared in the groups will only be accessible to the members of each group and the health coach. The health coach will post content and facilitate group discussion that follows a behavioral weight loss curriculum organized as a series of 24-week (6-month) cycles. Table 5 summarizes the content for the first 6-month cycle. Each subsequent cycle will follow the same format but will incorporate more advanced content and goals, dependent on group's progress. Health coaches will also monitor all group interactions, respond to inquiries from participants, and elicit interactions using the following group-coaching methods:

1. *Mission statement formation:* Health coaches will work with group members at start of intervention (week 1) to establish ground rules and roles for participants and health coach. This mission statement will be revisited every 6-months and revised as necessary.
2. *Informational content and resources:* Health coaches will provide relevant informational content and resources applicable to the weekly curriculum topic as well as the group's interests, recommendations

and goals. This includes, but is not limited to, local bike/running maps, healthy eating options on or near campus, recipes and exercise routines.

3. *Knowledge check-ins:* Health coaches will frequently assess group knowledge of weekly curriculum topics through polls and Q&A's. The intent is to give participants an opportunity to ask the health coaches questions relevant to weight loss and health behaviors.
4. *Shared experiences:* To elicit group cohesion and social support, health coaches will present open-ended questions designed to encourage participants to share their experiences with adopting and maintaining health behaviors and reaching personal weight loss goals. For example, a health coach may ask the group to share their favorite on-the-go healthy snack option.
5. *Goal-setting:* Through motivational interviewing techniques[55,56], health coaches will work with participants to create individual and group goals relating to the week's topic area and overall weight-loss goals. Additionally, health coaches will provide feedback on individual and group progress on meeting set goals.

Table 5. The SMART 2.0 behavioral weight loss curriculum

Week	Weekly Topic	Example
1	Intro to SMART 2.0	Building a roadmap of the program; modalities/technology; 6-month and 2-year goal-setting
2	Self-monitoring	Tracking calories with Fitbit; Checking sleep stats and active minutes using the Fitbit app; Weekly weighing
3	Understanding diet and calories	2015-2020 Dietary Guidelines; calories; reading food labels; visual calorie comparisons
4	Boosting active minutes	Strategies for increasing active minutes each day; fitting in exercise with a busy schedule; exercise routines you can do anywhere
5	Getting and staying healthy on campus	Healthy guide to each campus; meeting goals with a busy class/work schedule; dorm/apartment/commuting healthy living tips
6	Eating healthy made easy	Easy recipes you can make anywhere; recipe videos; grocery-list guide
7	Take 10 to exercise	Short breaks in sitting; environmental rearrangement; how-to get in 10-min bouts of exercise throughout your day
8	Sleep and mental health	Sleep hygiene tips; stress management tips
9	Portion control & smart food options	Skills for portion control; choosing and finding low-calorie; nutrient-dense foods
10	Organization & planning	Meal and exercise planning; suggestions for healthy cooking; exercise routines; creating a bedtime routine
11	Social support	How to get support for a healthy lifestyle; importance of mental health in getting healthy; fostering group support
12	Personal strategies for weight loss behaviors & problem solving	Reviewing 3-month progress; seeing what works; identifying barriers and solutions
13	Cardiovascular exercise	Cardio for any fitness level; gauging intensity and setting goals for progress; safety tips; get a buddy
14	Substitution & replacement	Healthy swaps; "eat this not that"; ways to make any recipe healthy
15	Strength training for a healthy body	Benefits of resistance training; sets/ reps; safety; getting a buddy; home- and gym-based calisthenics
16	Eating out, on-the-go & convenience food eating	Becoming menu-wise; indemnifying healthy options on- and off-campus; stimulus control; becoming aware of what is in the environment
17	Taking charge of your thoughts	How to replace harmful thoughts with helpful thoughts; link between negative affect and weight (re)gain
18	Managing social eating situations	Alternatives and tips for social eating (counter conditioning)
19	Healthy eating on a budget	Learning to make smart, but cost-effective food choices when eating out or shopping at grocery store
20	Getting enough sleep	Ways to get enough sleep with time constraints; Importance of sleep for overall health and weight loss/management
21	Vigorous intensity physical activity	Benefits of VPA; gauging intensity; safety; how to get VPA anywhere

22	Have healthy food you enjoy	Brainstorm enjoyable, healthy options; switching up your meal plan to stay on track
23	Staying active	Tips to stay active while on break/vacation and with schedule constraints; ways to get back on track with exercise
24	Maintaining a healthy lifestyle	Reviewing 6-month progress; seeing what works; identifying barrier and solutions; 6-month goal-setting; planning for next 6-month cycle

In addition to online groups, the health coach will also post general content related to weight loss/management, physical activity, healthy eating, sleep and resilience to the study's various pages on the following commonly used social media platforms[76]: Facebook, Instagram and Twitter. Participants will be required to at least "like" the SMART 2.0 Facebook page and will be encouraged to also "follow" the study's Instagram and Twitter accounts. By "liking" and "following" these respective pages, SMART 2.0 content will appear on their individual social media feeds and participants will be able to "like" and "comment" on each post, communicate with other participants through each post, and "save" any content.

Health Coaching

Participants randomized into the T1 intervention arm will receive individual technology-mediated, real-time personal health coaching that is theory- and evidence-based. Health coaching sessions will consist of components of effective health coaching interventions including motivational interviewing (MI), participant determined behavioral goal setting, accountability for behaviors, and health education as part of an active learning process[77-79]. Additionally, the health coach will utilize behavioral change techniques (BCTs) appropriate for individual coaching [80,59]. These BCTs include goal setting (behavior and outcome), action planning, problem solving, feedback on behavior, social support and instruction on how to perform a behavior[80]. All health coaches will have Master-level training in public health and at least two years' experience with individual health coaching. Sessions will last 10-15 minutes and will take place over the phone and/or through Google/Facetime/Skype/Zoom video-calls, depending on each participant's preference. Following each session, the health coach will send a session recap via e-mail that includes an outline of what was discussed, summary of behavioral and weight loss goals, and date/time of next session.

During year one of the intervention, the health coaching curriculum will follow the CDC's Prevent T2 Lifestyle Change Program (https://www.cdc.gov/diabetes/prevention/index.html). The Prevent T2 program's goals include weight loss of 5-7% of participants' baseline weight in the first six months and continued weight loss until participants reach their goal weight. Prevent T2 is a year-long program with curriculum outlined in Table 6. The program emphasizes self-monitoring, self-efficacy, and problem solving and requires weigh-ins at each session and the self-monitoring of diet and physical activity. Health coaches will receive this feedback digitally through the Fitbit activity tracker and Aria scale. Health coaches will cover the curricula provided by the CDC during each session and will provide participants with the respective CDC handouts via e-mail prior to each session. The Prevent T2 session topics and curriculum has been tailored for the intervention (e.g., replacing in-person group-based activities with related discussion topics) and for the young adult population (e.g., discussing causes and ways to mitigate stress applicable to participants' lifestyles, such as during finals). Table 6 outlines the original Prevent T2 topics, SMART 2.0 topic revision and an outline of content in each session.

Table 6. The SMART 2.0 health coaching curriculum, year one

Session Number	Session Frequency	T2 Original Topic	SMART 2.0 Revision	Content Outline
1	Weekly	Introduction to the program	Intro to SMART 2.0	Participant's motivations/reasons for joining; set short- and long-term weight/PA/diet/sleep goals
2		Track your food	Using Fitbit to track calories	Benefits of tracking; Fitbit tracking how-to; portions & food labels

3		Track your activity	Using Fitbit to track active minutes	Benefits of tracking; Fitbit tracking how-to; review baseline activity data
4		Manage stress	Stress and tracking sleep with Fitbit	Sources of stress; link between stress and sleep and weight; stress and sleep tips
5		Eat well to prevent T2	Eating well basics	Dietary guidelines; tips
6		Get active to prevent T2	Getting started getting active	Benefits of PA; ways to get PA; challenges/ barriers
7		Burn more calories than you take in	Balancing what you eat and do	Caloric deficit and weight loss
8		Shop and cook to prevent T2	Meal planning 101	Planning and preparing healthy meals
9		Get more active	Get more active	Ways to increase active minutes
10		Cope with triggers	Navigating triggers to eat unhealthily (social pressure)	Overcoming triggers to eat unhealthily; reducing social pressures
11		Find time for fitness	Find time for fitness	Challenges and solutions to finding time to exercise
12		Keep your heart healthy	Maintaining a healthy lifestyle	3-month review; progress/challenges so far; develop solutions
13		Take charge of your thoughts	Take charge of your thoughts	Mental health; helpful versus harmful thoughts
14		Get support	Social support	How to get social support from family/friends/etc. to lead healthy lifestyle
15		Eat well away from home	Eating well while eating out & on-campus	Challenges and solutions to eating well away when dining out and on-campus
16		Stay motivated to prevent T2	Staying motivated	Ways to stay motivated to exercise, eat well, and sleep
17	Bi-weekly	When weight loss stalls	Weight loss progress/ plateaus	Ways to overcome weight loss plateaus and to continue to lose weight
18		Get enough sleep	Sleep hygiene	Benefits of adequate sleep; challenges and solutions to getting at least 7 hours
19		Stay active to prevent T2	Staying active	Challenges and solutions to staying consistent with PA
20		Have healthy food you enjoy	Eating healthy on a budget	6-month review; ways to eat healthy on a budget
21	Monthly	More about T2	General health information	Participant guided – work on areas where there are the most challenges
22		Take a fitness break	Quick exercise ideas	10-minute exercise ideas; ways to stay active with any schedule
23		Stay active away from home	Staying on track while on break/ vacation	Challenges and solutions during school breaks/ vacations
24		More about carbs	More about macronutrients/ nutrient-density	Macronutrient information; benefits of nutrient dense foods
25		Get back on track	Get back on track	Staying positive after getting off-track; 5 steps to problem solving
26		Prevent T2 for life	Continuing progress in year two of SMART 2.0	1-year goal review; progress/challenges so far; action plan for year 2

During year two of the intervention, participants will continue with monthly 15-20-minute sessions with the health coach. Sessions will be guided by participants' unique behavioral goals, rather than predetermined topics as in year one. Each session will also consist of effective health coaching components[77,79] and BCTs[80].

Comparison Condition

The comparison condition will also receive a Fitbit Charge 3 and Aria Scale to use at their discretion. This will allow participants to access the Fitbit smartphone application which includes physical activity, dietary and sleep tracking.

The study is implementing mechanisms for preventing comparison group subjects from accessing the intervention components of the SMART 2.0 study. For example, tailored content, goal and behavior feedback, and participant-to-participant and participant-to-health coach interactions will be reserved only for private, invitation-only online groups for participants in the two treatment groups.

Standardizing Delivery of the Intervention

The SMART 2.0 intervention is comprised of four inter- and independent components: 1) Fitbit Charge 3 and Aria scale, 2) mobile text messages, 3) online social media pages and groups, and 4) individual health coaching (T1-arm only). We will standardize the delivery of the intervention using the following four strategies.

1. Intervention content will be delivered using all components throughout the intervention.

- To reduce the possibility of bias caused by the changing dominance of an intervention delivery component, the SMART 2.0 will use all platforms throughout the two-year intervention. Although exposure to each platform is expected to differ (for example, some participants may prefer to interact more so via the online group than mobile text messages), we plan to "push" all platforms equally.
- To reduce bias that may be caused by differential access to mobile technology (e.g., use of a smart phone vs. regular cell phone that receives text messages only), all participants will be required to own a smart phone, as part of the study's inclusion criteria, to ensure accessibility to all intervention components.

2. Ground all intervention content in common theory-driven principles of behavior change.

- The SMART 2.0 intervention is grounded in theory-driven principles of behavior change. Successive iterations of the social and mobile content will be rigorously evaluated for adherence to the theoretical principles described above. New content that deviates substantially from these principles or does not contain at least one behavioral self-regulation strategy will not be delivered.

3. Standardize intervention fidelity by using technology-mediated content delivery through mobile text messaging and online social media pages and groups and conducting regular fidelity-checks on health coaches' interactions with participants via online groups and individual coaching sessions.

- All content delivered via mobile text messaging and through online social media pages and groups will be standardized so that each participant in the intervention arms (T1 and T2) will receive the same content and feedback on Fitbit activity and Aria weight data.
- Health coach interactions with participants through online groups will be regularly checked to standardize intervention fidelity. This will be done by audio-recording a random sample of 5% of all health coaching calls and having an independent reviewer on the study team observe to ensure that

health coaches uniformly utilize BCTs including goal setting, feedback on behavior, and social support, when responding to participants and moderating discussion. Additionally, the use of each BCT will be recorded to measure each participants' dose.

- To standardize health coaches' interactions with participants through individual coaching sessions (T1-arm only), we will aim to deliver the same amount of sessions for each participant and conduct regular and random fidelity checks. Each participant will be prescribed the same number of sessions (26 in year one, 12 in year two) and sessions will be scheduled at a day and time convenient for the participant. In the event that a session is missed, the session will be rescheduled, if possible. If rescheduling is not possible (e.g., no other available days/times before next allotted session), the health coach will send session materials to the participant via e-mail and suggest session goals based on participant's weight loss progress. Each completed session and e-mail will be recorded to measure participants' dose. For the two-year intervention, the fidelity checks will ensure adherence to health coaching components and BCTs described above. For year one of the intervention, the checks will also ensure adherence to the modified Prevent T2 curriculum.

4. Intervention content will be tailored to how well participants are doing with their weight loss.

- Baseline physical measurements, collected at the first measurement visit, and baseline behavioral measures, collected through Fitbit activity trackers during the first week of the intervention, and ongoing physical and behavioral measures collected through Fitbit activity trackers and Aria scales will be used to reiteratively tailor the program's offerings. For example, if participants are making good progress then the intervention content delivered will acknowledge and reward this. If, on the other hand, if participants are finding it difficult to lose weight and adhere to healthy behaviors, alternative messaging with different content designed to encourage progress specific to each participant will be provided.

Measurement Overview and Schedule for the RCT

All participants will attend in-person measurement visits at baseline, 6, 12, 18 and 24 months. To maximize the likelihood that participants will continue with measurement visits and stay in the study, we will offer financial incentives for attending measurement visits and these will increase over time. All measures will be conducted at EPARC. Participants from SDSU and CSUSM will reimbursed $15 for travel expenses. The baseline measurement is expected to take approximately 3 hours and all other measurement timepoints are expected to take approximately 2 hours. Measures and collection time points are summarized below.

Demographic information

Age, sex, ethnicity, race, household income, tobacco and alcohol use, and medical history will be measured through self-report.

Anthropometric and Physiological Measures

- **Body weight** will be measured to the nearest 0.1 kilograms using a calibrated digital scale. **Height** (without shoes) will be measured to the nearest 0.1 cm using a stadiometer with the subject standing erect against a wall with heels close to the wall. Both weight and height will be measured with participants wearing lightweight clothes but without shoes, and two separate measurements will be averaged. **Body mass index (BMI)** will be calculated from the height and weight as kg/m^2. Seca703 (Seca GmbH & Co.

KG., Hamberg, DE), a combined digital scale and stadiometer, will be used for body weight and height measurements.

- **Waist, arm, and hip circumference** will be measured following standardized procedures implemented by trained staff. Waist circumference will be measured from the approximate midpoint between the lower margin of the last palpable rib and the top of the iliac crest. Hop circumference will be measured from the widest portion of the buttocks. Arm circumference will be measured from the approximate midpoint between the acromion process and the olecranon process. Waist, hip, and arm circumference will be measured to the nearest 0.1 cm using a stretch resistance measuring tape and two separate measurements of each will be averaged.
- **Blood pressure** and **heart rate** will be measured by a trained staff with a digital monitor (Critikon Dinamap 8100, GE Healthcare, Chalfont, UK). Two measures of blood pressure and corresponding measures of heart rate will be averaged. After 5 minutes of rest in a seated position, two consecutive measurements will be taken at 1-minute intervals from the right arm with the forearm supported on a table. If measurements of systolic and diastolic pressures differ by more than 10.0 mmHg or 6.0 mmHg, respectively, then a third measure will be taken and the average of the two measures that differ by less than 10.0 mmHg or 6.0 mmHg, respectively, will be taken. Heart rate variability will be measured from an electrocardiogram recording taken with a Biopac MP150 system (Biopac Systems Inc., Goleta, CA). After 10 minutes of rest in a supine position, 5 consecutive minutes of recording will be taken and data will be processed using AcqKnowledge version 4.0 or later (Biopac's proprietary software platform). This is an important measurement, because it is marker of autonomic nervous system function which is influenced by PA, diet, and sleep; alcohol, tobacco, and drug use; and anxiety,[81] and it is a marker of cardiorespiratory fitness.[82]
- **Body composition** and **bone density** will be measured with **Dual-energy X-ray Absorptiometry (DXA)**. Bone density scans of the anterior-posterior (AP) spine (L1 – L4), hip, forearm, and total body will be conducted on all participants. Total body and regional (arms, legs, trunk, and abdomen) body composition (fat mass, including an estimate of visceral adipose tissue, and lean mass) will be assessed by DXA on a Lunar Prodigy Advance densitometer (GE/Lunar Corp, Madison, WI) or a Horizon DXA system (Hologic Inc., Marlborough, MA). Quality assurance (QA) tests will be performed each morning of use. QA will be conducted using a standard with tissue-equivalent material with 3 bone-simulating chambers of known bone mineral content. In vivo BMD precision in our laboratory is 1.05% for the spine, 0.805% for the total hip, 0.85% for total body BMD, 1.46% for fat mass and 0.55% for lean tissue mass. The time required for this assessment is approximately 20-25 minutes; actual scan time is <15 minutes. Scans will initially be interpreted by state-certified DXA technicians. The minimal radiation dose is safe and appropriate for a pediatric population, and an experienced technician certified by the state of California will conduct all scans. Participants will be given a report of their results.

  Due to recent changes in DXA scan speeds recommendations, approximately 25% of total participants that receive scans in express mode at the baseline measurement appointment will have the proximal femur and AP spine scans completed two times each at the 12-month measurement timepoint. Once to match the previous scan speed (express) to establish longitudinal change, and once to create a new baseline scan in the new/proper mode (fast array). We expect that this will result in additional radiation exposure of 15μSv or less, or an amount similar to two days of exposure to San Diego sun.

<u>Behavioral Measures</u>

- **Eating Behaviors Inventory (EBI)** will be used to examine eating behaviors and is a widely used self-report assessment of behaviors related to weight loss and weight management (e.g., self-monitoring, refusing offers of food, eating in response to emotions). The measure has been used in over 20 weight

loss interventions. Reliability and validity of the 26-item total score has been demonstrated and the measure has been shown to be sensitive to change in weight management interventions.

- **Physical activity** and **sleep** will be measured objectively for 10 to 12 days consecutively after each measurement visit using the ActiGraph Link (ActiGraph Inc., Pensacola, FL), a previously validated, wrist-worn and waist-worn tri-axial accelerometer comparable to the device used in National Health and Nutrition Examination Survey.[83-86] Participants will be asked to wear the device continuously on their non-dominant wrist and around their waist, except while bathing or swimming. The wear location and time period are in-line with the best practices for the assessment of habitual PA and result in high levels of acceptability and compliance among participants (>90%).[87–90] After each wear period, data will immediately be downloaded and screened for wear time using ActiLife version 6.11.8 or newer (ActiGraph's proprietary software platform). Participants who do not wear the device for a minimum of 10 hours per day on at least 7 days, or who have irregularities in their data indicative of a device malfunction, will be asked to re-wear the device for another period of 10 consecutive days. PA will be defined as cumulative activity "counts" (ActiGraph's proprietary metric) per day. This metric incorporates intensity, frequency, and duration of acceleration into a single metric and is recommended for assessing the total volume of PA in a 24-hour period.[91] Sleep will be defined as total sleep time, sleep onset latency, wake after sleep onset, and number of awakenings after sleep onset per day determined by an algorithm developed by Cole et al.[92,93] Participants will also be measured using the Fitbit devices, which provide data on PA (i.e., intensity, energy expenditure, steps, distance traveled, and flights of stairs) and sleep (equivalent to those previously mentioned) at 1-minute epochs, and heart rate at epochs ranging from 1 to 15 seconds.
- Diet will be measured for 3 days (2 weekdays and 1 weekend day) after each measurement visit using the **Automated Self-administered 24-hour Dietary Recall (ASA24),** a previously validated web-based tool developed by the National Cancer Institute.[94–96] The ASA24 prompts individuals to recall, in detail, for each meal and snack, the foods and beverages they have consumed during the previous 24-hour period. The program calculates kcal and macronutrients (e.g., fats, protein, carbohydrates), as well as 90 micronutrients (i.e., vitamins and minerals), food groups (e.g., grains, vegetables), and other dietary constituents (e.g., added sugars). It also facilitates the calculation of the Healthy Eating Index, a measure of diet quality that can be used to assess compliance with the Dietary Guidelines for Americans.[97] ASA24 data will be collected via computer through HTML screen and directly formatted and stored in tables on the study's REDcap database.
- The **Global Physical Activity Questionnaire (GPAQ)** and **Paffenbarger Exercise Habits Questionnaire** will be the methods used to estimate physical activity. The GPAQ was developed by the World Health Organization. The Paffenbarger was developed for the Harvard Alumni Study to assess leisure-time physical behavior. The time reference for the GPAQ will be "in a typical week". The time reference for the Paffenbarger will be "in the past week". GPAQ and Paffenbarger data will be collected via survey through the study's REDcap secure database.
- **Sedentary behaviors** will be measured with the Last 7 Day Sedentary Behavior Questionnaire (SIT-Q-7d), which was developed and validated by Dr. Godino and colleagues.[98] The SIT-Q-7d assesses sitting or lying down in five domains (meals, transportation, occupation, non-occupational screen time, and other sedentary time), thus facilitating the calculation of domain-specific and total sedentary time. Strategies for weight management will be measured with a 35-item questionnaire that assesses the frequency of using evidence-based strategies to achieve decreased energy intake and increased energy expenditure for weight management (e.g., "Recorded or graphed my weight").[60,61] Frequency within the last 30 days is assessed on a 5-point response scale, ranging from "never or hardly ever" to "always or almost always".
- **The Quality of Well-Being Scale (QWB-SA)** will be used to assess general quality of life and for the subsequent cost-utility analyses. The QWB-SA is a comprehensive measure of health-related quality of

life that includes five sections measuring specific acute and chronic symptoms, self-care activities, mobility, PA, and social activity. The observed level of function and the subjective symptomatic complaints are then weighted by preference, or utility, on a scale obtained from independent samples of judges who rated the desirability of health states. The QWB-SA has been used in several multi-site NIH clinical trials.

Three-minute Step Test

The procedure for completing the 3-minute step test is as follows. All participants will be fitted with a chest-worn heart rate monitor (Polar, Finland) that will be used for real-time monitoring by trained EPARC staff throughout all of testing. Participants will then be instructed to step up and down from a single step 8 inches in height at a rate of 24 steps per minute for 3 minutes. The cadence of stepping will be monitored by trained EPARC staff. Upon completion of the test, participants will be asked to sit in a chair and rest.

Psychological Measures

- The **Rosenberg Self-Esteem Scale**, a well-established 10-item questionnaire, will assess self-esteem. items concerning positive and negative feelings about the self (e.g., "On the whole, I am satisfied with myself.").[99] Agreement with an item is evaluated on a 4-point response scale, ranging from "strongly disagree" to "strongly agree".
- Body image will be assessed with the body dissatisfaction subscale of the **Eating Disorder Inventory (EDI)**. This 9-item scale reflects the belief that specific parts of the body associated with increased 'fatness' are too large (e.g., hips, thighs, buttocks) (e.g., "I think my stomach is too large.").[100] Items are evaluated on a 6-point response scale, ranging from "never" to "always".
- Depression will be measured with the short form of the **Center for Epidemiologic Studies Depression Scale**, which consists of 10 items designed to assess depression in the general population (e.g., "I felt depressed.").[101] Items are evaluated on a 4-point response scale, ranging from "rarely or none of the time" to "most or all of the time".
- **Anxiety** will be measured using the short-form of the state scale of the **Spielberger State Trait Anxiety Inventory (STAI)**, which consists of 6 items that comprise the most highly correlated anxiety-present and anxiety-absent items from the full-form of the STAI (e.g., "I feel calm.").[102] Items are evaluated on a 4-point response scale, ranging from "not at all" to "very much".
- **Social Support** will be measured using the **Social Support and Eating Habits Survey** and the **Social Support and Exercise Survey**[124]. The surveys consist of items that assess the level of support individuals making changes to their eating habits and exercise are receiving from their family and friends.

Other Measures

- Homelessness will be assessed at each measurement visit after baseline with item A6 of the **RAND Homelessness Survey**. This item asks respondents to recall how many nights in the past week they spent in a non-permanent residence (e.g., shelter, car/vehicle, etc.)

Social Media and Network Connectivity Measures

We will collect participants' Facebook, Twitter and Instagram data via the application programming interfaces of the respective platforms, if possible according to the rules and regulations of the platforms. We have done this in previous studies,[41,103,104] while successfully maintaining participants' privacy and complying with

requirements from the UCSD institutional review board. These data will allow us to measure the frequency and composition of participants' online communication about healthy-active-living (HAL). Broadcasted posts (e.g., a status update or tweet) that include text will be classified with a dictionary consisting of PA (e.g., swimming) and diet (e.g., fruits) unigrams that was developed by Drs. Weibel and Patrick.[105]

Existing and study-engineered online social network connections (e.g., friends and followers) will be tracked, which will allow for the generation of a number of social network statistics that describe the local structural features (e.g., centrality, tie strength, transitivity) that previous research suggests could be important for health behavior change.[106]

Closest social network connections will be measured by asking participants to name up to 10 of their closest friends regardless of whether they are connected online and respond to 5 questions about the friendship (e.g., "How often do you interact with the friend in real life?"). This measure will be used to determine how real world tie strength may be inferred from easily quantifiable online social network interactions.[107]

Engagement with Intervention Modalities

We acknowledge that the measurement of engagement in the era of digital health is difficult, and throughout the proposed research, we will keep abreast of state-of-the-science methods to accomplish this.[108] Among intervention group participants, quantitative markers of engagement will include usage of Fitbit, SMS sent and replied to, interactions on Facebook and Twitter related to study content (e.g., a post or tweet, like or favorite), website log-ins and click-throughs, emails sent and replied to, and communication with the health coach.

Because this approach does not take into account the depth of interactions (e.g., liking a post is quantitatively the same as writing a post) nor the common practice of lurking (i.e., passively consuming content but not interacting in a visible way),[43] we will also collect qualitative markers of engagement. A previously used questionnaire that includes eight questions (e.g., "In the past week, on average, approximately how many minutes per day have you spent on Facebook?") meant to measure the intensity with which participants use a device or app will be adapted for use in the present study.[109] Importantly, the qualitative markers of engagement will be measured in both the intervention and control groups. These data, combined with the data from online social network connections, will allow us to explore the influence that contamination (i.e., control participants inevitably will use weight-related devices and apps and be connected to and interact with intervention participants on social media) has on intervention effects.

Usability and Acceptability

We will conduct audio recorded exit interviews of intervention participants to gain an understanding of which modalities, content areas, SWMs, and BCTs were used and how the overall user experience of the intervention was perceived. Our approach will be similar to that used in the SMART study.[43]

Table 7. List of measures and assessment timepoints

Measures	Assessment Time Point				
	0	6	12	18	24
Demographic information	X				
Weight, height, waist and arm circumference, blood pressure, heart rate, heart rate variability, PA, sleep, diet, sedentary behavior, strategies for weight management, self-esteem, body image, anxiety, depression, online communication about healthy-active-living, online social network connections, closest social network connections, quantitative and qualitative markers of engagement, contamination	X	X	X	X	X
Other measures (homelessness)		X	X	X	X
Body composition (DXA)	X	X	X	X	X
Three-minute Step Test	X	X	X	X	X

Usability and acceptability					X
Device- and app-based measures of weight, PA, sleep, diet, heart rate will be measured continuously among all participants	→	→	→	→	→

Additionally, the study team may recontact participants following the conclusion of the study to ask additional questions and/or inquire about participation in other research. Participants will indicate whether they agree to be recontacted on the study consent form. Only participants who agree to be recontacted will be contacted by study team and participants will be reconsented.

Data Entry and Management

All measures will be collected and managed using the secure, web-based tool Research Electronic Data Capture (REDCap) hosted at UCSD.[110] REDCap provides an intuitive interface for data entry; audit trails for tracking data manipulation and export procedures; automated export procedures for seamless data downloads to common statistical packages; and procedures for importing data from external sources (e.g., all study anthropometric and physiological measures).

Statistical Considerations

Power and Sample Size

In order to ensure that the RCT has adequate power to determine the efficacy of the SMART 2.0 intervention to improve weight in kg, we calculated the sample size based on a two-sided, two-sample t-test with 80% power at a significance level of 2.5% (a Bonferroni correction to account for two tests). In the SMART study, the standard deviation (SD) of change in weight at 6 and 12 months ranged from 3.87 kg to 5.97 kg, and we have assumed that the corresponding SD in SMART 2.0 will fall within this range.[41] Furthermore, the smallest statistically significant mean difference in change in weight between the two groups occurred at 12 months and was approximately -1.33 kg.[41] If we assume an SD of 4.92 and a modest increase in the between group difference (-1.60 kg), then we will need 182 subjects per group in order to detect a minimal standardized effect size of 0.33. Thus, we will randomize 642 participants (214 per group accounting for a 15% attrition rate).

Overall Approach

Analyses will be conducted using the latest version of the statistical software platform R and will be based on the intention-to-treat principle. All tests of significance will be two-sided and a p-value of 0.05 will be considered statistically significant. Summary statistics (e.g., mean, standard deviations, proportions) will be calculated for all variables of interest. Outliers will be assessed and variables whose distributions depart significantly from normality will be transformed. Appropriate non-parametric alternatives will be considered if parametric assumptions fail. No planned interim analyses for efficacy or futility will be conducted in this study.

- **Primary aim analysis:** The primary outcome of the study is change in objectively measured weight in kg, and the SMART 2.0 intervention groups will be compared to the control group using a mixed model of repeated measures (MMRM).[111] The model will include change in weight from baseline at each post-baseline visit (i.e., 6, 12, 18, and 24 months) as the dependent variable. Fixed effects will include study group, visit, study group-by-visit interaction, weight at baseline, and any variables determined to be confounders. Visit will be treated as a categorical variable, and an unstructured variance-covariance structure will be used. Results will be reported as point estimates (mean differences between groups) and

interval estimates (95% confidence intervals). An intervention effect will be concluded if the p-value for the study group-by-visit interaction contrast in the model at 24 months is statistically significant. Holm's method will be used to adjust the two p-values for multiple comparisons.[112] This approach uses all available data and is robust to data missing at random (MAR).[111,113] However, two additional approaches may be employed to examine the influence of missing data on the primary outcome analysis (which takes a likelihood-based approach to estimation, but does not directly impute data). First, we will model the probability of missingness as a function of baseline covariates and previous outcomes (using logistic regression). The inverse of the resulting probabilities will serve as propensity scores that will be included in the model of the primary outcome. If data are MAR or the probability of missingness can be fully explained by observable data, this approach produces asymptotically unbiased estimates. Second, in order to allow for the possibility that the MAR assumption may not hold (an assumption that is not empirically testable), we will use pattern mixture models in which the distribution of the primary outcome is assumed to follow a mixture of two distributions: one for those who complete follow-up and another for those who do not. These approaches will allow us to quantify the robustness of the study findings to missing data assumptions.

- **Secondary aim analyses:** Secondary aim 1 will be achieved by using the MMRM approach outlined above to compare differences between the SMART 2.0 intervention groups and the control group at 6, 12, 18, and 24 months in anthropometric and physiological outcomes, PA, diet, sleep, body image, anxiety, depression, and the frequency and composition of participant's online communication about weight-related behaviors (all of these measures are continuous). Secondary aim 2 will examine the dose response (i.e., engagement with intervention modalities) of the SMART 2.0 interventions on outcomes at 6, 12, 18, and 24 months. Engagement variables will be included as independent variables in multiple regression models with the study outcomes as the dependent variable adjusting for covariates. Secondary aim 3 will examine the usability and acceptability of the intervention using the framework advanced by Strauss and Corbin.[114,115] Transcribed audio recordings will be analyzed in three stages: open, axial, and selective coding.[116] During open coding, the data will be examined line-by-line and key concepts and their properties will be discovered. Axial coding involves identifying the relationships among the data, which will then become fully integrated through selective coding. These processes will be documented via memos, which will provide a roadmap of the analytic process.[117] Secondary aim 4 will be accomplished following methods outlined by MacKinnon and Kraemer. [118,119] We will examine factors that may mediate or moderate the effect of the SMART 2.0 interventions on study outcomes. Mediators (e.g., PA, diet, social support) will inform how the intervention may have worked to change the outcome, while moderators (e.g., sex, age, social network connectivity, contamination) will illuminate for whom and under what conditions the intervention may have been efficacious. Mediation will be tested via path analysis with regression paths from randomized group to change in the mediator and from change in the mediator to change in the outcome, along with a direct path from the intervention to change in the outcome. Adding interaction terms to the models assessing the intervention effects will test moderation. Secondary aim 5 will examine patterns of PA, diet, and sleep as measured over 24 months by Fitbit and MyFitnessPal using Gaussian process regression models.[120] Models will include separate long- and short-term trends for each of the intervention along with common terms for weekly and yearly periodic trends and indicator variables for holidays. We will also use the time-varying effect model to examine how changes in these behaviors over time influence weight.[121] For all secondary analyses of interest, no adjustments for multiple comparisons will be made and a p-value of 0.05 will be considered statistically significant.

9. HUMAN SUBJECTS

Up to a total of 642 young adults will participate in the proposed research.

Inclusion criteria: a) age 18 to 35 years; b) intending to be available for a 24 month intervention; c) affiliated with either UCSD, SDSU or CSUSM as a student, faculty or staff; d) willing and able to use Facebook and follow at least one of study's Facebook, Instagram or Twitter pages; e) willing and able to use a smartphone and text messaging; f) willing and able to use the Fitbit devices and app; g) willing and able to attend measurement visits at UCSD over the 2 year RCT; h) willing and able to engage in moderate to vigorous physical activity; i) overweight or obese, but not severely obese ($25 \leq BMI < 40$ kg/m^2).

Exclusion criteria: a) any comorbidities of obesity that require a clinical referral including eating disorders, pseudotumor cerebri, sleep apnea or hypoventilation syndrome, orthopedic problems, and meeting American Diabetes Association criteria for diabetes;[122] b) psychiatric or medical conditions that prohibit compliance with the study protocol; c) had a cardiovascular event (heart attack, stroke, episode of heart failure, or revascularization procedure) within the last 6 months; d) currently being treated for a malignancy (other than non-melanoma skin cancer); e) currently being treated and/or have an eating disorder; f) planning to have a weight loss surgery in the next 24 months (e.g., liposuction, lap band, gastric bypass); g) pregnant, gave birth within the last 6 months, currently lactating or breastfeeding within the last 3 months, or actively planning pregnancy within the next 24 months. This will be determined by participant self-report.; h) prescribed PA and dietary changes; i) prescribed medications that alter weight; j) enrolled in or planning to enroll in a weight loss program during the study period; k) lost more than 15 pounds within the past 3 months.

We will recruit young adults, including students, faculty and staff, from three institutions in San Diego County enrolling approximately 86,000 students and with over 40,000 faculty and staff members. The **University of California, San Diego (UCSD)** enrolls 36,624 students: 28,587 undergraduates (mean age: 21 years), 8,037 graduate students. Undergraduate students are 49.1% female, 37.6% Asian, 19.1% White, 17.8% Mexican-American or Latino, 2.5% African American, with the remainder other or not stated. **San Diego State University (SDSU)** enrolls 33,870 students: 29,513 undergraduates (mean age: X years), 4,357 graduate students (mean age: 22 years). Among all students, 55.1% are female, 13.4% are Asian/ Pacific Islander, 34.7% are White, 28.9% are Hispanic/ Latino, 3.9% are African American, with the remainder as other, multiple ethnicities, or not stated. **California State University, San Marcos (CSUSM)** enrolls 13,893 students (mean age: 22.6 years). Among all students, 61.1% are female, 9.6% are Asian, 27.2% are White, 44.2% are Hispanic/ Latino, 3.0% are African American, with the remainder as other, two or more races or not stated. These campuses enroll a diverse group of students in terms of race, ethnicity and SES background rendering the results of this study generalizable to a broad range of young adults nationwide.

10. RECRUITMENT AND PROCEDURES PREPARATORY TO RESEARCH

We will develop an enrollment strategy to ensure that we enroll students, faculty and staff across the broad age-range targeted in this initiative (18-35 years). Subjects will be recruited from three college and university settings within San Diego County including: UCSD, SDSU and CSUSM.

Participants will be recruited through the following channels: (1) digital advertisements in college e-newsletters; (2) targeted social media advertisements; (3) posting of print and digital flyers at UCSD and CSUSM; (4) e-mails sent by student health services via electronic distribution lists and by departmental listserv managers; (5) campus-wide events via tabling.

Interested individuals will be directed to complete an online screening form through the study's secure REDcap database. Once the subject arrives at the screening form, he/she will have an opportunity to read and learn more about the study. At this point, the subject will be explained that in order to determine whether he/she meets the criteria for participating, he/she will be asked a few eligibility questions (see eligibility criteria described above). After the participant completes the form, study staff will follow up accordingly. Participants who do not

meet the eligibility requirements will receive an email notifying them and thanking them for their interest in the study. Participants who meet the eligibility requirements will receive a call from a trained research staff notifying them that they qualify, informing them about the study purpose, procedures, risks and benefits, explaining that they may be randomized to a control condition that includes a Fitbit Charge 3 and Aria Scale, and to confirm information provided in the online screening form. Once this is complete and the subject still qualified, he/she will be invited to schedule an appointment at the research office. There they will be re-screened for inclusion and exclusion criteria, provide written informed consent, and complete the baseline measurement. After eligibility and consent are confirmed and baseline measurements are completed, participants randomized at a ratio of 1:1:1. The biostatistics team will generate the electronic randomization list using the latest version of the statistical software platform R (currently version 3.3.2, http://www.r-project.org)

11. INFORMED CONSENT

Written informed consent will be obtained in-person from each enrolled subject prior to completing the baseline measures. However, there are several steps, as described in section 11, Recruitment, that the subjects will navigate through before the first in-person baseline visit.

Potential participants who view recruitment materials and/or contact the research office will be directed to an online screening link describing the SMART study. The study purpose, procedures, risks and benefits will be described to them. If the potential participant expresses interest in participating in the study, he/she will be asked to complete an online screening form. Because the screening form poses no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context, we are seeking a waiver of signed documented consent for the online screening form. For those individuals who meet the online screening criteria, their inquiry will be followed up by a phone call to verify the data submitted via the online screening form. Since we are simply verifying information provided in the online screening form via phone call verbally and it involves no more than minimal risk of harm to the subjects and no procedures for which written consent is normally required outside the research context, we are requesting a waiver of written and verbal consent for the phone call. We have included a script for the oral consent as an attachment. We are not collecting any additional research data by phone; we are simply verifying the information that is provided in the online interest form. Once the potential participant has met screening criteria over the phone, he/she will be asked to set-up a baseline visit appointment. The SMART study staff will obtain written informed consent in person prior to beginning the RCT study, and it will be kept in a separate locked cabinet in EPARC/CWPHS.

12. ALTERNATIVES TO STUDY PARTICIPATION

The alternative to participation is to not participate.

13. POTENTIAL RISKS

Potential risks are psychological, social and physical.

During the RCT subjects may experience 1) anxiety or embarrassment related to one's personal exercise and nutrition practices and sharing this information with others via social media and health coaching, and when answering questions during the measurement questionnaires; 2) feelings of inadequacy or embarrassment if unable to succeed at agreed upon diet, physical activity, sleep and/or weight goals; 3) concern for privacy related to divulging personal information and security of providing personal information over the Internet and through Fitbit Charge 3 and Aria scale; 4) injury during physical activity; 5) rare occurrence of cardiovascular event during physical activity; 6) physical discomfort related to wearing the Fitbit device. Judging from our past experience and the current literature, the risks are relatively slight or low of likelihood.

During the measurement process subjects the potential risks are deemed by the research team to be no greater than minimal. Potential risks include: 1) anxiety when answering personal questions on medical and lifestyle history; 2) falling during the 3-minute step test; 3) light headedness or dizziness, nausea, dehydration, fatigue, delayed-onset muscle soreness and injury during the 3-minute step test; and 4) the effective dose of radiation to an individual received during the five to six scans that each participant will receive. The total amount of radiation projected for these scans of thespine, hip, and total body scan combined is approximately 0.285 to 0.305 mSv. This amount is less than a participant would receive from one year of natural exposure in the San Diego area, which is approximately 1.6 mSv. Additionally, approximately 25% of the total population that received the DXA express scan speed at the baseline measurement appointment will be exposed to an additional radiation exposure of 15μSv or less at the 12-month measurement appointment. This is because these participants will need a scan of the proximal femur and AP spine two times each; once to match the previous scan speed (express) to establish longitudinal change, and once to create a new baseline scan in the new/proper mode (fast array).

Additionally, participants will be responsible for contacting the team in the event that their device(s) are lost stolen, or damaged. The research team will handle the issue on a case-by-case basis and may determine that the participant is financially responsible.

The risks involved in this study are no more than minimal and are reasonable in relation to the potential knowledge that may result from this study.

14. RISK MANAGEMENT PROCEDURES AND ADEQUACY OF RESOURCES

The Human Research Protections Program of UCSD approved all methods utilized. Participants will be given copies of the Experimental Subjects Bill of Rights. The study is supervised by Dr. Job Godino, experienced in conducting clinical and population health research.

Risks of embarrassment and/or anxiety will be minimized by fully informing participants of the topics to be addressed and specific involvement required of them, e.g. participation in online groups, before they agree to participate. Subjects will be informed that they can discontinue their participation at any time, with no impact to the incentives previously received. Research staff will be trained to provide a very positive and supportive context for the intervention and assessments. Subjects will be told that all responses are confidential. Risks to privacy will be minimized by fully informing participants that all measurements and individual test results will be de-identified and treated confidentially. Written informed consent will be kept in locked files cabinets separate from participant data which will be kept on the study's secure REDcap database. This way individuals are not easily connected to the study results. All data from the Fitbit Charge 3 and Aria Scale will be continuously, passively, and securely streamed to the Fitbit website. It will then be retrieved using software developed by Fitabase Inc. (https://www.fitabase.com) and stored securely on their servers. All data that is subsequently downloaded from Fitabase Inc. servers for analytic purposes will remain de-identified and will be stored on secure, password-protected CWPHS/EPARC servers. There are two instances when researchers will contact Fitabase Inc in order to delete data associated with participants in this study: 1) anytime that a participant chooses to withdraw from the study and 2) at the completion of the study (when all data analysis has been completed). Researchers will contact Aaron Coleman, CEO of Small Step Labs, LLC and creator of Fitabase (aaron@fitabase.com) and he will initiate a deletion of the data from live servers and all data will be phased out of offline backups within 90 days. After 90 days Small Step Labs will have no data associated with the study on their servers.

Numerous privacy issues regarding the use of social networking platforms will be addressed with safeguards at multiple levels throughout the system. We will use Secure Socket Layer (SSL) protocol for communications with the Facebook, Instagram and Twitter servers. Engagement data collected from study's posts on social

media platforms will be collected using Sendible (https://www.sendible.com/), a social media management tool. Sendible collects social media reports which aggregates participants' engagement via "likes", "comments" and "shares". In turn, engagement of individual participants will not be collected reducing concerns for privacy.

The study's Facebook, Instagram and Twitter pages will protect user data and honor privacy choices. Participants will be issued guidelines as to appropriate information to publish and reveal on the social media pages and within their online groups. To ensure that all participants are aware of Facebook, Instagram and Twitter privacy policies and how they can control and/or change their privacy settings, each participant will be provided with a handout prior to the start of their participation in the study on how to set their privacy preferences. The SMART Health Coach will be a "friend" of all participants on Facebook in order to invite them to online groups on Facebook messenger. The Health Coach will monitor the Facebook, Instagram and Twitter study pages and each Facebook Messenger group and alert participants to any observed privacy risks.

Risks of anxiety, embarrassment, or feelings of inadequacy during the measurement process will be minimized by fully informing participants of the study procedures and explaining that they may refuse to participate or stop participation at any time if they are unable to complete a laboratory test. Participants will also be informed that the Fitbit Charge 3 is not considered to be a medical device or a significant risk device. Physical discomfort from wearing the devices will be minimized by providing instructions on how best to wear the Fitbit Charge 3 and study staff will be present to make any necessary adjustments.

Chances for falling during the 3-minute step test will be reduced through adequate warm-up and instruction. Participants will be asked to arrive to each testing session well-hydrated and in athletic attire. The chances of serious fatigue or injury will be further reduced by monitoring the participant at all times during tests, providing sufficient recovery time following testing.

To minimize exposure to radiation with the DXA scan, scans will only be conducted by highly skilled technologists certified by the state of California. These credentials help ensure correct subject positioning, selection of scan mode, and scan acquisition. This in turn minimizes the need for repeated scans and thus added radiation exposure.

Risks of injury of rare occurrence of a cardiovascular event due to physical activity will be minimized by ensuring participants selected for the study meet certain criteria and have no known serious physical or mental health problems. Injury during physical activity is reduced because lessons and instruction on how to reduce the risk of injury will be provided. Risk will be further reduced by having participants indicate medical problems that would contraindicate physical activity. Screening will occur prior to entry into the study, as ability to perform moderate physical activity is an inclusion criterion.

The research team will reduce the risk of lost, stolen, or damaged devices by providing participants with special care instructions prior to receiving the devices.

15. PRIVACY AND CONFIDENTIALITY CONSIDERATIONS INCLUDING DATA ACCESS AND MANAGEMENT

Risks to privacy will be minimized by fully informing participants that all measurements and individual test results will be de-identified and treated confidentially. Written consent forms will be kept in separate locked files cabinets separate from participant data on the study' secure REDcap database so that individuals are not easily connected to the study results. Audio recordings of health coaching sessions will be kept for the duration of the study and IRB approval and will be destroyed after all analysis is complete. Audio files will then be removed from the password protected server. All data from the Fitbit Charge HR will be continuously,

passively, and securely streamed to the Fitbit website. It will then be retrieved using software developed by Fitabase Inc (https://www.fitabase.com) and stored securely on their servers. All data that is subsequently downloaded from Fitabase Inc. servers for analytic purposes will remain de-identified and will be stored on secure, password-protected EPARC servers. There are two instances when researchers will contact Fitabase Inc in order to delete data associated with participants in this study: 1) anytime that a participant chooses to withdraw from the study and 2) at the completion of the study (when all data analysis has been completed). Researchers will contact Aaron Coleman, CEO of Small Step Labs, LLC and founder of Fitabase Inc (aaron@fitabase.com) and he will initiate a deletion of the data from live servers and all data will be phased out of offline backups within 90 days. After 90 days Fitabase Inc. will have no data associated with the study on their servers.

Breach of confidentiality is highly unlikely because all personally identifying information will be kept separate from data collected. No personally identifying information will be coded on the device-captured data or scoring sheets. Subject identification numbers are assigned to each participant and only the PIs and limited research staff have access to the file that links subject name with subject number. All data are stored in locked file cabinets in locked offices or password-protected computers located behind secure and maintained firewalls. Data and records are collected specifically for this research project by trained research associates who have completed on-line training in CITI human subject research, research data management and confidentiality, and training to criterion on project protocol. Research data will not be shared with Fitbit.

16. POTENTIAL BENEFITS

The risks to participants are both unlikely and minor. By conducting this study, we will obtain accurate information related to the efficaciousness of a theory-based intervention that utilizes multiple technological modalities to promote weight loss in young adults. Participants will receive feedback on their physical activity, diet, and sleep, however they may or may not benefit from their participation in the study. Long term benefits to society include helping bring about healthier lifestyles to prevent weight gain and reduce premature morbidity and mortality due to cardiovascular disease, cancer, and other health problems.

17. RISK/BENEFIT RATIO

The risks involved, including exposure to radiation from the 5 total DXA scans, are minimal and reasonable in relation to the importance of the knowledge that may be expected to result from the study. As addressed above in Background and Significance, efficacious technology-based behavioral interventions aimed at improving weight in young adults are critical for improving the health status of our country. Given the magnitude of the public health burden associated with overweight and obesity, it is important to evaluate whether real-time communication at critical point-of-decision moments will translate into decreased weight and improved health behaviors. There is very little research on how multiple modalities can be used to improve health behavior, yet these technologies are highly popular with young people. This study will advance health behavior research by examining the utility of devices and apps, smart phones, and social media and social networking to promote healthy weight-related behaviors. Moreover, because this research will be anchored in health behavior theory, it will permit us to examine cognitive, social, and ecological constructs and their role in mediating or moderating intervention effects.

18. EXPENSE TO PARTICIPANT

There will be no costs to the participants.

19. COMPENSATION FOR PARTICIPATION

To maximize the likelihood that participants will continue with measurement visits and stay in the study, we will offer incentives for attending measurement visits as follows: Fitbit Charge 3 and Aria Scale (valued at

$300 total) at baseline, $20 at 6 months, $25 at 12 months, $25 at 18 months and $30 at 24 months. Subjects affiliated with SDSU and CSUSM will receive an additional $15 for each measurement visit to compensate for additional travel costs.

20. PRIVILEGES/CERTIFICATIONS/LICENSES AND RESEARCH TEAM RESPONSIBILITIES

1. **Job Godino, Ph.D., Principal Investigator:** will lead the main efforts of this project including development, coordination, implementation, and monitoring of program activities. He will also lead the analyses, preparation of manuscripts, and dissemination of results. Dr. Godino holds a Masters and PhD in Epidemiology, is an Assistant Professor and Research Associate at the Center for Wireless and Population Health Systems (CWPHS) and Department of Family Medicine and Public Health at UCSD, and is the Director of Research and Applied Technology at the Exercise and Physical Activity Resource Center (EPARC) and the California Institute of Telecommunications and Information Technology's Qualcomm Institute (Calit2) at UCSD. He has obtained in-depth research training and experience in the primary and secondary prevention of obesity, diabetes, and cardiovascular disease. He has worked on 19 research studies (funded by the NIH, RWJF, and MRC of the UK) in different capacities, 11 of which have been randomized controlled trials. The majority of his current research focuses on the development and evaluation of interventions that utilize mobile and wearable technology to promote healthy changes in physical activity, sedentary behavior, diet, and sleep for the prevention of chronic disease.
2. **Eric Heckler, Ph.D., Co-Investigator:** holds a Masters in Clinical Psychology and a PhD in Clinical Health Psychology. He is an Associate Professor and Director in the Department of Family Medicine and Public Health and CWPHS at UCSD, respectively. His research focuses on the development of personalized digital health interventions for behavior change. Additionally, he has expertise in and will provide input on the overall direction of the project as it relates to the use of control systems engineering methods for behavioral interventions, just-in-time adaptive interventions, human-centered design methods and processes for advancing health behavior change, and mobile health (mHealth) interventions.
3. **Kevin Patrick, MD, MS, Co-Investigator:** holds a MD and a Masters in Community Medicine. Dr. Patrick will serve as the study physician and will be on the study steering committee. He will also contribute to the intervention development and implementation, interpretation of findings, and will assist in the preparation of manuscripts and dissemination of results. He has extensive experience in formative research, survey methodology, measurement technologies, behavioral interventions and informational technology. His work focuses on the use of text messaging, smartphone apps, mobile video, the mobile web and social media to measure health states and promote health behavior change.
4. **Cheryl Rock, Ph.D., Co-Investigator:** hold a Masters of Medical Science and a PhD in Nutritional Sciences. She will contribute to this project as a nutritional scientist with extensive knowledge and experience in conducting diet and weight loss intervention studies, biomarker measures, and clinical nutrition research. Dr. Rock has previously developed, led, and conducted several dietary and weight loss interventions and clinical trials focused on the role of nutritional and dietary factors in the development and progression of disease. Currently, she directs the Diet and Physical Activity Shared Resource at the UC San Diego Moores Cancer Center and is a co-investigator on other studies that are focused on diet, obesity, weight loss intervention, and behavioral and metabolic risk factors and disease management.
5. **Nadir Weibel, Ph.D., Co-Investigator:** holds a Masters and PhD in Computer Science and is a research faculty member in the department of Computer Science and Engineering at UCSD. Additionally, he is one of the faculty and an active member of the UCSD DesignLab, the UCSD's CWPHS, the Center for Microbiome Innovation, and the UCSD Interface and interdisciplinary program in multiscale biology. He is also appointed as Research Health Science Specialist at the VA San Diego. His research focuses on capturing, storing, managing and visualizing multimodal data from behavioral activity in real-world settings. He is skilled in a broad variety of computer science

techniques from information management to human-computer interaction, software engineering, and data visualization. He has a total 80+ publications, including 60+ published peer-reviewed articles both in renowned journals and in the most important venues in Human-Computer Interaction and Pervasive Healthcare during his 7 years at UCSD. Dr. Weibel will contribute to the intervention development and implementation and the assessment of usability and acceptability of the intervention.

6. **Sonia Jain, Ph.D., Co-Investigator:** holds a Masters and PhD in Statistics and is a Professor in the Division of Biostatistics and Bioinformatics in the Department of Family Medicine and Public Health at UCSD. Dr. Jain will contribute to the interpretation of findings and will assist in the preparation of manuscripts and dissemination of results.
7. **Shadia J. Assi, MPH, Study Manager:** holds a Masters in Public Health and has 4 years' experience working in academic health research. She will serve as the study manager for the project and will assist the PI in managing recruitment, development, coordination, implementation and monitoring program activities. Her previous research and training include health promotion, behavioral science, and individual and group-based behavioral change interventions.
8. **Natalie Golaszewski, Ph.D., Postdoctoral Scholar:** holds a Masters in Health Education and PhD in Health Behavior and Health Promotion. Dr. Golaszewski has a wide array of research experiences from managing and conducting large-scale, multi-year randomized control trails, lab-based validation studies, and qualitative studies. Currently, her research focuses on the social influences of physical activity, diet, and weight loss. She will contribute to the theoretical development of the project as well as understanding the meaning of online social behaviors in the small, online groups and whether these have an impact on physical activity and diet behaviors.
9. **David Wing, MS, Measurement Coordinator:** holds a Masters in Exercise Physiology, and has been involved in multiple studies of physical activity and function. Additionally, Mr. Wing is a member of CWPHS and serves as the Laboratory Director for EPARC. In this capacity he has developed extensive expertise in the objective measurement of physical activity, fitness, function, sleep, and overall health utilizing a variety of accelerometers, heart rate monitors, and other biological sensors individually and in concert. Under the direction of Dr. Godino, Mr. Wing will oversee all anthropometric and physiological measurements in the study. He will help train, supervise, and schedule Research Assistants.
1. **Victoria Costello, MPH, Health Coach:** will work under the Direction of Dr. Godino and in conjunction with Ms. Assi. The Health Coach will have a masters-level education, experience in motivational interviewing relevant to weight loss interventions, and a history of using health-related devices, apps, and multiple social media streams. The Health Coach will be responsible for the anonymous delivery of intervention content via multiple social media streams, email, and personally in one-on-one, real-time technology mediated health coaching sessions with relevant participants.
2. **Research Assistants (TBN):** will assist with recruitment, screening, measurement and data collection. In addition, they will assist the Study Manager and Health Coach in managing online social media pages.

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23. BIOLOGICAL MATERIALS TRANSFER AGREEMENT

NA

24. INVESTIGATIONAL DRUG FACT SHEET AND IND/IDE HOLDER

NA

25. IMPACT ON STAFF

NA

26. CONFLICT OF INTEREST

There are no known conflicts of interest.

27. SUPPLEMENTAL INSTRUCTIONS FOR CANCER-RELATED STUDIES

NA

28. OTHER APPROVALS/REGULATED MATERIALS

NA

29. PROCEDURES FOR SURROGATE CONSENT AND/OR DECISIONAL CAPACITY ASSESSMENT

NA