**Complete Title: A Micro-randomized Trial of JITAI Messaging to Improve Adherence to Multiple Weight Loss Behaviors in Young Adults**

**Sponsor: University of North Carolina, Chapel Hill**

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## University of North Carolina, Chapel Hill

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I confirm that I have read this protocol and understand it.

Principal Investigator Signature: 

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## ABBREVIATIONS AND DEFINITIONS OF TERMS

| Abbreviation | Definition |
|---|---|
| **AM** | Active Minutes |
| **API** | Application Program Interface |
| **ASA-24** | Automated Self-Administered 24-hour Recall |
| **BCT** | Behavior Change Technique |
| **BMI** | Body Mass Index |
| **CES-D** | Center for Epidemiological Studies Depression Scale |
| **DSMB** | Data Safety Monitoring Board |
| **EARLY** | Early Adult Reduction of weight through LifestYle intervention |
| **FAQs** | Frequently Asked Questions |
| **INCOM** | Iowa-Netherlands Comparison Orientation Measure |
| **IRB** | Institutional Review Board |
| **JITAI** | Just-in-Time Adaptive Intervention |
| **JIT** | Just-in-Time |
| **MAR** | Missing At Random |
| **MOST** | Multiphase Optimization Strategy |
| **MRT** | Micro-randomized Trial |
| **MVPA** | Moderate to Vigorous Physical Activity |
| **NCI** | National Cancer Institute |
| **NHLBI** | National Heart, Lung, and Blood Institute |
| **NIH** | National Institutes of Health |
| **OCT** | Office of Clinical Trials |
| **PAR-Q** | Physical Activity Readiness Questionnaire |
| **PAQ** | Paffenbarger Physical Activity Questionnaire |
| **PRS** | Protocol Registration and Results System |
| **PSS** | Perceived Stress Scale |
| **QEWP-5** | Questionnaire on Eating and Weight Loss Patterns |
| **REDCap** | Research Electronic Data Capture |
| **RCT** | Randomized Clinical Trial |
| **RF** | Red Food |
| **SD** | Standard Deviation |
| **SNAP** | Studies of Novel Approaches to Prevention |
| **SSRIs** | Selective Serotonin Reuptake Inhibitors |
| **TFEQ** | Three Factor Eating Questionnaire |
| **TraCS** | North Carolina Translational and Clinical Sciences |
| **UNC** | University of North Carolina at Chapel Hill |
| **WEL-Q** | Weight Efficacy Lifestyle Questionnaire |
| **WCSS** | Weight Control Strategies Scale |
| **YA** | Young Adult |

## PROTOCOL SYNOPSIS

| | |
|---|---|
| **Study Title** | A Micro-randomized Trial of JITAI Messaging to Improve Adherence to Multiple Weight Loss Behaviors in Young Adults |
| **Funder** | National Heart, Lung, and Blood Institute (NHLBI) |
| **Clinical Phase** | NA |

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| **Study Rationale** | An estimated 1 in 2 US adults will have obesity by 2030, which is a major cause of morbidity and mortality. The highest risk of weight gain is among young adults ages 18-35 years. In-person behavioral interventions generally produce clinically significant weight losses, but cost and reduced reach limit their ability to impact obesity at a population level. Web-based interventions that mimic the structure of weekly face-to-face treatment have proven a viable alternative, though weight losses are generally smaller than in-person treatment. Mobile treatments have the potential for high reach, but have been less effective, producing 1-3 kgs over 6 months. Newer digital intervention approaches called "just-in-time adaptive interventions" (JITAIs) promise to improve upon mobile outcomes by offering adaptive, personalized feedback on behavior, which consists of providing the "right type of support" at "the right time" rather than on a fixed schedule. This "just-intime," or JIT, approach is made possible by the emergence of low-cost and widely available digital health tools that allow for the collection of continually updated health data. However, to date, no JITAIs have successfully targeted multiple weight-related behaviors (weighing, activity, and diet), and there has been no systematic examination of what types of messaging interventions best promote adherence to these three weight loss behaviors, for whom they are effective, and under what conditions. To address this problem, we will use a micro-randomized trial to evaluate the effects of 7 types of intervention messages delivering specific behavior change techniques (i.e., BCT messages) in JIT moments on daily achievement of behavioral goals among n=201 young adults with overweight and obesity. Findings will guide how adaptive, behaviorally- and contextually-dependent messages are incorporated into future JITAIs for weight loss. |
| **Study Objective(s)** | • Evaluate the effects of each behavior change technique message (i.e., BCT message) on daily adherence to weight loss behaviors in a 6-month micro-randomized trial among young adults.<br>• Determine whether the effects of BCT messages on proximal outcomes change over time.<br>• Assess whether the effects of BCT messages on proximal outcomes are moderated by participants' contextual factors. |
| **Test Article(s)**<br>*(If Applicable)* | All participants will receive a core 6-month weight loss intervention that includes evidence-based lessons, behavioral skills training, and daily self-monitoring of weight, dietary intake, and physical activity. |
| **Study Design** | The Nudge trial applies the Multiphase Optimization STrategy (MOST) framework and uses a microrandomized trial design to test the effects of 7 types of behavior change technique (BCT) messages on achievement of daily weight-related goals among 201 young adults. All participants will receive a 6-month behavioral weight loss intervention using our Nudge mobile app, which includes evidence-based weekly lessons, tailored feedback, self-monitoring, and daily BCT messages. Participants will receive a wireless scale, activity tracker, and track "red" foods (high-calorie foods) in the app and have 3 goals: weigh daily, a daily active minutes goal that gradually increases if met, and a daily red foods limit. At 3 decision points per day, participants will be microrandomized to receive or not receive 1 of 7 types of BCT messages. The outcome to be tested is the effect of BCT messages on achievement of same-day goal achievement (weighing, active minutes goal, red food limit). Assessments of the primary outcomes will occur daily, with assessments of secondary outcomes at 0, 3 and 6 months. |

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| **Subject Population** | **Inclusion Criteria**<br>1. Age 18-39<br>2. Body mass index (BMI) of 25-45 kg/$m^2$<br>3. English speaking and writing<br>4. Own a smartphone with a data and text messaging plan<br>**Exclusion Criteria**<br>1. Type 1 diabetes or currently receiving medical treatment for Type 2 diabetes<br>2. Report a heart condition, chest pain during periods of activity or rest, or loss of consciousness on the Physical Activity Readiness Questionnaire (PAR-Q; items 1-4)<br>3. Other health problems which may influence the ability to walk for physical activity or be associated with unintentional weight change, including cancer treatment within the past 5 years or tuberculosis<br>4. Lost 10lbs. or more of body weight (and kept it off) in the last 6 months<br>5. Past diagnosis of or receiving treatment for a clinically diagnosed eating disorder (anorexia nervosa or bulimia nervosa)<br>6. Current symptoms of alcohol or substance dependence<br>7. Currently pregnant, pregnant within the past 6 months, or planning to become pregnant within the next 6 months<br>8. Untreated thyroid disease or any changes (type or dose) in thyroid medication in last 6 months<br>9. Hospitalization for depression or other psychiatric disorder within the past 12 months<br>10. History of psychotic disorder or bipolar disorder<br>11. Currently participating in a weight loss, nutrition, or physical activity study or program or other study that would interfere with this study<br>12. Currently using prescription medications with known effects on appetite or weight (e.g., oral steroids, weight loss medications), with the exception of individuals on a stable dose of Selective Serotonin Reuptake Inhibitors (SSRIs) for 3 months)<br>13. Previous surgical procedure for weight loss or planned weight loss surgery in the next year<br>14. Another member of the household is a participant or staff member on this trial<br>15. Reason to suspect that the participant would not adhere to the study intervention.<br>16. Reside outside of the United States<br>17. Have participated in another study conducted by the UNC Weight Research Program within the past 12 months |
| **Number Of Subjects** | 201 |
| **Study Duration** | Each subject's participation will last 6 months.<br>The entire study is expected to last four years. |
| **Study Phases**<br>**Screening** | (1) Screening: screening for eligibility and obtaining consent<br>(2) Baseline assessment procedures |

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| **Study Treatment**<br>**Follow-Up** | (3) Intervention: study intervention/experimental treatment<br>(4) Follow-up assessments at 3 and 6 months after start date<br>(5) Post-study interview with subset of participants |
| **Efficacy Evaluations** | The results of this micro-randomized trial (MRT) will be used to determine whether providing intervention messages tailored to recent behavior and context in just-in-time conditions, compared to no message, increases same-day achievement of 3 proximal behavioral weight loss goals (daily weighing, daily active minutes, daily red foods). |
| **Pharmacokinetic Evaluations** | NA |
| **Safety Evaluations** | All medical events and safety data will be assessed at assessment points or when interim events are reported by participants using a standard form used in our ongoing NIH funded trials. |
| **Statistical And Analytic Plan** | The primary outcome analysis will use generalized estimating equations (GEE) to evaluate whether any intervention message (versus no message) increases achievement of daily behavioral weight loss goals (weighing, active minutes, red food intake) among young adults. Additional analyses will use GEE to test the effects of receiving a behavior-specific intervention message (i.e., messages about weighing, activity, red foods), as well as the unique effect of each of the 7 different BCT message types. We will also examine whether the effects of BCT messages on daily adherence to weight loss behaviors change over time and are moderated by participants' contextual factors. |
| **DATA AND SAFETY MONITORING PLAN** | Data safety management in this trial is intended to achieve 4 objectives: 1) to minimize the occurrence of adverse effects, especially those related to intervention; 2) to effectively manage adverse events as they relate to the study; 3) to identify when the interventions should be suspended because of concerns for participant safety; and 4) to determine when interventions may be resumed after having been suspended. The Principal Investigator (PI) will have primary responsibility for the safety of participants as it relates to the study protocol, which has been approved by the UNC IRB prior to study initiation. The PI and Safety Officer will review safety reports assembled by the Study Coordinator. In addition, the North Carolina Translational and Clinical Sciences (TraCS) Institute Data Safety Monitoring Board (DSMB) is responsible for reviewing data from clinical trials approved by the UNC Biomedical IRB. Because the risks to subjects participating in this study are expected to be low, we do not anticipate the need for a formal Data Safety Monitoring Board. The research team will provide continuous monitoring of participant safety and periodic reporting to the IRB as required, including any Unanticipated Problems/Severe Adverse Events that may have occurred during the study. If risk or complexity is significant, the UNC Office of Human Research Ethics may require additional reporting or alternative data and safety monitoring. Data safety and monitoring activities continue until all participants have completed treatment and until all participants have been followed to the point at which study related adverse events would likely no longer be encountered. |

# BACKGROUND AND RATIONALE

## 1.1 Introduction

Young adults (18-39) are at higher risk of weight gain compared to other age groups, [1] which increases chronic disease risk.[2,3] Weight management interventions for young adulthood are critical,[4,5] but few have been designed specifically addressing the needs, barriers, and preferences of young adults.

## 1.2 Name and Description of Investigational Intervention

A total of 201 young adults with overweight or obesity will participate in a 6-month behavioral weight loss program delivered through the Nudge mobile app. The Nudge app integrates data from wireless scales, activity trackers, and a food log, and includes evidence-based weekly lessons, tailored feedback, self-monitoring, and daily behavior change technique (BCT) messages. Participants will work toward 3 daily behavioral goals: self-weigh, meet an active minutes goal, and staying within a "red" food limit (high-calorie foods). Three times per day, participants will be micro-randomized to receive, or not receive, 1 of 7 types of BCT messages. We will test the effects of BCT messages on daily proximal outcomes: weighing (assessed by wireless scale), meeting an active minutes goal (assessed by activity tracker), or staying at/under a red food limit (assessed by in-app food log).

## 1.3 Relevant Literature and Data

Mobile technology approaches have the potential to expand the reach and impact of weight loss interventions among young adults in the US given the vast majority own smartphones and use is common across subgroups of income, race/ethnicity, education, and residential areas. Prior digital obesity interventions, with fixed schedules of intervention delivery, regardless of recent behavioral or weight loss success, [6] may not adequately meet the needs of young adults, who desire technology-based, lower-intensity programs.[7] Digital tools such as smartphones, smart scales, and sensors enable real-time collection of data on individuals' behaviors and contexts, which can drive highly adaptive, tailored messaging that supports adherence to proximal behaviors that mediate weight loss. Just-in-time adaptive interventions (JITAIs) are designed to use this digital health data to deliver highly personalized messages (the "right" message) when the participant needs it (the "right" time), while limiting burden on the participant.[8]

Despite the promise of JITAIs as a scalable approach to health promotion, key gaps remain. First, little is known about which behavior change techniques (BCTs) are most effective for daily weight loss behaviors, when and for whom they work, or under what conditions.[9,10] Second, existing JITAIs often target single behaviors, are short-term, and focus on feasibility rather than efficacy.[11,12] Few have addressed dietary behaviors or combined multiple behaviors such as self-weighing, physical activity, and diet.[13–15] Our pilot study was the first to report on the use of JITAI messaging for promoting adherence to multiple proximal behaviors (self-weighing, physical activity, and dietary intake) that mediate weight loss.[16] Further, little is known about the type of support needed to improve adherence to multiple weight loss behaviors.[17] Overall, evidence is limited on what types of just-in-time supports to provide, for whom, and under what conditions.[8,18,19]

Microrandomized trials (MRTs) are a newer experimental design that offers promise for identifying effective treatment components that can be delivered within JITAIs for weight loss. Using a MRT design as part of the optimization phase of the Multiphase Optimization Strategy (MOST), an engineering-inspired framework,

can efficiently address multiple questions during JITAI development. While meta-analyses show that mobile interventions with personal and frequent interactions are associated with greater weight loss (Schippers et al., 2017), experimental evidence is lacking on which types of tailored intervention messages best promote daily behavior changes. A formal taxonomy of Behavior Change Techniques (BCTs) has identified observable and replicable components of interventions designed to bring about change in behavior (e.g., feedback, action planning, social comparison, among others.[9,20] Secondary analyses and other meta-analyses have identified BCTs that are commonly used in weight management interventions for young adults,[21,22] but systematic evidence on which BCTs are efficacious, for whom, and under what conditions is limited.[9] There is a critical need to experimentally test BCTs to address these gaps.[23,24] MRTs can fill these efficacy gaps by repeatedly randomizing individuals to receive or not receive specific BCT messages and measuring proximal outcomes, generating data on the most efficacious components for proximal behavior change, while also informing optimal timing and individual contexts.[8,19,25]

Few MRTs have optimized JITAIs for weight loss,[16,26] and most published MRT trials have focused on single behaviors such as physical activity,[25,27] engagement with apps,[28–30] or stress management.[31] While MRTs excel at testing the effect of delivering a single treatment component and measuring proximal outcomes, few have examined daily JITAI messages for the 3 key weight loss behaviors (self-weighing, physical activity, dietary intake) or systematically tested individual BCTs. Most MRTs have been short (e.g., 30 days–8 weeks),[27,32–34] and although JITAI messaging for physical activity shows promise over 6 weeks, there is a need to identify an optimal package of BCT-based components that promotes adherence to the multiple behaviors essential for weight management.

To address these gaps, we will use an efficient MRT design to test the effect of tailored JITAI messages, compared to no message, on same-day adherence to three daily weight-related behaviors. Young adults (n=201) with overweight/obesity will be recruited to a 6-month trial that includes 3 microrandomizations per day to evaluate whether 7 different intervention components that deliver distinct BCTs (i.e., BCT messages) improve adherence to same-day self-weighing, physical activity, and dietary intake goals. This trial will identify efficacious BCTs to optimize JITAI messaging that delivers BCT messages at specific times and under certain contexts to maximize adherence to multiple weight loss behaviors. Findings will inform future JITAIs and scalable public health interventions tailored to individual characteristics, behaviors, and contexts.

## 1. STUDY OBJECTIVES

The objectives of this study are:

**Aim 1: Evaluate the effects of each behavior change technique message (i.e., BCT message) on daily adherence to weight loss behaviors in a 6-month micro-randomized trial among young adults (N=201).** We will use an experimental microrandomized design, powered to detect both the effect of any BCT message (versus no message), and the unique effects of 7 different BCT messages (versus no message), on daily achievement of weight-related behavioral goals (weighing, active minutes, red food intake).

**Aim 2: Determine whether the effects of BCT messages on proximal outcomes change over time.** We will evaluate whether the effects of BCT messages (any message and by type of BCT) on daily achievement of weight-related behavioral goals change over time (day in program, time of day), and if so, the nature of the change (e.g., when effects disappear).

**Aim 3: Assess whether the effects of BCT messages on proximal outcomes are moderated by participants' contextual factors.** The primary moderators to be tested are participants' 7-day history of

contextual factors at the time of randomization (achievement of weight-related behavioral goals, streaks/lapses in self-monitoring, weight change, previous BCT messages received). Exploratory moderators include sex, age, and initial BMI status.

Efficacious intervention messages identified in this study will be used to create an optimized JITAI to be tested in a subsequent RCT examining weight losses at 6 and 12 months. This trial will expand our understanding of what BCT messages are effective, when they are effective, and for whom. Findings will guide how adaptive, behaviorally- and contextually-dependent messages are incorporated into future JITAIs for weight loss.

## 2. INVESTIGATIONAL PLAN

### Study Design

### 2.1 Overview and study design

The Nudge microrandomized trial (MRT) will enroll 201 young adults and test whether providing daily intervention messages tailored to recent behavior and context and targeting one of 7 different behavior change techniques (BCTs), compared with not providing a message, increases subsequent achievement of 3 daily weight-related behavioral goals (self-weighing, active minutes, red food intake). Participants will receive a mobile-delivered behavioral weight loss program and be micro-randomized three times a day over a 6-month period (i.e., 504 randomizations per individual).

| **Questions answered through Nudge MRT** | |
|---|---|
| • Does providing a BCT message increase goal attainment on the same day it is delivered? (**Aim 1**)<br>• Do each of the BCT message types have different effects on goal attainment? (**Aim 1**)<br>• Do BCT messages' effects change over time? If so, what is the nature of the change (i.e., when does the effect disappear)? (**Aim 2**)<br>• Do BCT messages work differently when delivered under different contexts (e.g., time in program, time of day, previous dose of BCT messages, recent behaviors)? (**Aim 3**) | |
| **Intervention components to be tested across 3 behaviors: 7 behavior change techniques (BCT messages)** | |
| 1.4 Action planning | Message prompts detailed planning of performance of behavior via implementation intentions |
| 1.6 Discrepancy between current behavior and goal | Message draws attention to discrepancies between a person's current behavior and previously set outcomes goals, behavioral goals, or action plans |
| 2.7 Feedback on outcome of behavior | Message provides feedback on the outcome of performance of the behavior (i.e., weight) |
| 3.1 Social support | Message advises on or provides social support for performance of the behavior |
| 6.2 Social comparison | Message draws attention to others' performance to allow comparison with person's own performance |
| 10.4 Social reward | Message delivers positive reinforcement, if and only if there has been effort and/or progress in performing behavior |
| 15.3 Focus on past success | Message advises to think about or list previous successes in performing the behavior (or parts of it) |

### 2.2 Intervention Overview

All participants will receive a 6-month core intervention adapted from the Diabetes Prevention Program specially for young adults and to be delivered remotely via an automated program. The program, Nudge, will be delivered through a native smartphone app that includes weekly lessons, weekly tailored feedback, a native food log to track red foods, visual displays of behavioral progress, and in-app messages. All participants will receive a wireless scale and an activity tracker (Fitbit, San Francisco, CA) in the mail followed by an individual videochat session with an interventionist. For each of the 24 weeks of the program, at 3 scheduled time points per day, participants will be randomized to receive or not receive a BCT message promoting achievement of proximal weight management behaviors (weighing, activity, red food intake). Thus, participants will receive 0-3 messages per day. The primary outcome is same-day achievement of daily goals (weighing, active minutes goal, red food limit), evaluated among observations in which participants received a message compared to observations in which the participant did not receive a message.

### Study Population

Individuals will be eligible if they meet the following criteria: age 18-39; body mass index (BMI) of 25-45 kg/m$^2$; English-speaking and writing; and own a smartphone with a data and texting plan. Exclusion criteria include being currently pregnant, pregnant within the past 6 months, or planning to become pregnant within the next 6 months; type 1 diabetes or receiving medical treatment for type 2 diabetes; a heart condition, chest pain, or other health problems that influence the ability to follow physical activity recommendations; lost 10 pounds or more in the past 6 months; history of weight loss surgery or planned weight loss surgery in the next year; currently taking weight loss medications; report a past diagnosis of or receiving treatment for an eating disorder; current symptoms of alcohol or substance dependence; untreated thyroid disease or any changes (types or dose) in thyroid medication in last 6 months; hospitalization for depression or another psychiatric disorder in the past 12 months or history of bipolar or other psychotic disorder; another member of the household is a participant or staff member on this trial; currently participating in another weight loss, nutrition, or physical activity study or program; reason to suspect the participant would not adhere to the study intervention; reside outside of the United states; have participated in another study conducted by the UNC Weight Research Program within the past 12 months. Individuals that reported joint problems, some prescription medications, or current treatment for hypertension or hyperlipidemia will be required to obtain written physician consent to participate.

The trial is registered on clinicaltrials.gov (NCT05625061) and was approved by the Institutional Review Board at the University of North Carolina at Chapel Hill on May 13, 2022.

## 3. STUDY PROCEDURES

### Data Collection

Measures of the primary outcomes (daily weighing and achievement of active minutes goal and red food limit) will be collected daily throughout the study via self-monitoring tools (described below). All study participants will complete objective weight measurements and self-administered online surveys at baseline, 3 months, and 6 months post-intervention. Participants will also complete two dietary recalls at baseline and two dietary recalls at 6 months to measure average dietary intake. Participants will receive $50, $25, and $75 for completing baseline, 3, and 6-month assessments, respectively. Online surveys will include measures of theoretical mediators, other psychosocial constructs, and process measures. We will send emails and texts prompting participants to complete assessments, with follow-up emails and phone calls to non-respondents, as necessary. Measures and timing are described below.

### Measures

***Primary Proximal Outcome Measures (collected daily)***

Intervention messages are intended to promote achievement of 3 daily weight-related behavioral goals: weigh daily, meet a daily active minutes (AM) goal, and stay at or under a daily RF limit. Thus, the primary outcome is the achievement of behavioral goals on the day of randomization (i.e., until 12:00AM).

*Met daily weighing goal*. Weighing behavior will be objectively measured daily using a smart scale (Fitbit Aria Air, San Francisco, CA) at the participant's home. Participants will be instructed to weigh themselves daily on the scale in light clothing and without shoes. A dichotomous indicator of whether the participant weighed will be calculated.

*Met daily active minutes (AM) goal*. Participants will have a daily AM goal that may change or stay the same at the beginning of each program week. Fitbit trackers will be used to collect daily AM data, defined by

Fitbit as physical activity of at least moderate-to-vigorous intensity that is accumulated in 10-minute bouts. We will calculate a dichotomous outcome of whether a participant met their daily AM goal (days with no tracker wear are counted as not meeting the goal) on the day of randomization.

*Stayed at or under red foods (RF) limit*. Participants will have a daily RF limit that is determined by their sex and baseline weight. Daily RF intake will be calculated from participants' recorded RF in the study app. We will calculate a dichotomous outcome of whether a participant stayed at or under their RF limit (days without complete tracking [defined as tracked RF consumed during dinner plus breakfast or lunch, or if they reached or exceeded their RF limit], are counted as not meeting the RF limit).

***Secondary Outcome Measures***

*Weight* will be measured at baseline, 3 months, and 6 months at home using the smart scale. Participants will be asked to weigh themselves three times in a row, upon waking and before eating, in light clothing, without shoes, and the three weights will be averaged and used to calculate absolute weight change and percent weight change over time.

*Proportion of days met daily weighing goal* will be calculated as the percentage of study days (out of 168) a participant weighed. *Proportion of daily AM goal met* will be calculated as the proportion of daily AM goal met each day of the study using activity tracker data. *Proportion of daily RF limit* will be calculated as the percentage of the daily RF limit recorded each day of the study in the study app. The *total number of AM* and the *total number of RF* on the day of message randomization will be measured for each day of the study. Following the day of message randomization, we will measure *met daily weighing goal tomorrow*, *met daily AM goal tomorrow*, and *stayed at or under daily RF limit tomorrow*.

***Tertiary / Exploratory Measures***

*Behavioral measures*

- *Self-reported dietary intake* will be assessed using the NCIs Automated Self-Administered 24-hour Recall (ASA-24; National Cancer Institute) at baseline and 6 months. Participants will complete two unannounced self-reported recalls; one weekday and one weekend day.
- *Self-reported physical activity* at baseline, 3, and 6 months will be assessed with the Paffenbarger Physical Activity Questionnaire (PAQ) which assesses leisure-time activity and provides an estimate of minutes per week of moderate-to-vigorous intensity, and calories/week of light (5 kcal/min), medium (7.5 kcal/min), and high (10 kcal/min) intensity activities (Paffenbarger et al., 1978).
- *Sedentary Activity* at baseline, 3, and 6 months will be assessed with the Sedentary Behavior Questionnaire from the EARLY trials (Rosenberg et al., 2010; Lytle et al., 2014).

*Psychosocial measures*

- *Self-efficacy for eating*, measured using the Weight Efficacy Lifestyle Questionnaire (WEL-Q; 20 items).[35]
- *Self-efficacy for exercise*, measured using the 12-item Self Efficacy and Exercise Habits Survey.[36]
- *Self-regulation for exercise*, measured with the 10-item Exercise Goal-Setting Scale and the 10-item Exercise Planning and Scheduling Scale.[37]
- *Motivation for making changes in diet* (15 items) *and exercise* (15 items), measured using the respective Treatment Self-regulation Questionnaires.[38]
- *Perceived competence for diet* (4 items) *and exercise* (4 items).[39]
- *Health-related quality of life*, measured using the CDC Healthy Days measure (CDC 1993).
- *Depressive symptoms*, measured using the Center for Epidemiological Studies Depression Scale (CES-D). [40]

- *Weight control strategies*, measured with the Weight Control Strategies Scale (WCSS; 30 items).[41]
- *Hunger, restraint, disinhibition* measured using the Three Factor Eating Questionnaire (TFEQ; 51 items).[42]
- *Perceived stress*, measured using the Perceived Stress Scale (PSS; 10 items).[43]
- *Binge eating* measured using the revised Questionnaire on Eating and Weight Patterns (QEWP-5.[44]
- *Social comparison orientation* measured using the Iowa-Netherlands Comparison Orientation Measure (INCOM; 11 items).[45]
- *Weight-related information avoidance* (10 items).[46]
- *Relatedness* measured with a scale adapted from Basic Need Satisfaction at Work Scale (3 items).[47,48]
- *Message relevance* measured using 2 items from our previous work,[49] which was adapted from previous studies.[50,51]

*Other measures*

We will assess several supporting measures, including sociodemographic characteristics, medical events, and medication use. Program engagement (app views, lessons accessed, feedback messages viewed, goals set or modified), process, and adherence measures (self-weighing, activity tracking, red food tracking, daily goal achievement) will be collected throughout the study period and used to calculate behavioral adherence in the prior 7 days and streaks and lapses in goal achievement. Program acceptability and satisfaction will be assessed using post-intervention program evaluation questions and in post-intervention semi-structured interviews after 6 months.

## 4. STATISTICAL CONSIDERATIONS

### Sample Size and Power

Our power analysis is based on a sample size calculator built in an R package (MRT-SS)[52] for detecting proximal treatment effects in microrandomized trials developed by Liao et al,[53] expanding on more general results for sample size calculations for longitudinal trials from Tu et al.[54] Inputs to the sample size calculator are: desired alpha (.05), the number of outcome occasions ($T$ =168 days for each proximal outcome), average probability of message availability each day, the randomization probability for a given message if it is available (0.5), and the standardized proximal treatment effect $\bar{d}_A = \sum_T d_A / T$ across all time points. Based on our prior research [16] and the previous MRTs with published effects sizes,[31,32,55] we assume that $\bar{d}_A$ ranges from .03 to .15. Based on our previous studies with young adults[56,57] and the pilot MRT,[16] assuming 17% attrition by day 168, we estimated that a sample size of N=201 would be required to have an average of 150 usable days per person (168 days*.83 + 84 days*.17 = 154), for a total of 30,954 person-day observations (N=201*154; i.e., over 4400 person-day observations per each of 7 BCT message interventions across 3 behaviors). This is consistent with a prior MRT that evaluated 6061 available decision points to test 2 different options for an intervention component (i.e., walking suggestions, anti-sedentary suggestions) among 37 participants.[32] We will use all available data points in these analyses and test the sensitivity of our findings to dropout status by conducting completer-only and dropper-only analyses. The estimated minimum detectable standardized effect size with 80% power across the planned analyses ranges from .04 to .13.

### Statistical Analysis Plan

Data analysis will be performed using R statistical software (version 4.0.3). Baseline demographic and descriptive characteristics will be summarized globally, using frequencies and percentages for categorical variables, and means and standard deviations (SD) for inherently quantitative variables. Prior to conducting data analyses, we will audit the data for completeness and quality, including missing data. We will evaluate response distributions to ensure that they meet assumptions of planned analyses (see below), including the detection of outliers.

*Analysis of primary outcomes*

We will test: 1) whether any intervention message (versus no message) increases adherence to daily weight loss behaviors among young adults, 2) whether a behavior-specific message (versus not receiving the behavior-specific message) increases adherence to the respective behavioral goal, and 3) finally the unique effect of each BCT message for the three proximal outcomes. We will use generalized estimating equations (GEE) with an independence working residual correlation matrix to account for nesting of observations within individuals.[58] and use Benjamini-Hochberg-Storey correction for multiple testing.[59]

*Analysis of whether effects of BCT messages change over time*

We will also examine whether the effects of BCT messages on daily adherence to weight loss behaviors change over time (week in program, time of day) and, if so, the nature of the change (e.g., when effects disappear). Thus, we will expand upon the model described above by: 1) including linear and quadratic main effects of time and interaction terms, between an indicator of day in the program and treatment assignment, to test whether the treatment effect changes over time.[58] We will examine differences in the average and estimated time trends in treatment effects of receiving a behavior-specific message, and then the unique effect of each BCT message for the three proximal outcomes.

*Analysis of whether effects of BCT messages are moderated by participants' contextual factors*

We will evaluate whether the causal effect of receiving a BCT message interacts with participants' contextual factors, including past behaviors and individual characteristics. We will use standard moderation analysis within the GEE framework for these analyses, which involves the inclusion of main effects and interaction terms. Significant moderation effects will be probed using simple slopes analysis to determine the conditional region and direction of significance. The primary moderators to be tested are participants' 7-day history of contextual factors at the time of randomization (achievement of weight-related behavioral goals, streaks and lapses in self-monitoring, weight change, previous BCT messages received). Exploratory time-invariant potential moderators include demographic and health characteristics (e.g., sex, age, baseline BMI).

## 5. SAFETY MANAGEMENT

Data safety management in this trial is intended to: 1) minimize the occurrence of adverse effects, especially those related to intervention; 2) effectively manage adverse events; 3) identify when the interventions should be suspended because of concerns for participant safety; and 4) determine when interventions may be resumed after having been suspended. The Principal Investigator (Valle) will have primary responsibility for the safety of participants as it relates to the study protocol, which has been approved by the UNC IRB prior to study initiation. The PI and Safety Officer will review safety reports

assembled by the Study Coordinator. In addition, the North Carolina Translational and Clinical Sciences (TraCS) Institute Data Safety Monitoring Board (DSMB) is responsible for reviewing data from clinical trials approved by the UNC Biomedical IRB. Because the risks to subjects participating in this study are expected to be low, there is no formal Data Safety Monitoring Board. The research team will provide continuous monitoring of participant safety and periodic reporting to the IRB as required, including any Unanticipated Problems/Severe Adverse Events that may have occurred during the study. If risk or complexity is significant, the UNC Office of Human Research Ethics may require additional reporting or alternative data and safety monitoring. Data safety and monitoring activities continue until all participants have completed treatment and until all participants have been followed to the point at which study related adverse events would likely no longer be encountered.

## Participant Safety

The risks to human subjects in this study, including psychological and physical risks, are judged to be minimal. The anticipated benefits are great, insofar as the results will be used to determine if mobile-delivered behavior change strategies are effective for obesity risk reduction in a sample of young adults. The primary risks, while minor, include: discomfort with being asked about personal information related to their diet, physical activity, and weight; risks of increasing physical activity (injuries, blood pressure changes, dizziness, fainting, fatigue, and in very rare cases heart attack, stroke, or even death); a low risk of extreme dieting and/or extreme psychological reaction to dietary restriction; risk of breach of confidentiality via telephone calls, emails, text messages, or the smartphone app.

## Adequacy of Protection Against Risks

### a. Informed Consent and Assent

Recruitment and Informed Consent: The UNC IRB has approved the study protocol and has reviewed and approved the informed consent document. Once an individual has been deemed potentially eligible to participate through online and telephone screening, study staff will provide more study details and describe the concept of random assignment, and assessment procedures over the telephone. Individuals who remain interested will receive an email directing them to a unique and secure REDCap link to an online informed consent. After clicking on the link, they will be directed through a series of screens that present the informed consent document. The online informed consent records will be retained, and recruitment of participants will be done by adhering to HIPAA regulations. Accrual reports will list enrolled participants and excluded participants throughout the stages of the research. This routine monitoring allows for early identification and resolution of potential problems during the recruitment phase. The anticipated recruitment duration is 20 months. All key personnel have attended the required courses on human subject protection and HIPAA regulations, and certificates of IRB training completion are on file with the University of North Carolina.

### b. Protections Against Risk

Protections against Psychological Risks: Participants are not required to share information in online questionnaires and can elect not to share sensitive and confidential information with the study. Participants will be encouraged to contact the Principal Investigator if they feel they have incurred any emotional distress as a result of study participation. As this is a voluntary study, a participant is free to exit at any point if discomfort should occur. Individuals scoring >16 on the Center for Epidemiological Studies Depression Scale (CES-D) at baseline, 3- or 6-month assessments (indicating levels of depressive symptoms that might benefit from follow up with a health care provider) will be given a letter explaining the survey and providing information and referral to resources.

Protections against Physical Risks: To ensure medical readiness to begin physical activity, participants will complete a physical activity readiness questionnaire (PAR-Q). The PAR-Q assesses the following medical conditions: heart problems, chest pains, faintness or dizzy spells, high blood pressure, bone or joint

problems such as arthritis, that have been or could be aggravated by exercise, prescription medication use, and other medical reasons why exercise would not be advisable. Participants endorsing yes to any items 1-4 on the PAR-Q (experience of heart problems, frequent chest pains, faintness or dizziness, bone or joint problems) will be excluded from the study. We also will monitor any major musculoskeletal problems that develop during the intervention (e.g. broken bones) using a medical events questionnaire at 3 and 6 months and will determine whether these appear related to our study. Participants who develop musculoskeletal problems or other health problems that may affect safe participation will be instructed to stop exercising until the problem resolves and their physician approves resuming physical activity.

All participants will be advised about safe weight loss practices including dietary change and increasing physical activity at their initial study visit. Participants will be advised to gradually increase their physical activity and to use walking as a primary form of activity and will be taught that the appropriate rate of weight loss is 1 to 2 pounds per week. In addition, we will carefully monitor changes in weight during our trial. We will collect information at each assessment timepoint on hospitalizations for any psychiatric problem, including depression and eating disorders. We will track weight changes using smart scale weights and will identify any individual who loses more than 20% of their body weight, has a BMI ≤ 18.5 $kg/m^2$ at any point during the program, or loses more than 15 pounds in any month during the trial., We will have a telephone call with these participants within 2 weeks, discuss our concerns with them, and make referrals if appropriate. If there is no improvement in weight status, the participant will be unable to continue to participate in the intervention.

Protections to Ensure Confidentiality of Participants: All data records related to a participant's involvement in this research study will be stored in encrypted files on servers that adhere to the University policy on storage and transmission of sensitive data. Participant identity on these records is indicated by an ID number and the information linking these numbers with participant identity will be kept separate from the research records. In addition, all research databases will have password-controlled access.

The Fitbit API will be used to access data from the participant's scale, activity tracker, and Fitbit app. During the consent process, participants will consent for the data from their specific devices to be accessed by our study. They will need to enter their Fitbit username and password during the app setup process to allow Fitbit data to be sent to our study server. The study smartphone app uses a Standard OAuth 2.0 security model for logging in to Fitbit. Fitbit usernames and passwords will not be stored in any way with this study. Instead, the weight and tracker data will be connected to participants by their unique study ID that they will also enter during the app setup process. Data are transmitted on secure servers that adhere to university policy on Sensitive Data. The risk of breach of confidentiality over the Fitbit websites will be partly subject to each individual's comfort in sharing information in their individual profile. To further minimize the risk of breach of confidentiality, all participant activities on the Fitbit websites will be voluntary. Consent forms will also clearly communicate the risk of this type of disclosure to participants.

Removal of Patients from Protocol**.** Participants will be removed from the protocol should they experience greater than minimal risk as detailed above. Participants will be reminded that their participation is voluntary and that they may withdraw from the study at any time without consequence by contacting the Principal Investigator. In addition, we expect that pregnancies will occur. We will stop all intervention activities for anyone who becomes pregnant.

## 6. DATA COLLECTION AND MANAGEMENT

Participants will provide physical data (objective weight and self-reported height) and self-reported questionnaire data online specifically for research purposes using the REDCap computer-assisted program that has built-in validation checks for range, data type, and completeness. All measurements will undergo consistency and outlier checks, compared with raw data, and edited as required. REDCap includes detailed audit logs that document any database changes, and we will document protocols for

cleaning data. Identifiable information collected in online surveys will include the participant's name, address, phone numbers, and date of birth. Food log data from the study smartphone application and weight and activity data from Fitbit will be transmitted to study servers.

## 7. RECRUITMENT, CONSENT, AND RETENTION STRATEGY

### Recruitment

Young adults will be recruited using a multi-pronged approach including: 1) postings on social media including Facebook and Instagram 2) direct mail to heads of households in select geographic areas; 3) emails through listservs comprised of the target audience; 4) advertisements on select media accessed by young adults, including television, radio, Spotify; and 5) targeted mailings, emails and advertisements to young adult men and minority groups.

On Meta (Facebook/Instagram), we will purchase advertisements and "Boosted Posts" with recruitment information about the study that will link to the recruitment website and online screening survey. The ads and posts will be targeted specifically to reach adults between the ages of 18 and 39 that live in the United States and can also be targeted specifically to reach subgroups based on sex or race/ethnicity if needed.

We plan to enroll 10 participants per month over 20 months. Initially, no groups will be excluded or limited based on sex, race, and or/ethnicity. However, women are generally over-represented in weight control studies; therefore, to be able to test for differences in the treatment effect by sex, we may need to specifically target recruitment of men. Our research group has had success in recruiting higher percentages of men by using pictures of men in Facebook/social media advertisements, and by using terms such as "wellness" and "health" instead of "weight loss." Therefore, we will use these strategies to increase our recruitment of men if we are under our targets. Additionally, to recruit a sample of at least 30% non-white participants (as outlined in our NIH recruitment plan), we will identify minority groups through social media platforms and community groups, and tailored recruitment materials.

All recruitment efforts will direct participants to a study website with a more detailed description of the research study and FAQs about participating in research. Interested individuals will click through to a REDCap web screening survey to determine initial eligibility. Those who are preliminarily eligible will be contacted by trained study staff and will undergo additional phone screening. Eligible and interested individuals will receive an email directing them to a unique REDCap link to an online informed consent. After providing consent, participants will be instructed on procedures for 1) completing one weekday and one weekend self-reported 24-hour dietary recall, 2) completing baseline online questionnaires, and 3) completing their baseline weight measurement using a Bluetooth-connected scale. The Fitbit scale and activity tracker will be mailed to the participant. After completion of baseline assessments, the participant will be scheduled for a one-on-one telephone/videochat session during which they will be informed about study procedures, assisted with downloading of the study smartphone app, and questions about getting started will be answered.

### Retention

A systematic protocol will be followed to minimize dropouts. At baseline, the names and addresses of several friends and family members who can be contacted are obtained for use if we lose touch with the participant and need to contact them for study assessment completion. The study provides incentives for completing the follow-up assessments to offset any time costs and to promote retention ($50 for completing the baseline assessment, $25 for the abbreviated 3-month assessment, and $75 for completing the 6-month assessment). For each assessment visit, we will send participants an email that will include a link to online questionnaires with an expected completion date as well as a scheduled date and time to step on their scale. Participants will be sent email and/or text reminders the day prior to their

telephone appointment based on their preference. Missed weights and/or calls will be immediately followed up by phone and rescheduled.

We will review participant engagement with the Nudge app weekly and will use structured protocols for promoting engagement with the intention of also promoting retention.

## 8. PLANS FOR PUBLICATION

As Principal Investigator of this grant application and clinical trial, Dr. Valle will comply with the clinical trial information dissemination expectations of the NIH policy to register and submit summary results at ClinicalTrials.gov. Karen Hatley, Project Manager, will be responsible for handling ClinicalTrials.gov requirements for this project under the Dr. Tate's oversight. Consistent with the terms and conditions of NIH funding, we will ensure the submission and updating of registration and results information for this clinical trial in the timeframes established by the Final Rule. Registration and results reporting in ClinicalTrials.gov will be completed within the following timeframes:

- Registration of the trial at ClinicalTrials.gov no later than 21 days after enrolling the first participant
- All submitted information will be updated at least once a year.
- Any apparent errors, deficiencies, and/or inconsistencies identified by NIH as part of the quality control review process and any other errors identified will be addressed by the responsible party.
- Corrections to submitted information will be made within 15 days for registration information and 25 days for results information.
- Trial results will be submitted no later than one year after the primary completion date.

Informed Consent Documents for the clinical trial will include a specific statement relating to posting of clinical trial information at ClinicalTrials.gov. The UNC IRB has template language explaining that the study will be posted on ClinicalTrials.gov that investigators are required to include in the consent document for the trial.,

As PI, Dr. Valle will work closely with the UNC-CH Office of Clinical Trials (OCT), which serves as the university's internal PRS. The OCT has responsibility for ensuring that clinical trial registration and reporting occurs in compliance with NIH policies. The OCT has support staff to facilitate the process of registration and results reporting to ClinicalTrials.gov, and our team will work closely with them to register this trial and to submit summary results to the website in a timely manner, in keeping within the required timeframes. Once data collection is complete, our research team will work to prepare and submit trial results no later than one year after the primary completion date.

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