Charge: A Text Messaging-based Weight Loss Intervention

STUDY PROTOCOL, INFORMED CONSENT & STATISTICAL ANALYSIS PLAN

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STUDY PROTOCOL

Charge Full Research Protcocol

Optimal iOTA (Charge): Optimizing a standalone text messaging-based weight loss intervention

Overall study aim: This will be a 12-month experimental trial among 448 adults with obesity to determine which stand-alone text messaging intervention components produce a meaningful contribution to 6-month weight change. We operationalize meaningful text messaging components as those having an effect size of > .15, using the Pellegrini et al. definition.[34] We will use the multiphase optimization strategy (MOST)[1] to help us assemble multicomponent interventions comprised only of components that meaningfully affect our chosen outcomes.

All participants will receive a core 6-month weight loss texting intervention (based on our iOTA approach) that includes tailored behavior change goals, interactive self-monitoring, automated feedback, and skills training. We will use a full factorial design to randomize participants to experimental conditions that reflect the texting intervention components: motivational messaging (self- vs expert-generated), texting frequency (daily vs weekly), reminders (one reminder v. multiple reminders), feedback type (summary score v. specific feedback) and comparison unit (to self v. to a group of people). The full factorial design is power efficient, logistically feasible (because we manipulate conditions using technology) and will allow us to examine the most important main and interaction effects among components.

Our primary outcome will be absolute change in weight from baseline to 6 months. We will estimate the main effects and 10 pairwise interactions of each of the five components on the outcome at each follow-up time point using a linear mixed effects model. The model will include fixed effects for: time point (baseline, 3- or 6-months), component (motivational messaging, frequency, reminders, feedback type, and comparison unit), pairwise interactions of each component and the time-by-component and time-by-pairwise interactions.

Background: More than 69% of U.S. adults are currently overweight or obese; 35% are obese.[2,3] Obesity continues to increase for all men and for Black and Hispanic women.[4 6] The rapid rise in severe obesity is especially troubling. Obesity heightens risk for hypertension, type 2 diabetes, dyslipidemia, and insulin resistance.[7 10] It also drives premature mortality and U.S. health system spending.[11 13] Traditional behavioral weight loss treatments usually including frequent interactions with a trained counselor and regular self-monitoring of diet/exercise produces 7-10% weight loss after 6-12 months.[14,15] However, the intensive nature of these interventions constrains their widespread dissemination. We need innovative approaches to deliver effective weight loss interventions to Americans with obesity.

We are interested in learning how to optimally design a standalone texting intervention that maximizes weight loss outcomes. Although there has been a proliferation of texting trials, none have been fully standalone (i.e., delivered entirely via texting). Standalone approaches have great population-level potential because they are low cost, highly scalable, and modular in nature. They can reach into broad, diverse, and geographically dispersed populations that do not have stable access to other approaches (e.g., counseling, web, email, video) frequently employed in mHealth weight loss trials. Efficacious texting approaches could also be employed in multicomponent treatments to enhance outcomes. If we could improve the outcomes of standalone texting interventions, we might make major population-level impact. However, it is challenging to move the science forward because texting intervention designs have varied considerably. This study is designed to remedy this omission. We will use the MOST framework to develop an optimized treatment package that will deliver the most effective 6-month standalone texting intervention for weight loss.

Experimental Trial Overview: We propose to conduct a 6-month full factorial trial with up to 700 adults with obesity. All participants will receive a core 6-month weight loss texting intervention (based on our iOTA approach). Consistent with the MOST framework, we will randomize participants to one of 32 experimental conditions to test the intervention components we identified in phase 1. The components and their levels include: motivational messaging (self- vs expert-generated), texting frequency (daily vs weekly), reminders (one reminder v. multiple reminders), feedback type (summary score v. specific feedback) and comparison unit (to self v. to a group of people). We will collect follow-up measures at months 3, 6, and 12 months.

Design rationale: Two considerations are important when choosing an experimental design for a MOST trial. First, it should allow us to estimate the independent effects of a component on our outcome. Second, it must be economical, in terms of its actual cost and utilization of resources.[1] We considered several designs and chose the full factorial design for this trial.

Table 2 shows our experimental conditions. To estimate the main effect of texting frequency, we compare the mean of conditions with a weekly (conditions 1-16) to the mean of the conditions in which frequency is daily (conditions 17-32). Similarly, we compare the mean of conditions receiving self-generated motivational messages (1-8; 17-24) to those with expert-generated motivational messages (9-16; 25-32) to examine the main effect of motivational messaging. A similar process is used to test interactions.

Condition	Frequency	Motivational Messaging	Reminders	Feedback Type	Comparison Unit
1	weekly	Self-generated	One	Summary Score	Self
2	weekly	Self-generated	One	Summary Score	Group
3	weekly	Self-generated	One	Individual Goal	Self
4	weekly	Self-generated	One	Individual Goal	Group
5	weekly	Self-generated	Multiple	Summary Score	Self
6	weekly	Self-generated	Multiple	Summary Score	Group
7	weekly	Self-generated	Multiple	Individual Goal	Self
8	Weekly	Self-generated	Multiple	Individual Goal	Group
9	Weekly	Expert-generated	One	Summary Score	Self
10	Weekly	Expert-generated	One	Summary Score	Group
11	Weekly	Expert-generated	One	Individual Goal	Self
12	Weekly	Expert-generated	One	Individual Goal	Group
13	Weekly	Expert-generated	Multiple	Summary Score	Self
14	Weekly	Expert-generated	Multiple	Summary Score	Group

15	Weekly	Expert-generated	Multiple	Individual Goal	Self
16	Weekly	Expert-generated	Multiple	Individual Goal	Group
17	Daily	Self-generated	One	Summary Score	Self
18	Daily	Self-generated	One	Summary Score	Group
19	Daily	Self-generated	One	Individual Goal	Self
20	Daily	Self-generated	One	Individual Goal	Group
21	Daily	Self-generated	Multiple	Summary Score	Self
22	Daily	Self-generated	Multiple	Summary Score	Group
23	Daily	Self-generated	Multiple	Individual Goal	Self
24	Daily	Self-generated	Multiple	Individual Goal	Group
25	Daily	Expert-generated	One	Summary Score	Self
26	Daily	Expert-generated	One	Summary Score	Group
27	Daily	Expert-generated	One	Individual Goal	Self
28	Daily	Expert-generated	One	Individual Goal	Group
29	Daily	Expert-generated	Multiple	Summary Score	Self
30	Daily	Expert-generated	Multiple	Summary Score	Group
31	Daily	Expert-generated	Multiple	Individual Goal	Self
32	Daily	Expert-generated	Multiple	Individual Goal	Group

Intervention design: At baseline, we will randomize participants to one of the 32 experimental conditions (see Table 2). Each participant will receive the core weight loss intervention, based on our iOTA approach.

iOTA the interactive obesity treatment approach (iOTA): iOTA is an approach that we developed and have used in several recent obesity treatment trials.[43,55,56,58] iOTA creates an energy deficit sufficient to produce weight loss through the modification of routine obesogenic lifestyle behaviors.[55,58] We designed iOTA specifically for delivery via mHealth channels, where sustained intervention engagement is critical. Individuals expect their mHealth experience to be straightforward, highly personalized, and minimally effortful. Accordingly, iOTA is straightforward and does not require expert knowledge or expensive resources. From the participant perspective, s/he simply takes a short survey and is immediately assigned a set of personally-

tailored behavior change goals. Participants then use text messaging to self-monitor their adherence to these goals. They receive tailored feedback based on their progress, skills training videos and motivational texts.

Behind the scenes, iOTA is sophisticated, but uses low cost, highly disseminable digital health technologies. It relies on a series of interconnected algorithms and content libraries. After participants take their initial surveys, our prescription algorithm assigns 4 tailored behavior change goals. The prescription algorithm prioritizes behaviors in highest need of change, those for which the participant has high self-efficacy and readiness, and those that achieve the intended caloric deficit. A feedback algorithm tailors feedback, selecting content from a vast feedback content library. From our skills training library, we send videos to assist behavior change efforts. Based on self-monitoring data, we can select motivational messages to support

that can be easily disseminated. For this reason, several research groups are testing iOTA in a range of populations.

Theoretical framework: All core iOTA intervention components are designed to target self-efficacy, which we selected from social cognitive theory (SCT),[59,60] given its consistent association with weight loss outcomes.[61 63] Bandura identified 4 primary factors[64] that influence self-efficacy: mastery experiences, social modeling, social persuasion, and somatic and emotional reactions. These are noted in Table 3, along with details about the core iOTA intervention address each component. SCT also indicates that behavior change can be facilitated through a number of self-regulatory processes, including self-monitoring,[65 67] goal setting,[31,63] and social support.[68,69]

The intervention will support these self-regulatory processes, further heightening self-efficacy. Our conceptual framework integrates TAM and self-efficacy. The intervention will target self-efficacy. Our experimental components were selected to increase perceived usefulness and ease of use, with the goal of enhancing intervention engagement, given its importance in driving weight loss.[16]

Table 3. Strategies to used to enhance participant self-efficacy

Construct	Behavior change technique	Intervention component
Mastery experiences	provide opportunities; provide social support.	teach behavioral skills through tailored skill training texts; regular self-monitoring with tailored feedback (which emphasizes long-term change success vs. quick wins) to reinforce mastery experiences
Social modeling	correcting misconceptions; providing healthful norms	tailored feedback and motivational messages discussing social norms
Social persuasion	model positive outcomes; prompt self-monitoring of behaviors; reinforce progress	tailored feedback and motivational messages structured to boost efficacy by teaching behavioral skills and validating behavior change efforts
Emotional reactions	help participants manage emotions that might complicate behavior change; promote change-supporting emotion	algorithms that progressively increase activity; feedback and motivational messages are designed to boost positive emotions; offer stress coping skills

Obesogenic behavior change goals: Participants track 4 behavior change goals that produce an energy deficit sufficient to produce weight loss. At baseline, each participant will complete a short risk behavior assessment using a tablet computer. Our prescription algorithm assigns 4 goals that achieve the required energy deficit. We have a library containing over 35 obesogenic behavior change goals that have been selected based on their: 1) empirical support; 2) population relevance; 3) ease of self-monitoring; and 4) concreteness. We will leverage the goal library that was deemed efficacious in our previous studies, Shape (Protocol

2938) and Track (Protocol B0033) (See Appendix F). During study startup, we will make efforts to identify population-relevant goals that might be missing from our library.

Self-monitoring and tailored feedback: Regular self-monitoring is a robust predictor of weight loss, although adherence typically wanes over time.[65,67,70] Disengagement likely results from usability limitations, cognitive complexity, and lack of immediate feedback. As a result, our trials have involved extensive testing to ensure that that our texting self-monitoring tools are engaging. Our text messaging system is fully automated, currently operational, uses open-source technologies and is designed for scalability.

Depending on their randomization status, we will contact participants either daily or 3 times weekly. An outbound text requests self-monitoring data. Participants then text their self-monitoring data. We immediately provide tailored, real-time feedback on participant's progress via text. Feedback considers both short- and long-term progress. We also provide skills training tips, tailored to a part A sample self-monitoring exchange can be found in Appendix G.

Tailored skills training videos: We have skills training videos (2-5 min) for each of the goals in our library. For example, for those assigned a fast food reduction goal, we provide skills training materials on eating out, social eating, and lunch packing. We also have a larger library of general behavior change lessons (e.g., stimulus control, problem solving, social cues, stress management). Our materials include tailored narratives, and information about cost and community resources. We use expectancy priming throughout to heighten salience of materials.[71] We will deliver adapted skills training videos that we have implemented with success in Track and send links to videos presented on responsive websites like a private channel on YouTube.com.

Motivational messages: We will send motivational messages on 3 weekdays and 1 weekend day. For participants randomized to the expert condition, we will send texts from our extensive library of motivational messages. Each is designed to enhance motivation for behavior change and heighten self-efficacy for the assigned set of behavior change goals. To prevent habituation, the messages do not repeat in 30-day cycles.

Participants randomized to the self-generated condition will create text messages in two areas at baseline: reasons and competence for weight loss. The former will target autonomous self-regulation (i.e., change stems from within), while the latter targets efficacy for weight-related behavior change. We will send texts from these pools randomly. Every two weeks, we will give participants the opportunity to create new messages. We will do this for several reasons. First, participants may think of new messages as they engage in behavior change. Second, the creation and receipt of new messages may promote intervention engagement. Finally, crafting new messages can increase their sense of autonomy and competence. A sample motivational message from our library can be found in Appendix G.

Study start-up: During the first 6 months of Year 1, we will adapt the goal library, skills training materials, message library and tailoring algorithms. We will draw from the library of intervention content that we have used in previous studies. We will adapt the iOTA sy
the experimental conditions. We will assess usability and test all systems prior to starting the trial. We have extensive experience with software engineering and will use the resources of the Duke Global Digital Health Science Center (led by Dr. Bennett).

Pilot Testing: We will enroll up to 75 participants prior to the start of the large randomized trial to test the connections between our webpage, Qualtrics survey, texting platform and RedCap database. Participants will be enrolled similarly to our larger trial. We will place geographically

targeted advertisements via Facebook and Nextdoor. The inclusion and exclusion criteria will mirror that of our larger trial.

Those who respond to study marketing will undergo preliminary eligibility screening via a Qualtrics eligibility survey linked to a website created for this study. If deemed eligible via the online screening, participants will be invited to complete the stu
and baseline surveys online via a Qualtrics survey. Those who complete all surveys will be randomized to one of the 32 intervention groups. Those participants will then receive 2-weeks of our text messaging intervention. Pilot participants will not have any in-person visits and there will be no 3,6, or 12 month follow-ups. Pilot study participants will receive a $10 Amazon gift card for their participation.

In addition to our true pilot, the first 20 participants in our larger trial will be pilot-extension participants. These participants will complete all measures and in-person visits as all other participants, but their data will not be included in our study analysis. The rationale is that programming issues or bugs arise every time a new programming component (new goals, survey changes, software updates) is introduced. By having the pilot extension, we can catch these issues before they affect our intervention.

Data collection: Research data will be collected from several sources. During the baseline visit and at subsequent follow-up visits at 3, 6 and 12 months, study staff will collect anthropometric data, including height and weight. Participants will complete a Qualtrics survey before coming to their baseline visits, as well as at 6-months to collect social, psychosocial, and health status data, including data on sociodemographics, physical activity, dietary patterns, self-efficacy, and depression. We will gather self-monitoring data via intervention text messages. In keeping with our practices on prior trials, only trained and certified research staff will obtain data according to detailed study protocols (described in the Data Safety Monitoring Plan). All research staff are required to have human subjects training. All gathered data will be used specifically for research purposes.

As part of enrollment, participants will self-report baseline age, gender, race/ethnicity, health insurance, education, income, employment, health status, marital status, health literacy/numeracy,[85] and smartphone/texting history via a Qualtrics survey.[17] Additional measures by study aim are listed below in Table 4.

Table 4: Outcome measures

	BL	3	6	12
Weight[1]	x	x	x	x
Height[1]	x			
REAP[2] (Rapid Eating and Activity Assessment)	x		x	
Weight Control Strategies[2]	x		x	
GPAQ[2] Physical Activity	x		x	
SF-12[2] Health Survey	x		x	x
Body Related Guilt and Shame	x			
Weight Bias Internalization Scale	x		x	
Confusion, Order and Hubbub Scale	x			
iOTA	x			

Intervention Engagement[2a]	x	x	x	x
Non-use attrition[2b]	x	x	x	x
System Usability Scale[2]		x	x	
Participant Preference[2]	x		x	
Intervention acceptability[2]			x	
Weight loss treatment history[2]	x		x	x
Incentive paid in Amazon e-card	*$20/$ 10**	*$25*	*$25*	*$30***

1= in-person; 2= online via Qualtrics
*$10 if ineligible at in-person visit
** Participants who complete all 3 follow-up evaluation visits after baseline will be reimbursed an additional $15 amazon e-card at his/her 12-month visit.
a The primary measure is self-monitoring episodes (texts received/requests successfully sent). We will also examine skills training video views (completed views/video links successfully sent) and changes in motivational message content (content changes/change requests successfully sent).
b Defined as those who cease intervention participation, but do not drop out of the trial (i.e., they complete 6-month assessments). For each, we will define the week of nonuse as the week in which all intervention participation ceased, and the participant did not return to the intervention.

Baseline Enrollment Survey: Participants who express interest in Charge will be asked to take a series of Qualtrics surveys before coming in for a baseline visit. First, participants will take a short eligibility screener. Eligible participants will go through the informed consent process via Qualtrics and to sign an electronic informed consent form. Participants who sign the informed consent will be asked to fill out baseline surveys and the iOTA goal assignment survey. This survey was tested prior to implementation via mTurk to ensure they are not burdensome (pilot testing was approved in previous amendments).

Baseline Evaluation Visit: At the baseline evaluation visit, study staff will collect written informed consent, administer the motivational message survey (if applicable based on condition), and confirm participant eligibility. This will be followed by an individual orientation to the intervention. Participants will be reimbursed for their time at baseline visits.

We will randomize participants at the baseline visit. Randomization sequences will be generated by a computer algorithm using a covariate adaptive randomization method, in which group assignment will be informed by the balance of race/ethnicity and gender in the previously assigned participants. This method minimizes imbalance between groups for these characteristics, even in a small sample where the risk of imbalance is high and when the exact composition of the sample is not known a priori. Due to the nature of the interventions, it will be difficult to completely blind staff collecting data to treatment assignment. However, we will ensure that different study staff collect follow-up data and we will take all possible steps to blind those data collection staff to treatment assignment. Outcomes will be analyzed blind to allocation status.

Follow-up Data Collection: In addition to the baseline visit, trained study staff will also collect anthropometric data, specifically weight, at subsequent follow-up visits at 3, 6 and 12 months. Participants will complete a self-report survey at baseline and at 6-months to collect social, psychosocial, and health status data, including data on sociodemographics, physical activity, dietary patterns, self-efficacy, and depression. We will gather self-monitoring data via

intervention text messages. In keeping with our practices on prior trials, only trained and certified research staff will obtain data.

2. Subject Selection

Inclusion Criteria: The study involves males and females aged 18-65 years who have English language proficiency, and a BMI above 25 kg/m2. Participants will own a smartphone and be willing to receive multiple text messages daily.

Exclusion Criteria: Participants will be excluded from the study under the following conditions: prior or planned bariatric surgery; psychiatric hospitalization in past 12 months; pregnancy, nursing, or planned pregnancy; history of a cardiovascular event; history of an eating disorder; history of a condition (e.g., end stage renal disease, cancer, schizophrenia) or use of medications (e.g., lithium, steroids, anti-psychotics) that would affect weight measurement, for which weight loss is contraindicated, or might promote weight change; current participation in a weight loss trial and/or recent weight loss > 10%; investigator discretion for safety reasons.

Sample size: We will recruit up to 700 males and females aged 18-65 years who have English language proficiency, and a BMI above 25 kg/m^2. We will recruit a sample that is 30% male and 40% racial/ethnic minority (similar to the demographics of Durham, N.C.). We will waitlist participants if needed in order to reach our target recruitment percentages for males and minorities.

Using the FactorialPowerPlan SAS Macro, developed by the Penn State Methodology Center, we computed the sample size needed for a full 2^5 factorial design. We expect a minimal difference between groups, defined as an effect size of 0.15.[34] With a standard deviation estimate from a recent weight loss trial[90] of 5 kg, and a within-participant correlation of 0.9, this translates into a 0.75 kg difference in weight loss at 6 months between groups given an intervention component and those groups without the intervention component (main effects). We determined that a total sample size of 282 subjects would be required to achieve an overall power of 80% to detect a 0.75 kg difference in weight loss. We conservatively assume 30% dropout at 6 months, so we inflate the sample size to 403. To obtain an equal number of participants in each treatment combination (condition), we further inflate this sample size to up to 700, which is a final sample of 14 participants in each of the 32 conditions. The main effects are then estimated with 224 participants receiving either level of each component. Likewise, pairwise interactions are based on comparisons of means for 224 participants who receive both or neither component compared to those who received only one.

Recruitment: We will recruit participants using a multi-pronged strategy: 1) direct marketing; 2) local media; 3) social media, 4) snowball recruitment and; 5) community organizations. We have used these methods successfully in many of our
experience with general recruitment and have consistently met our recruitment goals. Direct marketing has been particularly useful recently. In the CITY trial,[57] recently conducted at Duke, 40% of the 365 enrolled participants were recruited from direct marketing. Accordingly, we will mail postcards describing the study to potentially eligible households in the 3-county Research Triangle area. We will also advertise online, including the Duke Clinical Trials website, which enrolled participants. For this study, we will also leverage our strong relationships to attract earned media placements. We have been successful attracting earned stories on television, radio, and in print media. These media mentions have consistently led to participant inquiries. We will also advertise in local newspapers (circulation: > 150,000), television, and radio. We will work with local websites and bloggers to advertise the study. We will also place geographically targeted advertisements via Facebook and Google. Our group is

also very active on Twitter (with both local and national followers); we will advertise the study and answer questions using the service. We maintain excellent relationships with several community organizations, including those that service high risk populations. This includes faith-based organizations with whom we have worked on previous trials of mHealth weight loss interventions (e.g., Shape Plan) and a large, local historically Black university (North Carolina Central University). We have been particularly successful using endorsements from key community figures (e.g., college sports stars, church pastors, etc.). Of note, two of our most recent mHealth trials were conducted in a community health center system with more than 42,000 patients that operates in 7 counties in central North Carolina. They have expressed continued interest in serving as a recruitment site. It is important for our sample to be diverse, particularly considering evidence that racial/ethnic minorities both experience the health effects of obesity at disproportionately high rates, *and* that use of text messaging in these groups is almost ubiquitous. [18] We will recruit a sample that is 30% male and 40% racial/ethnic minority (similar to the demographics of Durham, N.C.). We have extensive experience in this area.

Screening, randomization and blinding: Those who respond to study marketing will undergo preliminary eligibility screening via a Qualtrics eligibility survey linked from our study website. As with our other trials, we will request a waiver of written consent to screen and consent participants by web. Those deemed potentially eligible will be invited to complete the study informed consent process and baseline surveys via a Qualtrics survey. Participants who complete the informed consent process and all surveys will be invited for an in-person visit. At the visit, study staff will collect written informed consent and confirm participant eligibility. Study surveys will eliminate or define medical terms, and use simple sentence structure and vocabulary. We have successfully used this approach in several studies. This will be followed by an individual orientation to the intervention.

We will randomize participants at the baseline visit. Randomization sequences will be generated by a computer algorithm using a covariate adaptive randomization method, in which group assignment will be informed by the balance of race/ethnicity and gender in the previously assigned participants. This method minimizes imbalance between groups for these characteristics, even in a small sample where the risk of imbalance is high and when the exact composition of the sample is not known a priori. Due to the nature of the interventions, it will be difficult to completely blind staff collecting data to treatment assignment. However, we will ensure that different study staff collect follow-up data and we will take all possible steps to blind those data collection staff to treatment assignment. Outcomes will be analyzed blind to allocation status.

Retention: Our team has an excellent record of retaining our trial participants. In Shape, we retained 96% of participants (in a profoundly socioeconomically disadvantaged population) at the 18-month
follow-up. In our current study, Track, we also have a >90% 6-month retention rate in a medically vulnerable population. We will use strategies that have been successful in prior studies (e.g., contacting through multiple channels, incentivizing provision of changed contact information, birthday/holiday cards, using family contacts, text messaging and social media). To maximize retention, participants will receive reimbursements at each of the evaluation visits: baseline, 3, 6, and 12 months. Participants who come to all 3 follow-up visits (after baseline) will receive another $15. Home visits will be used when other contact strategies are exhausted. Despite our experience with participant retention, we have set a conservative floor of 70% retention at 6 months. We have exceeded this rate in all of our recent trials.

Phase II

After enrollment is completed for the in-person cohort (Phase I), we will enroll up to 5000 participants in a virtual cohort where there will be no in-person data collection. Participants will be recruited similarly to phase I, with 1) direct marketing; 2) community forums; 3) social media, 4) snowball recruitment and; 5) community organizations. Those who respond to study advertisements will take an eligibility survey via Qualtrics, consent and complete a baseline questionnaire. Eligible participants will be randomized via Prompt and receive the same 6-month iOTA-based intervention.

Since phase II participants will not come in for in-person follow-up assessments, participants will send us picture of their feet on a scale, with the weight visible wearing only light clothing with empty pockets and no shoes at 3-, 6- and 12-months.

3. Risks and Benefits

This is a minimal risk study, and thus we do not anticipate problems beyond our control that involve risks to subjects.

Physical activity: Risks from increased physical activity will be minimized by: 1) recommending physical activity in line with national guidelines; 2) encouraging moderate activity; and 3) directing participants to their physicians when appropriate. If exercise-related symptoms are reported, we will advise participants to get clearance from their PCPs before they can restart physical activity.

Participants will be counseled to change behaviors that will maintain or reduce weight. If individuals follow this advice and decide to change their health behaviors, there should be few risks or side effects. The materials and counseling will provide guidance on preventing and managing the side effects of health behavior change.

Data confidentiality: We will use the standard operating procedures that have been used on our prior trials for survey conduct and data management. These procedures have been developed and used in many studies and we will adhere to these procedures for the proposed study. All paper files related to the study will be stored in a secure location at Duke University in a locked file cabinet accessible only to key study personnel. The privacy, security, and durability of accumulated personal health information are of paramount importance. Our existing practices

physical access to computing resources (hard drives, servers, networking equipment) is secure, audited, and restricted to skilled personnel; virtual access (login and system administration) is encrypted, audited, and limited to skilled personnel; all databases are encrypted and access from the public Internet is precluded; all software and servers are reachable only via a virtual private network (VPN); and al
interface (API) and third-party software is encrypted using SSL. Personnel will have access to perform regular maintenance duties. However, this constituency is limited to senior system administrators and the director of the research group.

Breach of confidentiality: All participant information collected in the context of this study, and even the fact that an individual is participating in the study, will be considered confidential. Confidentiality will be assured through several mechanisms. First, each participant will be assigned an anonymous study ID that will be used on all study forms. Second, all study forms

and paper records that contain participant information (e.g., address lists) will be kept in secured, locked areas or in encrypted databases. In addition, such materials, when in use, will be kept away from public scrutiny. Materials that need to be discarded will be destroyed. Third, access to all participant data and information will be restricted to authorized personnel. In the case of computerized study data, access to data will be password protected and staff members will be assigned individualized passwords that allow them access to only those elements of the data management system to which they are authorized. In addition, all study personnel will maintain certification with the Duke IRB that they have completed training in research ethics, which includes training on confidentiality. Finally, participants will not be identified by name in any reports or publications, nor will data be presented in such a way that the identity of individual participants can be inferred.

All information obtained in the course of the study that identifies an individual will be treated as confidential in accordance with section 903C of the Public Health Service Act (42 U.S.C.299a-1). We will strip all identifiers from analytic data sets after data merging and will keep all personal identifiers in a separate location from the analytic data. No individual participant will be identified in any reports from the study. Data storage will involve computer files that will be password protected and encrypted and will be accessible only to personnel who need to contact participants.

Study surveys, including the online eligibility screen, will be administered using Qualtrics. We will deliver separate surveys to participants in order to minimize drop off and maximize participant security. Each participant will be asked to fill out one survey with his or her name and contact information; participants will thereafter use only study ID or a unique link when completing surveys. At various timepoints throughout data collection and after, we will download survey data from Qualtrics for analyses. Data sets will be de-identified before being downloaded. Data will be downloaded using the Qualtrics export feature. Data will be

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protected. A copy of the raw de-identified data set and/or the results of the analyses will be uploaded to a Box sensitive folder. When the study biostatistician is ready to analyze the data in SAS, a statistical analysis program. She will upload the de-identified data, and SAS will store a copy locally to work from. This data set will be deleted from SAS after analyses are completed.

In order to send and receive text messages, we will use a software engine designed by Duke software engineers, called Prompt. Prompt uses Twilio, Heroku, and Amazon S3. Prompt will receive self-monitoring data that participants send via text message. The data will be automatically analyzed each week according to algorithms we embed. Study staff will log into a password-protected database using multi-factor authentication to view and edit participant information. We will use Twilio to send text messages to participants each week. We delete data from Twilio at least every 2 weeks. We will use Heroku to process data for the engine. We will use Amazon S3 to store data; data will be encrypted when it is stored. If these companies or their business partners disclose data, it may no longer be covered under the Duke privacy protections. Text messaging does not provide a completely secure and confidential means of communication. Participants will be made aware of these risks as well as those that are inherent in using text messaging during the informed consent process. We have used these processes on several previous studies conducted in this population.

Potential Benefits: Potential benefits for study participants include improved lifestyle, lower weight and blood pressure and consequent reduction in cardiovascular risk. An additional benefit for some participants may be personal satisfaction in being part of a study that may have major public health implications for the community. No benefit from participation can be

guaranteed. Potential benefits to others include the possibility that this research will lead to the dissemination of an intervention that can help maintain weight, with consequent reduction in the risks associated with diagnoses of diabetes, high cholesterol, and hypertension. The minimal health risks to participants listed above are offset by the potential benefits to them and to society.

4. Confidentiality

In the present study, we will collect identifying demographic information including: names, addresses, telephone numbers, email addresses, age, gender, race/ethnicity, health insurance, education, income, employment, health status, and marital status. We will use the standard operating procedures that have been used on our prior trials for survey conduct and data management. All paper files related to the study will be stored in a secure location at Duke University in a locked file cabinet accessible only to key study personnel. The privacy, security, and durability of accumulated personal health information are of paramount importance. Physical access to computing resources (hard drives, servers, networking equipment) is secure, audited, and restricted to skilled personnel; virtual access (login and system administration) is encrypted, audited, and limited to skilled personnel; all databases are encrypted and access from the public Internet is precluded; all software and servers are reachable via a password-protected database that is enabled with multifactor authentication; and all communication (API) and third-party software is encrypted using SSL. Personnel must have access to these databases to perform regular maintenance duties. However, this constituency is limited to senior system administrators and the director of the research group.

Strategies for protecting electronic PHI: Screening, outcome measures (height, weight, sociodemographics) and surveys will be entered into Qualtrics and Redcap. We will also enter some participant information (phone number, study group, and behavioral goals) into a software engine developed by Duke software engineers. Prompt is developed on Heroku, a managed container system for data. We will use Heroku to process data analytics. All web-transmitted data are encrypted using a protocol called Transport Layer Security (TLS) or Secure Sockets Layer (SSL). This type of security is most often used for web sites that are doing eCommerce (selling products/services over the Internet). The reason for the increased security is to protect the privacy of visitors/customers and transmission of personal, confidential, financial or billing information over the Internet. We will also password protect study data on Prompt and use multifactor authentication processes. As described above, physical access to computing resources (hard drives, servers, networking equipment) is secure, audited, and restricted to skilled personnel; virtual access (login and system administration) is encrypted, audited, and limited to skilled personnel; all databases are encrypted and access from the public Internet is

(API) and third-party software is encrypted using SSL. Only research staff who have received CITI Certification and are listed on the Duke University Institutional Review Board protocol will have access to the study database. Information in the database will not be shared with anyone outside the research team. On the study consent form (Appendix A), we inform participants that we do collect identifying information and that we take all appropriate measures to minimize the risk of unintentional breach of confidentiality.

The information generated by this study will be kept for seven years after the date of last publication. Then it will be destroyed by shredding the paper copies and by securely deleting the computer files.

Data management will take place under the supervision of Dr. Bennett. Our group has developed extensive quality assurance procedures, including on-going quality control checks.

Some participants will choose to be reimbursed with an electronic Amazon gift card. Participants who choose this method of compensation will be asked to provide their email address, so we can email the gift card to them. Their email address will be stored in a password-protected, encrypted study database. They will not need to provide their social security numbers.

After data analysis, we plan to disseminate the results of the study via journal publications and presentations.

We will not collect information about illegal activities. Further, we do not expect that participants will reveal information subject to reporting because our coaches are instructed to maintain close adherence to a protocol that involves discussing only behavior change efforts related to diet and exercise.

5. Compensation

Participants will be reimbursed in the form of an electronic Amazon gift card for their time at each of the evaluation visits: baseline, 3, 6, and 12 months (20,25,25,30 respectively). If a participant is determined to be ineligible at the time of the screening baseline visit, s/he will be compensated $10 amazon e-card for his or her time. Participants who complete all 3 follow-up evaluation visits after baseline will be reimbursed an additional $15 amazon e-card at his/her 12-month visit.

If a participant does not wish to provide their social security or tax identification number, they can be reimbursed using an electronic Amazon gift card for each visit. Participants who choose this method of compensation will be asked to provide their email address, so we can email the gift card to them. Their email address will be stored in a password-protected, encrypted study database.

6. Informed Consent

Please see the consent form attached (Appendix A).

7. Deception

Deception will not be used in the present study.

8. Debriefing

We do not anticipate a need for debriefing.

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10. Appendices

A. Informed Consent
B. Baseline Survey
C. iOTA Survey
D. Web-based Eligibility Screen
E. Recruitment Postcard
   E.1. Recruitment Radio Spot
F. IRB Personal Data Disclosure Form
G. iOTA Goal Library
H. Sample text messages from Charge
I. Phase II Welcome Email
J. Full Protocol

INFORMED CONSENT

Appendix A

Duke University
Informed Consent form for participation in *Charge*
(Online Consent for Online Baseline Survey and In-Person Consent for Baseline Visit)

What is *Charge*?

Charge is a research study. Researchers at Duke University are doing this study. The goal of the study is to find the best way to use text messaging to help men and women lose weight and take care of their health.

Charge is open to men and women who are between 18 and 65 years old. To be eligible for the study, we will weigh you and take your height. Your weight and height must be in a certain range to be eligible for the study.

To be eligible for this study, you must have a smartphone and be willing to send and receive text messages.

A total of up to 700 patients will be invited to take part in this study.

What is the reason for this form?

We are inviting you to join *Charge*

This consent form explains the study and your part in it.

Please read the form carefully. Feel free to ask any questions at any time about the study.

If you decide to take part in the study, you are a volunteer. You can join the study now and stop later if you change your mind.

You may quit the study at any time.

What will happen if you join the study?

If you decide to join, your participation will last 12 months.

We will ask you to take a 30-
personal information, like your age, gender, race/ethnicity, education, and marital status. Once you finish the survey, our staff will call you to schedule a time come to our study office for a baseline visit. This visit should take 30 minutes. We will take your height and weight at the visit to confirm your eligibility.

Using a computer, all participants in this study will be randomly placed into one of 32 experimental groups. While group assignment is random, the computer will make sure
We will tell you which group you are in at your baseline visit. Depending on
fill out another short survey.

We will ask you some questions about certain behaviors like what you eat and how much walking you do.

We will ask you to change some of these behaviors to help you maintain or lose weight.

We will ask you to monitor these behaviors by answering our questions. The study will

will answer these questions by using the buttons on your phone.

You will receive information about your health via short videos we will send you by SMS.

You will also have 20-minute follow-up visits for weight measurements at:

- 3 months
- 6 months
- 12 months

We will send you surveys before the follow-up visits at 3 months, 6 months and 12-months via a text message link.

What are the risks or discomforts of the study?

The study will help you follow general health guidelines from the National Institutes of Health. The activities we ask you to do (such as walking more, eating healthy) have very little risk to your body.

We may ask you to get more exercise as part of this study. You will mostly be asked to do activities (like walking) that usually do not cause injuries. However, sometimes injuries like muscle strains and sprains can happen. We will talk with you about ways to not get hurt.

Most people do not have problems when they get more physical activity. We may only recommend that you do some brisk walking and this is consistent with public health guidelines. If you have any pain from exercise, we would want you to see a doctor right away.

If you become pregnant, we will ask you to leave the study. Changes in diet and weight may not be healthy for a baby during pregnancy.

If study investigators think you should not continue in the study for health reasons, we will ask you to leave the study.

- There is a potential risk of loss of confidentiality of the information you send us via text message. Text messaging is not a completely secure method of communication. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

You can refuse to take part in any part of the study. You can also refuse to answer any questions that make you uncomfortable. You can drop out of the study at any time, and your relationship with your health care professionals will stay the same. Your health insurance benefits will not change.

What are the benefits of taking part in the study?

We cannot promise that you will you will lose weight while participating in our study but, by taking part, we hope that you will learn ways to be healthy.

Participation in the study helps us learn more about ways to keep men and women in your community healthy.

Will I be paid for taking part in *Charge*?

You will receive reimbursements for your time at each of your study visits, including baseline, 3-, 6-, and 12-months in the form of an amazon e-card. Amounts will vary from $10 - $45.

If you quit the study or become ineligible for the study for any reason, you will be paid for your participation to that point.

How will my privacy be protected?

Every effort will be made to keep your information private; however, this cannot be guaranteed. The information we gather from you (name, address, phone number, etc) will be kept in databases on password-protected computers at Duke and we will use code numbers on data collected. The information we collect will be used only for this study. Only study staff approved by the Duke Institutional Review Board (IRB) will be able to see your information. None of your data will ever be sent to third parties except as described in this consent form, with your permission, or as may be required by law. We will only report information about the whole study group, not about individual people.

We realize that no data security system is completely safe, but we will take all appropriate measures to minimize the risk of violating your privacy.

Many applications on your phone and email services you commonly use work with text messaging and cloud-based companies to send and receive information. In order to send you send text messages, we use Twilio, Heroku, and Amazon S3. These companies encrypt your information on their servers, but no system is completely safe. If these companies decide to share these data, it may no longer be covered under the privacy protections.

When we interview you, we will speak to you in a private space.

We will destroy copies of all personal health information and other study information seven years after the date of last publication.

Since you will receive an electronic Amazon gift card, we will collect your email address, so we can email you the Amazon gift card. We will keep this information in a password-protected, encrypted study database. This information will also be shared with Duke accounting, but this information will not be connected to your data.

Will the study pay if there is an injury?

If you get hurt from taking part in this study, you should contact Jamiyla Bolton (919-613-5456), after contacting a health professional (like first aid, your primary care provider, or emergency treatment). However, the study will not pay for the treatment. Your health insurance may be billed for the cost.

Where can I get more information?
For questions about your rights as a research participant, please call:
Chair
Duke University
Institutional Review Board
(919) 684-3030

For questions about the study, please call:
Jamiyla Bolton, MS
Project Director
Duke University
(919) 684-1953

What does my signature on this page mean?

Your signature means that:

- You have read this form
- You have been given an opportunity to ask questions.
- You agree to join the study

[For written consent only, not Qualtrics consent]

_____ has been informed of the nature and purpose of the procedures described above, including any risks involved with participation in the study. He or she has been given time to ask any questions, and these questions have been answered to the best of the investigator's ability. A signed copy of this consent form will be made available to the subject.

_____Research Assistant _____Date

I have been told about this research study and its possible benefits, risks, and discomforts. I agree to take part in this research as a subject. I know that I am free to change my mind and quit this project at any time.

_____Participant _____ Date

Charge study: consent form phase II

What is *Charge*?

Charge is a research study. Researchers at Duke University are doing this study. The goal of the study is to find the best way to use text messaging to help men and women lose weight and take care of their health.

Charge is open to men and women who are between 18 and 65 years old. To be eligible for the study, you will be asked to report your weight and height. Your weight and height must be in a certain range to be eligible for the study.

To be eligible for this study, you must have a smartphone and be willing to send and receive text messages.

Up to 5000 participants will be invited to take part in this study.

What is the reason for this form?

We are inviting you to join *Charge.*

This consent form explains the study and your part in it.

Please read the form carefully. Feel free to ask any questions at any time about the study.

If you decide to take part in the study, you are a volunteer. You can join the study now and stop later if you change your mind.

You may quit the study at any time.

What will happen if you join the study?

If you decide to join, your participation will last 12 months.

We will ask you to take a 30-
personal information, like your age, gender, race/ethnicity, education, and marital status.

Once you finish the survey, a computer, all participants in this study will be randomly placed into one of 32 experimental groups. While group assignment is random, the

will tell y
asked to fill out another short survey.

We will ask you some questions about certain behaviors like what you eat and how much walking you do.

We will ask you to change some of these behaviors to help you maintain or lose weight.

We will ask you to monitor these behaviors by answering our questions. The study will

different number of text messages
will answer these questions by using the buttons on your phone.

You will receive information about your health via short videos we will send you by SMS.

You may also be asked to complete 3 more follow-up surveys for weight measurements at:

- 3 months
- 6 months

- 12 months

If you are asked to complete follow-up surveys, we will send you links to these online via an email link.

What are the risks or discomforts of the study?

The study will help you follow general health guidelines from the National Institutes of Health. The activities we ask you to do (such as walking more, eating healthy) have very little risk to your body.

We may ask you to get more exercise as part of this study. You will mostly be asked to do activities (like walking) that usually do not cause injuries. However, sometimes injuries like muscle strains and sprains can happen. We will talk with you about ways to not get hurt.

Most people do not have problems when they get more physical activity. We may only recommend that you do some brisk walking and this is consistent with public health guidelines. If you have any pain from exercise, we would want you to see a doctor right away.

If you become pregnant, we will ask you to leave the study. Changes in diet and weight may not be healthy for a baby during pregnancy.

If study investigators think you should not continue in the study for health reasons, we will ask you to leave the study.

- There is a potential risk of loss of confidentiality of the information you send us via text message. Text messaging is not a completely secure method of communication. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

You can refuse to take part in any part of the study. You can also refuse to answer any questions that make you uncomfortable. You can drop out of the study at any time, and your relationship with your health care professionals will stay the same. Your health insurance benefits will not change.

What are the benefits of taking part in the study?

We cannot promise that you will you will lose weight while participating in our study but, by taking part, we hope that you will learn ways to be healthy.

Participation in the study helps us learn more about ways to keep men and women in your community healthy.

How will my privacy be protected?

Every effort will be made to keep your information private; however, this cannot be guaranteed. The identifiable information we gather from you (name, address, phone number, etc) will be kept in secure online servers and databases on password-protected computers at Duke and we will use code numbers on data collected. The information we collect will be used only for this study. Only study staff approved by the Duke Institutional Review Board (IRB) will be able to see your identifiable information. None of your data will ever be sent to third parties except as described in this consent form, with your permission, or as may be required by law. We will only report information about the whole study group, not about individual people.

We realize that no data security system is completely safe, but we will take all appropriate measures to minimize the risk of violating your privacy.

Many applications on your phone and email services you commonly use work with text messaging and cloud-based companies to send and receive information. In order to send you text messages, we use Twilio, Heroku, and Amazon S3. These companies encrypt your information on their servers, but no system is completely safe. If these companies decide to share these data, it may no longer be covered under the privacy protections.

We will destroy copies of all personal health information and other study information seven years after the date of last publication.

Will the study pay if there is an injury?

If you get hurt from taking part in this study, you should contact Jamiyla Bolton (919-613-5456), after contacting a health professional (like first aid, your primary care provider, or emergency treatment). However, the study will not pay for the treatment. Your health insurance may be billed for the cost.

Where can I get more information?
For questions about your rights as a research participant, please call:
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Duke University
Institutional Review Board
(919) 684-3030

For questions about the study, please call:
Jamiyla Bolton, MS
Project Director
Duke University

(919) 684-1953

What does my signature on this page mean?

Your signature means that:

- You have read this form
- You have been given an opportunity to ask questions.
- You agree to join the study

I have been told about this research study and its possible benefits, risks, and discomforts. I agree to take part in this research as a participant. I know that I am free to change my mind and quit this project at any time.

_____ _____

Participant Date

Duke University
Informed Consent form for participation in *Charge Pilot*
(Online Consent)

What is *Charge*?

Charge is a research study. Researchers at Duke University are doing this study. The goal of the study is to find the best way to use text messaging to help men and women lose weight and take care of their health.

This portion of Charge is a pilot study. A pilot study is used to make sure all study parts are working as they should before we enroll participants in a larger study.

Charge is open to men and women who are between 18 and 65 years old. To be eligible for the study, we will weigh you and take your height. Your weight and height must be in a certain range to be eligible for the study.

To be eligible for this study, you must have a smartphone and be willing to send and receive text messages.

Up to 75 patients will be invited to take part in this study.

What is the reason for this form?

We are inviting you to join *Charge*

This consent form explains the study and your part in it.

Please read the form carefully. Feel free to ask any questions at any time about the study.

If you decide to take part in the study, you are a volunteer. You can join the study now and stop later if you change your mind.

You may quit the study at any time.

What will happen if you join the study?

If you decide to join, your participation will last 2 weeks.

Using a computer, all participants in this study will be randomly placed into one of 32 experimental groups. While group assignment is random, the computer will /ethnicity and gender are balanced. We will tell you which group you in after you fill out your initial surveys. Depending on what

We will ask you some questions about certain behaviors like what you eat and how much walking you do.

We will ask you to change some of these behaviors to help you maintain or lose weight.

We will ask you to monitor these behaviors by answering our questions. The study will text you on your cell phone. These texts will come from a computer and

phone.

You will receive information about your health via short videos we will send you by SMS.

What are the risks or discomforts of the study?

The study will help you follow general health guidelines from the National Institutes of Health. The activities we ask you to do (such as walking more, eating healthy) have very little risk to your body.

If study investigators think you should not continue in the study for health reasons, we will ask you to leave the study.

- There is a potential risk of loss of confidentiality of the information you send us via text message. Text messaging is not a completely secure method of communication. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

You can refuse to take part in any part of the study. You can also refuse to answer any questions that make you uncomfortable. You can drop out of the study at any time, and your relationship with your health care professionals will stay the same. Your health insurance benefits will not change.

What are the benefits of taking part in the study?

We cannot promise that you will you will lose weight while participating in our study but, by taking part, we hope that you will learn ways to be healthy.

Participation in the study helps us learn more about ways to keep men and women in your community healthy.

Will I be paid for taking part in *Charge*?

You will receive a $10 Amazon gift card for participation.

If you quit the study or become ineligible for the study for any reason, you will be paid for your participation to that point.

How will my privacy be protected?

Every effort will be made to keep your information private; however, this cannot be guaranteed. The information we gather from you (name, address, phone number, etc) will be kept in databases on password-protected computers at Duke and we will use code numbers on data collected. The information we collect will be used only for this study. Only study staff approved by the Duke Institutional Review Board (IRB) will be able to see your information. None of your data will ever be sent to third parties except as described in this consent form, with your permission, or as may be required by law. We will only report information about the whole study group, not about individual people.

We realize that no data security system is completely safe, but we will take all appropriate measures to minimize the risk of violating your privacy.

Many applications on your phone and email services you commonly use work with text messaging and cloud-based companies to send and receive

information. In order to send you send text messages, we use Twilio, Heroku, and Amazon S3. These companies encrypt your information on their servers, but no system is completely safe. If these companies decide to share these data, it may no longer be covered under the privacy protections.

We will destroy copies of all personal health information and other study information seven years after the date of last publication.

Since you will receive an electronic Amazon gift card, we will collect your email address, so we can email you the Amazon gift card. We will keep this information in a password-protected, encrypted study database. This information will also be shared with Duke accounting, but this information will not be connected to your data.

Will the study pay if there is an injury?

If you get hurt from taking part in this study, you should contact Jamiyla Bolton (919-613-5456), after contacting a health professional (like first aid, your primary care provider, or emergency treatment). However, the study will not pay for the treatment. Your health insurance may be billed for the cost.

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For questions about the study, please call:
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Project Director
Duke University
(919) 684-1953

What does my electronic signature on this page mean?

Your signature means that:

- You have read this form
- You have been given an opportunity to ask questions.
- You agree to join the study

I have been told about this research study and its possible benefits, risks, and discomforts. I agree to take part in this research as a subject. I know that I am free to change my mind and quit this project at any time.

STATISTICAL ANALYSIS PLAN (SAP)

1 Study Overview

Background/Introduction:

1.1 Study Aims

- Determine the effect of each of the five intervention components on absolute weight change from baseline to 6 months.
- Assemble a multicomponent treatment package including the comparator level of components with standardized main effect sizes of ≥ 0.7 kg. Otherwise, include the default level, unless interactions of ≥ 0.7 kg are present that would cause us to include the comparator level.

2 Study Population

2.1 Inclusion Criteria

- English language proficiency
- BMI above 25 kg/m^2
- Own a smartphone
- Be willing to receive multiple text messages daily.
- We aimed to recruit a sample that is 30% male and 40% racial/ethnic minorities.

2.2 Exclusion Criteria

- Exclusion criteria include the following conditions: prior or planned bariatric surgery; psychiatric hospitalization in past 12 months; pregnancy, nursing, or planned pregnancy; history of a cardiovascular event; history of an eating disorder; history of a condition (e.g., end stage renal disease, cancer, schizophrenia) or use of medications (e.g., lithium, steroids, anti-psychotics) that would affect weight measurement, for which weight loss is contraindicated, or might promote weight change; current participation in a weight loss trial and/or recent weight loss > 10%, and; investigator discretion for safety reasons.

2.3 Sample size

Sample size: We plan to recruite 448 males and females aged 18-65 years who have English language proficiency, and a BMI between 25-40 kg/m2. We plan to recruit a sample that is 30% male and 40% racial/ethnic minority.

Using the FactorialPowerPlan SAS Macro,[1] we computed the sample size needed for a full 2x2x2x2x2 factorial design. We expect a minimal difference between groups, defined as an effect size of 0.15.[2] With a standard deviation estimate from a recent weight loss trial[3] of 5 kg, and a within-participant correlation of 0.9, this translates into a 0.75 kg difference in weight loss at 6 months between groups given the comparison level of the intervention component and those groups with the default level of the intervention component (main effects). We determined that a total sample size of 282 subjects would be required to achieve an overall power of 80% to detect a 0.75 kg difference in weight loss. We conservatively assume 30% dropout at 6 months, so we inflate the sample size to 403. To obtain an equal number of participants in each treatment combination (condition), we further inflate this sample size to 448, which is a final sample of 14 participants in each of the 32 conditions. The main effects are then estimated with 224 participants receiving either level of each component. Likewise, pairwise interactions are based on comparisons of means for 224 participants who receive both or neither component compared to those who received only one.

2.4 Data Acquisition

Fill in all relevant information:

Study design	Factorial trial
Data source/how the data were collected	Primary data collection from participants in North Carolina
Contact information for team member responsible for data collection/acquisition	Sandy Askew sandy.askew@duke.edu
Date or version (if downloaded, provide date)	October 21, 2019
Data transfer method and date	Transferred from Box to CRU drive on November 11, 2019
Where dataset is stored	A shared Box folder called "Charge Data Cleaning"

3 Outcomes, Exposures, and Additional Variables of Interest

3.1 Primary Outcome(s)

- The primary outcome is absolute change in weight from baseline to 6 months. Weight is measured in duplicate by trained, certified staff.

3.2 Secondary Outcome(s)

- Absolute change in weight from baseline to 12 months.

3.3 Other variables of interest.

- Absolute change in weight from baseline to 3 months. Will be included for statistical modeling purposes.
- Engagement:

3.4 Primary predictors

The primary predictors are the five text messaging intervention components listed in the table below. Detailed descriptions of these components are provided in Appendix A.

Intervention component	Default Level	Comparator Level
Motivational Messages	Expert generated	Self-generated
Texting frequency	Weekly	Daily
Reminders	One	Multiple
Feedback	Individual goal	Summary Score
Performance comparison	Self	Others (group)

4 Statistical Analysis Plan

Notes: *Participants in the full-length pilot will be included in the main analysis*, since they ended up being recruited right about when the full trial started, and were not actually used to fix bugs in the program. In the primary analysis, *those whose data is collected outside of the study window will be treated as missing for that time point*. Sensitivity analyses will be performed including such data.

For each of the five components, participants' weights and demographics will be summarized by levels of the component. Continuous variables will be summarized using means, standard deviations, medians, quartiles, and ranges, and categorical variables will be summarized using counts and percentages.

The primary outcome is absolute change in weight from baseline to 6 months. We will estimate the main effects of each intervention component on the primary outcome and of all pairwise interactions of those components at each follow-up time point using a linear mixed effects model. In order to estimate effects on weight change, the model will include as outcomes absolute weight at baseline and each follow-up time point. The model will include fixed effects for: time point (3 months, and 6 months, and 12 months), the time-by-component and time-by-pairwise up to five-way interactions, and gender (the variable by which the randomization was stratified). We do not include the effects of the components at baseline. This constrains the baseline comparisons to be equal, which is appropriate in a randomized trial and increases power.[4,5] The model will allow us to estimate weight change and percentage weight change at the interim time point (month 3) and final follow-up time point (month 12), but the main estimate of interest will be the five treatment indicators by month 6 interaction.

After examining the model, we will assemble a multicomponent intervention package. If a component has a main effect on weight loss at 6 months greater than or equal to 0.7 kg (1.5 lbs), and no significant interaction with another component, then the superior level of the component will be retained for the intervention package. Otherwise, if there is no significant main effect or interaction, the default (reference) level of the component will be retained. We will reconsider inclusions based on the presence of large (effect ≥ 0.7 kg) interactions. This decision making is based on the approach outlined in Collins et al.[6] Although the secondary outcome of 12-month weight will not be used in the *primary* decision-making process, we may reconsider our inclusions if there is a large change in effect between 6 months and 12 months.

Given the factorial design, we will use effect coding, rather than dummy coding, for analyzing the effects of the intervention components.[7] If the sample size is equal per condition, all of the tests of main effects and interactions are uncorrelated—that is, the main effect of a condition is the same even if other treatment conditions and interactions are included in the statistical model. Even with unequal sample sizes across conditions (as may occur with differential dropout by condition), if the imbalance is minor, the correlations between effects should be small.[8]

Missing outcome data due to dropout or missing intermediate visits is expected to be at most 30%. Since the mixed model will be fit using a full maximum likelihood method, we will be able to account for predictors of missingness in the model in order to obtain valid estimates of the main component effects, thanks to the property that the response can be missing at random (MAR) as defined by Little and Rubin.[9] In practice, we will compare baseline characteristics of completers and non-completers. If we find that any covariates predict missingness, we will adjust for these variables in the model in order to obtain valid estimates.

In addition, we will examine gender as a potential moderator, where those who answered "non-binary" will be excluded from the analysis, given the extremely small numbers of participants who

answered this way. We acknowledge that we are not powered to detect moderators, but these results may be used to guide future studies.

Engagement data will be summarized and displayed in a table.

5 Table shells and proposed figures

Potential format of table 1 (from Piper et al.[10]):

Table 1 Demographic and smoking history characteristics.

	Total sample	*Preparation gum*		*Preparation patch*		*Preparation counseling*		*In-person counseling*		*Phone counseling*		*Medication duration*	
		On	*Off*	*On*	*Off*	*On*	*Off*	*On*	*Off*	*On*	*Off*	*On*	*Off*
Women (%)	54.6	54.3	55.0	55.3	53.9	54.6	54.7	55.4	53.9	53.8	55.5	56.3	53.2
Age (mean, SD)	45.8 (12.0)	45.3 (11.9)	46.2 (12.2)	45.2 (11.8)	46.3 (12.3)	46.2 (12.2)	45.3 (11.9)	45.8 (12.2)	45.7 (11.9)	45.1 (12.0)	46.4 (12.0)	45.1 (12.2)	46.4 (11.6)
High School diploma or GED only (%)	31.4	32.0	30.7	31.4	31.5	34.5	28.4	30.1	32.7	32.5	30.4	30.6	32.2
At least some college (%)	58.7	57.2	60.2	57.6	59.7	55.7	61.5	58.7	58.2	58.1	59.1	60.1	57.3
White (%)	87.8	87.8	87.8	87.8	87.7	88.5	87.0	87.8	87.7	89.5	86.0	87.0	88.4
African American (%)	7.8	9.0	6.5	8.6	7.0	6.7	8.9	8.4	7.2	7.0	8.6	9.3	6.4
Hispanic (%)	3.9	4.5	3.1	3.1	4.7	4.2	3.5	4.2	3.5	4.5	3.2	5.1	2.8
Health system A (%)	57.3	55.5	59.4	59.9	54.5	56.8	57.8	61.1	53.6	59.1	55.5	60.9	54.1
Cigs/day (mean, SD)	17.7 (8.2)	17.5 (8.4)	17.9 (7.9)	18.1 (8.0)	17.2 (8.4)	17.8 (8.4)	17.5 (8.1)	17.9 (8.2)	17.4 (8.2)	18.1 (8.4)	17.3 (7.9)	17.8 (7.8)	17.6 (8.5)
Baseline carbon monoxide (mean, SD)	20.3 (11.4)	20.3 (11.7)	20.4 (11.0)	20.6 (10.7)	20.0 (12.1)	20.6 (11.3)	20.0 (11.4)	20.3 (11.6)	20.4 (11.1)	20.2 (11.4)	20.4 (11.3)	19.6 (10.8)	21.0 (11.9)
FTND (mean, SD)	4.8 (2.2)	4.8 (2.1)	4.8 (2.3)	4.9 (2.2)	4.7 (2.1)	4.9 (2.2)	4.7 (2.1)	4.9 (2.1)	4.7 (2.1)	4.9 (2.2)	4.8 (2.1)	4.8 (2.2)	4.8 (2.1)
Heaviness of Smoking Index (mean, SD)	3.1 (1.4)	3.1 (1.4)	3.1 (1.4)	3.2 (1.4)	3.0 (1.4)	3.1 (1.5)	3.0 (1.4)	3.2 (1.4)	3.0 (1.5)	3.2 (1.4)	3.0 (1.4)	3.1 (1.4)	3.1 (1.4)

On = factor was present or at the intensive level or longest duration (e.g. intensive counseling, 16 weeks of medication). Off = factor was not present or was at the minimal level or shortest duration (e.g. minimal counseling, 8 weeks of medication). The study was conducted in two healthcare systems (A and B). FTND = Fagerström Test of Nicotine Dependence; SD = standard deviation; GED = general educational development.

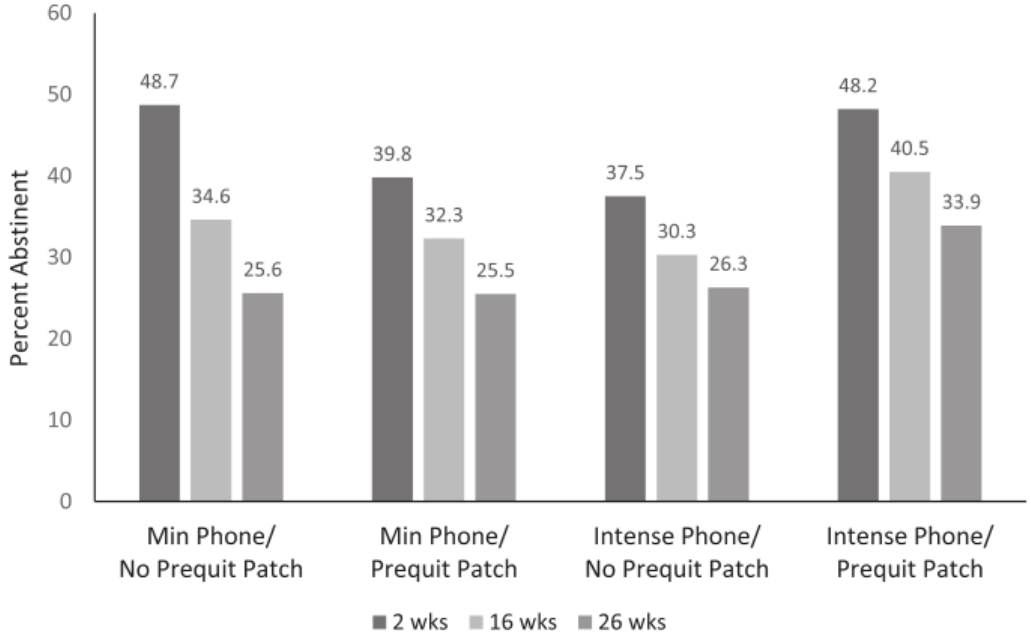
Table 2. Potential format of regression results table (from Piper et al.)

Table 3 Logistic regression models for 2-, 16- and 26-week point-prevalence outcome.

	2 weeks post-TQD				*16 weeks post-TQD*				*26 weeks post-TQD*			
	Unadjusted		*Adjusted*[a]		*Unadjusted*		*Adjusted*[a]		*Unadjusted*		*Adjusted*[a]	
Variable	*b*	*P-value*	*b*	*P-value*	*b*	*P-value*	*b*	*P-value*	*b*	*p-value*	*b*	*P-value*
Intercept	–0.26	0.001	0.43	0.45	–0.70	< 0.001	–0.69	0.25	–1.04	< 0.001	–0.34	0.59
Preparation patch	0.01	0.87	0.04	0.66	0.08	0.34	0.11	0.22	0.09	0.34	0.11	0.24
Preparation gum	–0.01	0.95	–0.00	0.96	0.11	0.21	0.12	0.19	0.12	0.20	0.12	0.23
Preparation counseling	0.03	0.69	0.04	0.60	0.18	0.04	0.19	0.03	0.11	0.23	0.11	0.23
Cessation in-person counseling	0.14	0.10	0.15	0.07	0.05	0.54	0.06	0.48	–0.04	0.68	–0.03	0.80
Cessation phone counseling	–0.03	0.72	–0.03	0.75	0.05	0.59	0.06	0.54	0.12	0.21	0.12	0.20
Medication duration	0.02	0.78	0.01	0.91	0.08	0.39	0.07	0.46	–0.02	0.80	–0.03	0.73
Preparation patch × preparation gum	0.05	0.56	0.05	0.54	0.04	0.68	0.04	0.65	0.06	0.54	0.06	0.53
Preparation patch × preparation counseling	0.16	0.050	0.18	0.04	0.15	0.10	0.17	0.07	0.18	0.07	0.19	0.06
Preparation patch × cessation in-person	0.14	0.09	0.15	0.08	0.19	0.03	0.20	0.03	0.22	0.02	0.22	0.02

Another example of showing effects:

a. Preparation Patch x Cessation Phone Counseling – Significant at Weeks 2 and 16



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7 Appendix A

Motivational messaging (self- vs expert-generated)

Self: As part of Charge, we'd like you to write some motivational messages to yourself. These messages will help you stay positive and encouraged. Your next step to get started is to write yourself a few messages to get you started. We will text these to you a few times a week.

Expert-generated: As part of Charge, we'll be sending you motivational text messages a few times a week. These messages were written by people who are experts in helping people lose weight, and are meant to help you stay positive and encouraged.

Texting frequency (daily vs weekly)

Daily: Every day, we will text you to ask how you did yesterday with each of your 4 Charge goals. The text will look like this: "Yesterday, did you: eat any red zone foods, drink any sugary drinks, eat 5+ fruits and vegetables, eat any sweet snacks?"
You will reply to this message with your answers to each yes/no question - like this:
"y, y, y, n"
After we get your reply, we'll send you personalized feedback and some tips/ideas about how to reach your goals. Taking a few seconds to reply to us every day helps us keep track of your progress over time – by doing that, we can give you the most personalized and helpful feedback.

Weekly: Every week, we will text you to ask how you did with each of your 4 Charge goals. The text will look like this: "Last week, how many days did you: eat any red zone foods, drink any sugary drinks, eat 5+ fruits and vegetables, eat any sweet snacks?"
You will reply to this message with your answers to each yes/no question - like this:
"2, 3, 2, 1"
After we get your reply, we'll send you personalized feedback and some tips/ideas about how to reach your goals. Taking a few seconds to reply to us every week helps us keep track of your progress over time - by doing that, we can give you the most personalized and helpful feedback.

Reminders (one vs multiple)

One: If you don't reply to the first text we send you each [day/week], we will text you one more time to remind you to track your progress. We recommend replying to the first text we send you, so you get it out of the way!

Multiple: If you don't reply to the first text we send you each [day/week], we will text you a few more times over the [day/week] to remind you to track your progress. We recommend replying to the first text we send you, so you get it out of the way!

Feedback type (summary score vs individual goal)

Summary score: When we send you feedback every [day/week] we will send one number, an overall score, that considers how you're doing on all of your goals.

Individual goal: When we send you feedback every [day/week], we will give you feedback on specific goals. You may not get feedback on how you're doing on every one of your goals individually, but we'll send you smart feedback based on how you're doing over time.

Comparison unit (self vs group)

Self: The feedback we send you each [day/week] will take into account how you've been doing. The more [days/weeks] you track your goals, the better our feedback will be. For example, we may say "You've been getting better at meeting all your goals!" or "Looks like your progress is slowing on each of your goals".

Group: The feedback we send you each [day/week] will take into account how you've been doing compared to other people in Charge. For example, we may say, "Only a quarter of Charge participants are doing better than you are" or "Your scores have placed you in the top 10% of program participants".

Condition	Frequency	Motivational Messaging	Reminders	Feedback Type	Comparison Unit
1	Weekly	Self-generated	One	Summary Score	Self
2	Weekly	Self-generated	One	Summary Score	Group
3	Weekly	Self-generated	One	Individual Goal	Self
4	Weekly	Self-generated	One	Individual Goal	Group
5	Weekly	Self-generated	Multiple	Summary Score	Self
6	Weekly	Self-generated	Multiple	Summary Score	Group
7	Weekly	Self-generated	Multiple	Individual Goal	Self
8	Weekly	Self-generated	Multiple	Individual Goal	Group
9	Weekly	Expert-generated	One	Summary Score	Self
10	Weekly	Expert-generated	One	Summary Score	Group
11	Weekly	Expert-generated	One	Individual Goal	Self
12	Weekly	Expert-generated	One	Individual Goal	Group
13	Weekly	Expert-generated	Multiple	Summary Score	Self
14	Weekly	Expert-generated	Multiple	Summary Score	Group
15	Weekly	Expert-generated	Multiple	Individual Goal	Self
16	Weekly	Expert-generated	Multiple	Individual Goal	Group
17	Daily	Self-generated	One	Summary Score	Self
18	Daily	Self-generated	One	Summary Score	Group
19	Daily	Self-generated	One	Individual Goal	Self
20	Daily	Self-generated	One	Individual Goal	Group
21	Daily	Self-generated	Multiple	Summary Score	Self
22	Daily	Self-generated	Multiple	Summary Score	Group
23	Daily	Self-generated	Multiple	Individual Goal	Self
24	Daily	Self-generated	Multiple	Individual Goal	Group
25	Daily	Expert-generated	One	Summary Score	Self
26	Daily	Expert-generated	One	Summary Score	Group
27	Daily	Expert-generated	One	Individual Goal	Self
28	Daily	Expert-generated	One	Individual Goal	Group
29	Daily	Expert-generated	Multiple	Summary Score	Self
30	Daily	Expert-generated	Multiple	Summary Score	Group
31	Daily	Expert-generated	Multiple	Individual Goal	Self
32	Daily	Expert-generated	Multiple	Individual Goal	Group

8 Appendix B

***Description of Track**: Track was a 12-month weight loss intervention delivered between 2013-2015 that utilized the iOTA framework. Similar to Charge, participants (n= 175 in the intervention arm) were asked to change 4 weight-related behaviors at a time and to report their progress via text message (or automated phone calls) every week. In Track, each participant was assigned 4 goals to track at a time, in 8 week cycles. So some people tracked sugary drinks for the first Cycle (weeks 1-8) and some people tracked it in a different cycle, later in the study. We have self-

monitoring data for 175 participants for 1 year on the same goals as we are assigning in Charge. Track participants were patients at Piedmont Health with obesity and at least 1 obesity-related co-morbidity.

In the **summary score + group comparison** condition (in both self-monitoring conditions), we'll calculate an average score across all 4 goals a participant is tracking each day or week.

We will create a score from the ***same 4 goals*** as the participant has using the ***mean score of each goal*** for all participants who tracked it the **same cycle week** as the participant. This would mean we could include everyone who ever tracked "No Sugary Drinks" - whether they track it in Cycle 1, 3, or 5. We'd match the score to their cycle week - so if a Charge participant is in the 4th week of Cycle 2, they'd be compared to Track participants who ever tracked "No Sugary Drinks" in the 4th week of any cycle.

We will calculate the following variables to use as referent data:
For the people who get a summary score:

a. Average summary score for each week (All participants, all goals)
b. % of people who get each summary score for each week
c. Mode for each summary score each week
d. Median for each summary score for each week

For people who get feedback on specific goals:

a) the average score *for each goal* each week
b) The percent of people who got each score for each goal each week
c) the mode for each individual goal each week
d) the median for each goal score for each week.

This allows us to analyze the data differently to provide feedback variety - we can tell people their percentile (you're in the top 10%!) or how they're doing compared to most other people, or how they are doing compared to the group's average.