Study Protocol

Title: Research Intervention to Support Health Eating and Exercise
NCT#: 04353258
Date: December 17, 2025

Clinical Trial/GCP Training

Is this a research study in which one or more human subjects are prospectively assigned[1] to one or more biomedical or behavioral interventions[2] (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes[3] (i.e a clinical trial)? Indicate "yes," "no," or "N/A" in the space immediately below.

Yes.

Is the study fully or partially funded by the NIH? Indicate "yes," "no," or "N/A" in the space immediately below.

Yes.

Have the required key personnel completed Good Clinical Practice (GCP) Training? Indicate "yes," "no," or "N/A" in the space immediately below. (Note that IRB approval will not be given for NIH funded clinical trials until all required key personnel complete the GCP training.)

Yes.

For EACH Participant Population State the Number of Participants to be Enrolled and Screened and/or the number of participant records reviewed (including, HIPAA covered health records and FERPA covered school records), if applicable:

This study will include N=195 participants. Participants will be adults (ages 18-75) from all sex (male, female, non-binary) and racial/ethnic groups. They will also be from all education levels and have an income of <=300% of the federal poverty line or quality for benefits (e.g., WIC, SNAP, etc.). Given that this is a weight loss study, participants will have a body mass index (BMI) in the overweight/obese range (25-55kg/m^2). In order to meet our participant randomization goal, a total of 300 participants will need to be enrolled into the study / sign consent.

Justification of Sample Size:

The trial is powered for the primary aim: efficacy of BE mHealth vs. mHealth at month 12. We aim to detect a clinically meaningful difference of 2.5 kg between arms.[99] Based on previous trials with

[1]The term "prospectively assigned" refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.

[2]An intervention is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive/behavioral therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.

[3] 3.Health-related biomedical or behavioral outcome is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical or behavioral status or quality of life. Examples include: positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and /or information retention, behavioral intervention for psychiatric symptoms); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and, positive or negative changes to quality of life.

similar designs and our own trials, we expect a common within-group standard deviation of 5kg and a 20% attrition rate. [10-12] Hypothesis testing will be based on linear mixed effects models for longitudinal data, which increase power by fully exploiting the strong correlation in weight measures across time. Given these assumptions, if a total of N=160 participants (BE mHealth: N=80; mHealth: N=80) are enrolled, the trial will have 88% power to detect a statistically significant result. Accounting for attrition, 35 more participants will be added, so a total of 195 participants will be needed for this trial.

For EACH Participant Population Describe Screening Procedures, if applicable:

Using approved advertisements / fliers, participants will be recruited from several sources: relevant neighborhoods, federally qualified / community health centers, primary care offices, hospitals, community organizations, health department/health ministry, Hispanic Health Council, Nurturing Families Network, Brighter Future Family Centers, WIC, low-income housing authority, Hartford Food System, Churches, listservs, community newspapers, and social media. Our team has experience recruiting from these organizations and has been successful in the past. Individuals who respond to study advertisements will be screened. Screening will occur online and/or over the phone. That is, participants will initially be instructed to complete our online screener. Any item responses from the online screener that require follow-up information will be completed via phone. Participants will be notified at the end of the screening if they are eligible to participate in the study. Those who report BMIs near the study cut-offs (24.7-25 or 55-55.3) on the screener will have their BMI objectively confirmed at their orientation visit in a private room; if their BMI is below/above the cut-off, they will not attend orientation and be given resources for community weight loss programs in the area (e.g., the YMCA's Diabetes Prevention Program, which offers a sliding scale fee). In the event that an individual is unable to answer screening questions due to lack of recent doctor visit, s/he will be encouraged to visit a doctor and study staff will provide information on low/no-cost providers in the area. Those not meeting eligibility criteria will be provided an appropriate community referral (e.g., YMCA sliding scale membership information). Eligible individuals will attend an orientation session via Zoom (Zoom privacy policy: https://zoom.us/trust. Zoom specifications: https://support.zoom.us/hc/en-us/articles/201362023-System-requirements-for-Windows-macOS-and-Linux). At the orientation, questions will be answered, and informed consent will be obtained. Specifically, participants will be invited to a pre-scheduled Zoom meeting. Prior to meeting start, participants will be sent all orientation materials either electronically or via postal mail and encouraged to review the materials prior to the virtual meeting. During the virtual meeting, all study procedures will be described in detail via shared PowerPoint slides and questions will be answered. Informed consent will be obtained by having participants indicate whether they consent; this will be done via raising their hand, verbally, or via the chat function (written consent will not be obtained). Research staff will record all individuals who provide consent. We also encourage all participants to inform their treatment providers that they are participating in a weight loss study.

Anticipated Study Time Frame:

Participants will be recruited in 4 Cohorts. Recruitment and screening for Cohort 1 is anticipated to begin in the summer of 2021. All intervention and assessment visits will be completed by Year 6 (no cost extension year; COVID delays), Quarter 3. The last quarter of Year 6 will be reserved for data analysis, manuscript preparation, and dissemination of study findings. An updated, detailed timeline is presented below (Q=Quarter; C=Cohort).

	Year 1				Year 2				Year 3				Year 4				Year 5				Year 6			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Start-up	X	X	X	X	X	X	X	X																
C1 recruitment								X																
C1 measurement								X	X	X	X	X	X	X										
C1 treatment								X	X	X	X	X	X	X										
C2 recruitment										X														
C2 measurement										X	X	X	X	X	X	X								
C2 treatment										X	X	X	X	X	X	X								
C3 recruitment													X											
C3 measurement													X	X	X	X	X	X	X					
C3 treatment													X	X	X	X	X	X	X					
C4 recruitment																	X							
C4 measurement																	X	X	X	X	X	X	X	
C4 treatment																	X	X	X	X	X	X	X	
Data analyses & dissemination																								X

Design, Procedures, Materials and Methods:

Design overview. This study will examine the efficacy of a mHealth Behavioral Economics weight loss treatment for adults from economically disadvantaged backgrounds. Participants will be randomly assigned to either the Behavioral Economics mHealth intervention (BE mHealth) or mHealth only (no behavioral economics treatment components). Both interventions will: (a) include behavioral weight loss material tailored to this population, (b) be matched for interventionist contact, and (c) be 12 months in duration. The only difference between the two arms is the inclusion of behavioral economics strategies in BE mHealth. Specifically, BE mHealth will involve provision of reinforcers (small monetary reinforcers) and training in Episodic Future Thinking (see below for details). Assessments will occur at baseline, 2, 6, and 12 months (primary endpoint) and at the 18-month follow-up (C1-C3). The 18-month follow-up is included to explore whether participants continue to engage with the two interventions and the durability of treatment effects in the two arms. The primary outcome for which the trial is powered is weight change at month 12. Mediators (reinforcing value of food, delay discounting), moderators (e.g., stress, resilience, environment), and cost-effectiveness of the two interventions will also be explored. Visits (orientation / consent, assessments, and intervention) will be conducted via a video conferencing platform like Zoom.

Randomization. Eligible participants will be randomized to either BE mHealth or mHealth. The statistician will conduct the randomization and will use a permuted block randomization scheme for each cohort. Given evidence of differential weight loss by racial / ethnic background and sex[40, 64] randomization will be stratified on these variables. A 1:1 randomization scheme will be used.

Overview of the two interventions. The two interventions are matched on treatment modality, participant contact, treatment duration, and tailored weight loss content. That is, the only way in which BE mHealth and mHealth differ is in behavioral economics strategies. Please see table and details below.

Similarities		
	BE mHealth	mHealth
mHealth treatment platform	✓	✓
Tailored behavioral weight loss treatment materials	✓	✓
Up to 16 sessions	✓	✓
12-months of treatment	✓	✓
Differences		
Reinforcement for weight management Key challenge addressed: lack of reinforcement	✓	
Episodic Future Thinking cues Key challenge addressed: bias for the present	✓	
Healthy Thinking cues (controls for EFT contact)		✓

Similarities between BE mHealth and mHealth. The two interventions will be matched on treatment modality (primarily mHealth), contact (a total of 16 sessions),

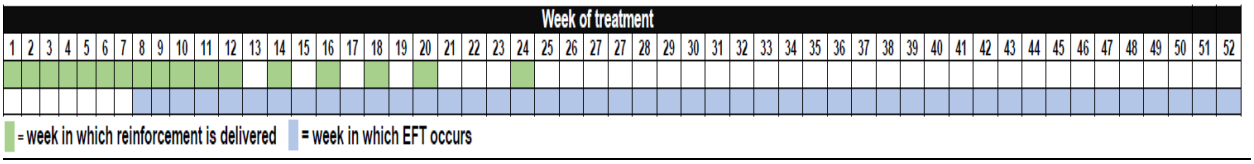
and duration (12 months). We anticipate that each of the sessions will take 1 hour in duration or less and that interacting with the mHealth weight loss program will take approximately 10-15 minutes per week for the duration of the program. Sessions will occur via Zoom or phone; if the interventionist needs to share information via screen to best convey material, the session will be via Zoom, if not, the session will be via phone. The mHealth intervention platform includes evidence-based weight loss strategies tailored to this population delivered via a hybrid native app and hosted by UNC Chapel Hill. mHealth intervention content shared by both arms is detailed below.

mHealth intervention content for both arms. The mHealth program will include behavioral weight loss content based on the DPP and tailored to adults from economically disadvantaged backgrounds including weight, calorie, activity goals, and evidence based behavior change strategies. Given the known link between income and education, all intervention materials will be at a 6th grade literacy level and will favor visual content (graphic representation of concepts) over written content. Tailored online content will be delivered via weekly multimedia videos, a self-monitoring feedback platform, and supplemental online material (e.g., PDFs and links to resources). Details are provided below.

Components unique to the Behavioral Economics mHealth treatment arm.

BE mHealth overview. Tailored evidence-based obesity treatment content may be necessary but not sufficient for adults from economically disadvantaged backgrounds. Newly identified behavioral and cognitive processes – lack of reinforcement and bias for the present – if addressed, may optimize treatment success in this underserved population. Thus, behavioral economics strategies designed to target lack of reinforcement and bias for the present will be included in this arm. Specifically, the proposed behavioral economics intervention will include the mHealth, tailored intervention (described above); small monetary reinforcers to immediately engage participants in treatment and promote initial weight loss; and Episodic Future Thinking to address bias for the present and promote longer-term weight loss success. BE mHealth intervention details are provided below. All proposed behavioral economics treatment content and contact schedules are based on our previous, successful approaches.

BE mHealth strategies. In addition to the online mHealth tailored intervention described above, the BE mHealth intervention platform will include two behavioral economics intervention strategies: a reinforcement paradigm and Episodic Future Thinking. These intervention strategies will target lack of reinforcement and bias for the present. Given strong evidence that monetary reinforcers promote treatment engagement, small financial reinforcers will be used immediately at treatment start. However, such reinforcers cannot be delivered indefinitely. Thus, as weight loss occurs, which naturally provides its own reinforcement (e.g., improved mood, energy, appearance, health),[39-42] monetary reinforcement will taper. EFT training will begin at week 8. The 8-week time point was chosen by examining the weight loss trajectories in our pilot, as suggested by a previous reviewer. Indeed, there was a reduction in magnitude of weight loss with financial reinforcement alone at month two (month 1: -3.6kg; month 2: -1.8kg; month 3: -1.3kg). Thus, EFT will be added at this time to promote additional and sustained weight loss. Taken together, we believe this scaffolding approach that first provides financial reinforcement and then transitions to longer-term sustainable weight management strategies (EFT) is most beneficial. Detailed information on reinforcement delivery and EFT is provided below.



Reinforcement. Small financial reinforcers will be delivered consistent with our previous, successful paradigms in this population. During the first three months of treatment, participants will receive reinforcement each week, which will then taper to every other week, once a month, and eventually end (see figure above). During reinforcement weeks, small financial reinforcers will be delivered contingent

upon behavior change and weight loss. Specifically, each week participants self-monitor at least 5 days of weight, diet, and activity, they will receive a monetary reinforcer, which will range anywhere from $1 to $10 (e.g., Week 1: $10, Week 9: $2). The maximum amount of monetary reinforcement to be earned for self-monitoring behavior will be a total of $65 for the entire 12-month program. Participants will also complete an objective virtual weigh-in at months 3 and 6. Those who lose 5-10% of initial body weight will receive $50 and those who lose ≥10% will receive $100 at their weigh-in visit. Self-monitoring banks will also be 'paid-out' at these visits. As participants are developing success experiences with weight loss, which naturally provides its own reinforcement,[39-42] monetary reinforcers will taper and eventually end. During this time period, training in Episodic Future Thinking will begin.

Episodic Future Thinking (EFT). EFT will begin at week 8. EFT involves the production of positive, vivid, meaningful future events (e.g., church get-together, family gathering, wedding) for which the behavioral goal (weight loss) is important; vivid imagination of events is created through integration of basic cognitive systems (narrative, emotional, sensory, and spatial).[37, 69] These vividly imagined events are then distilled into brief cues that conjure the event. Cues can take the form of approximately a few sentences that capture the event, pictures that embody the event, or brief audio recordings of the event.[37, 38] Participants are then exposed to these cues on a daily basis via our mHealth platform.

Component unique to the mHealth only treatment arm.

Healthy Thinking. To control for contact associated with EFT sessions and daily cue delivery in BE mHealth, mHealth only will include Healthy Thinking cues. Healthy Thinking cues have been used as a successful control in our EFT studies.[38] To control for the BE mHealth contact schedule, at months 1, 2, 3, 6, and 9, mHealth only participants will also attend individual virtual sessions. During these sessions, participants will be given a list of Healthy Thinking educational cues (e.g., decrease snack intake) and choose which cues they wish to receive on a daily basis via the app.

Assessments. Assessments will occur virtually. Primary outcome is weight change during the 12-month treatment. Demographics will be collected at baseline.

Demographics. Gender, age, race, ethnicity, education, income, and household size will be collected.

Weight. Weight will be collected using a bathroom digital scale, or via an e-scale that securely transmits participant weights back to study staff via cell tower. To ensure gold-standard research-based weigh-in procedures are used, under such circumstances, participants will complete this remote weigh-in via Zoom. During the virtual meeting, research staff will provide the participant with detailed weigh-in instructions (place scale on hard surfaced floor, one layer of clothing, no shoes or heavy jewelry, empty pockets, etc.). Weight will then either be remotely transmitted (in the use of e-scales) or participants will show research staff their weight (in the use of regular digital bathroom scales). Height will be assessed via self-report. No other physical measures are included.

Adverse Event Interviews. The occurrence of adverse events will be assessed via Qualtrics, email or phone instead of in person.

Quality control.

Data management. Survey data will be collected using Qualtrics (see Human Subjects for security details). Forty-eight hours prior to their visit, participants will receive a link to complete their measures. On the day of the visit, the assessor will log on and review participant responses for completion; missing data will be addressed during the visit. The assessor will record all physical measurements in Qualtrics or via standardized form. Any data not captured electronically (e.g., Qualtrics form) will be entered into a password protected data entry and storage system, which provides programmatic protection against

invalid data entries, and provides second-party, blinded double-entry data verification to validate accuracy of data entry. Dr. Heudo-Medina's biostatistics team will be responsible for data cleaning, error checks and preliminary analyses of all data to ensure accuracy.

Treatment fidelity. The mHealth behavioral weight loss treatment platforms for both arms will be automated and tech issues will be troubleshooted as soon as they arise. In person EFT and Healthy Thinking intervention sessions will be manualized and staff responsible for conducting these sessions will be fully trained in all skills and concepts being delivered. Detailed interventionist and participant manuals will be available for each session. All intervention sessions will be audiotaped; the PI will review each tape and provide immediate feedback. Finally, two master's level interventionists, trained by the PI in the skills and concepts being delivered, will review audiotapes to formally assess adherence, competence, and the presence of any cross-contamination between treatment arms using a treatment fidelity checklist. Any issues with fidelity will be addressed immediately.

Missed visits and drop outs. All participants will receive weekly, automated prompts to submit self-monitoring information into the mHealth platform. They will also receive prompts to complete EFT trainings / engage with Healthy Thinking cues and reminders for visits. Participants who miss a visit will be texted or called to schedule a make-up visit. We will use several strategies recommended to address retention in this population, including: implementing a tailored intervention and establishing strong rapport with participants, eliminating transportation and childcare costs and burden associated with in-person visits by conducting the study remotely, and offering escalating compensation for assessment completion (Month 2: $30, Month 6: $50, Month 12 (primary end point): $100, Month 18: $50). Furthermore, we will offer maximum flexibility with respect to appointment days and times and provide both reminder calls and emails/texts (participant preference).

Data Analysis:

The primary outcome for which the trial is powered is weight change from baseline to month 12. Differences in baseline characteristics in BE mHealth vs. mHealth participants will be examined using either t-test, Chi-Square tests or analysis of variance when appropriate. If baseline differences exist, they will be controlled for in outcome analyses. Distributional properties of continuously scaled variables will be examined to determine if normalizing transformations should be applied or if distributions other than normal should be used in the models. Pairwise contrasts among study groups using linear mixed effects models will be fitted by restricted maximum likelihood using REML as implemented in the PROC MIXED procedure or PROC GLIMMIX SAS 9.3 if residuals do not meet normality. Unconditional models will be fitted to assess for variability in participant intercepts and slopes, and determine whether these factors should be treated as random effects in conditional models. Unconditional models will also be used to evaluate whether the trajectory of the outcome is best characterized as linear / non-linear (quadratic and cubic). Estimated mean differences will be developed using linear contrasts and assessed with Wald statistics. These analyses will result in a detailed model of weight change across the 12-month trial. Within the linear mixed effects model, an a priori test of the difference between least squared means for treatment arms at the 12-month time point, adjusted for covariates, will test for between-arm differences at the 12-month assessment.

Missing data. Although concerted effort will be made to minimize missing data, we anticipate missing data due to refuted responses or lost to follow-up. Type of missingness will be evaluated and missing values will be imputed using full information or restricted maximum likelihood estimation[100] depending on type of missing data, completely at random or just random missing data. All variables in our models will be used to impute missing data. Sensitivity analyses will be used to compare results with and without imputed values.

Inclusion/Exclusion Criteria:

Participants will be 18-75 years of age, and have a BMI between 25-55kg/m^2. All sexes (male, female, non-binary) and racial/ethnic groups will be invited to participate. An upper age limit of 75 was chosen as individuals over 75 may have increased medical comorbidities and risks associated with unsupervised exercise. Obesity trials targeting adults from economically disadvantaged backgrounds have defined 'economically disadvantaged' as a household income of ≤300% above the federal poverty level, which takes into account both income and household size.[51] [9, 10, 52] This trial will do the same. During screening, participants will be asked to report their total household income and number of individuals in their household; those at or below 300% of the federal poverty line,[51] or those qualifying for federal, state or local benefits (e.g., WIC, Husky Health, heat assistance, etc.) based on income, will be eligible. Participants will be required to have smartphones and use it daily for research purposes.

Individuals will be excluded if they: report being unable to walk 2 blocks without stopping; are currently participating in weight loss treatment, have a history of bariatric surgery, or lost ≥5% in the past 6-months; have a current eating disorder; are pregnant or plan to become pregnant during the study period; report chest pain or loss of consciousness on the Physical Activity Readiness Questionnaire[55]; have diabetes and are on insulin; are unable to read and write English; report a medical condition that could jeopardize their safety in a weight loss program with diet and exercise guidelines (e.g., planned/current pregnancy, cancer); or report conditions that, in the judgment of the PI, would render them unlikely to follow the protocol (e.g., relocation, dementia). During times of national emergency (e.g., COVID-19), participants without reliable internet (e.g., Wi-Fi or hardwired) or those unwilling to use their smartphone data plans will be excluded. If, during the study, a participant reports a medical condition (e.g., cancer, pregnancy) for which his/her doctor believes participation in the weight loss program is unsafe, the participant will be withdrawn from the weight loss intervention. The participant will, however, be asked to attend assessment visits for trial data completion.

Potential Harms/Risks and Inconveniences:

Risks associated with this study are considered to be minimal (similar to those experienced during common activities of daily living); these risks are detailed below.

Intervention risks. The intervention involves a reduced calorie diet. There may be some initial hunger associated with eating fewer calories. The prescribed diet is balanced, with approximately only 1000 kcal per day deficit from the participant's usual intake, thereby minimizing risk. The physical activity recommendation is for moderate-intense activities. Although increasing your physical activity can have great benefits, you may feel tired or develop sore muscles or joints from being active. It is also possible that you could fall or be injured during physical activity. Being physically active at very high intensity has been known to cause heart attack and sudden death related to heart problems in 1 in 20,000 adults. To minimize risk, participants will be instructed to engage in brisk walking and gradually increase their activity over time. Participants may try unhealthy dietary or physical activity practices to lose weight. However, this is not common in adult behavioral weight loss programs; yet, to be cautious, participants' weight, self-monitoring information, and weight management behaviors will be monitored by intervention staff and, if participants are losing weight too quickly (i.e. more than 10 pounds in a week) and/or there is suspicion of unhealthy practices (e.g., consistently reporting under 800 calories per day, reporting over 1400 minutes physical activity per week, or reporting unhealthy weight control behaviors [e.g., fasting, use of diuretics]), an interventionist will call and speak with the

participant and make a referral, if necessary. Another potential risk is that participants may not lose weight in the program. However, this is a potential risk in any weight loss program. Alternative treatments for overweight and obesity include diets with lower daily calorie recommendations, pharmacological interventions, and surgical procedures. These treatments are considered to have greater risks than the diet and activity program prescribed in this intervention. There is also a risk with using free WiFi networks when transmitting data. If smartphone settings have text notifications turned on (thus allowing people to see texts when the phone is locked), individuals around the participant may be able to see their text messages, reducing confidentiality re: study participation. If desired by participants, study staff will provide information on how to lock their phone and turn off locked-screen text message notifications such that the content of the text is not visible when the phone is locked. Locking the phone also mitigates risk of any phone data being obtained. It is also possible that participants may not lose weight or that they may lose weight and regain it. Finally, as noted in the protocol above, participants will be expected to spend time on intervention-related activities (e.g., meal preparation, physical activity, self-monitoring, platform use, visits); such time/effort is in service of participants' weight loss goals and participants can ultimately choose how much time/effort they wish to expend on such activities. To optimize your time during the study, research staff will help to ensure that all procedures and visits are conducted as efficiently as possible.

Assessment risks. Participants may become uncomfortable when completing assessment procedures; if this occurs, participants will be informed that they do not have to engage in any assessment procedures / answer any survey questions that are uncomfortable. Participants will also be expected to spend time on assessment-related activities; however, as noted above, assessments will be conducted as efficiently as possible and participants will be compensated for assessment completion.

Benefits:

The risks of participating in a behavioral weight control intervention that involves patient-provided care are minimal and outlined above. In comparison to the risks, the potential health benefits associated with this study are significant. Weight loss, as well as healthful dietary changes and increases in physical activity, have the potential to substantially improve the health of all participants in this study. Findings from this study will have important implications for the treatment of obesity in individuals with lower income and could inform clinical practice and public policy.

Risk/Benefit Analysis:

As noted above, there are minimal risks associated with study participation. We will minimize the modest risks of this study by having highly qualified investigators and well-trained staff administer all intervention and assessment procedures and carefully explain the study prior to study entry. If a participant is uncomfortable completing study activities, s/he does not have to complete them. We are using standardized intervention material, questionnaires and assessments protocols that have been used by our lab and/or in the literature. We believe this project is significant because it deals with obesity, a major public health problem. This study could have important implications not only for the individual (e.g., weight loss and improvements in health)

but also for the treatment of obesity. Further, this study may provide knowledge to inform treatment of other health problems, such as drug and alcohol abuse, that may respond well to behavioral economic interventions. The anticipated benefits are considered to be much greater than the minimal risk.

Economic Considerations:

All participants will receive $30 for completion of their 2 month assessment, $50 for completion of their 6- and 18-month assessment, and $100 for completion of their 12-month assessment visit. Participants in the behavioral economics intervention will receive up to a total of $65 for weekly participation in the program; if they achieve a 5-10% weight loss they will receive an additional $50, if they achieve a >=10% weight loss they will receive $100. Intervention-related payouts will be provided immediately following intervention visits via electronic gift cards or money order.

Data Safety Monitoring:

The proposed randomized controlled trial aims to examine the efficacy of a behavioral economics intervention for weight loss in adults from economically disadvantaged backgrounds. The intervention and measurement protocols pose minimal risk to participants. Consistent with NIH recommendations, because of this low risk status, the data safety monitoring (DSM) plan for this trial focuses on close monitoring by the principal investigator (PI) in conjunction with an external DSM Officer, along with prompt reporting of excessive adverse events and any serious adverse events to the IRB at the University of Connecticut, Office of Sponsored Programs, and, if necessary, the NIH.

The Project Coordinator will be responsible for assembling the data and producing DSM reports, as well as assuring that all parties (e.g., PI, Co-Is, Data and Safety Monitoring Officer, etc.) obtain copies of these reports. The injury/illness survey and adverse events form are attached to this document. Safety reports will be sent to the study statistician, the PI, Co-Is, and the Data Safety and Monitoring Officer.

Stopping Rules:

In this minimal risk intervention trial it is more likely that enrollment/randomization or retention issues may arise that could require stopping the trial, not excessive adverse events. However, as outlined elsewhere, we will monitor injury rates in all participants and the safety monitor, together with the study investigator, will alert the DSM Officer, IRB, and the NIDDK if a larger than reasonably expected injury rate should occur in any of the intervention conditions. Other issues related to stopping rules for this trial include:

> New Information. It is exceedingly unlikely that any new information will become available during this trial that would necessitate stopping the trial.
>
> Limits of Assumptions. It is possible that baseline differences between groups, excessive study dropouts, and/or missing data by the interim measurement time points will limit the value of data analysis of measurements at the post-treatment time point. Baseline differences will be evaluated after the first measurement time point and effects on the power to detect differences in the primary outcome will be examined and communicated to the PI, safety monitor, and NIDDK. Given the monitoring plans outlined elsewhere in this document, and the fact that this is a randomized trial, it is exceedingly unlikely that there will be baseline differences between groups of any magnitude to threaten the validity of the study.

Our retention rates have been historically excellent (e.g., >90%), however, excessive drop-outs could occur. In the grant proposal, we allowed for 20% dropout in the recruited numbers. With 20% dropout rate in all groups and 5% Type I error, the primary hypothesis is testable at 88% power. Dropout rates higher than 20% would be of concern, so we propose to monitor the dropout rate quarterly. Alert points are set at dropout rates of 20% (low alert), 30% (mid-alert), 35% (high alert), and 40% (extreme alert). With early alerts to problems, action would be taken to avoid higher level alerts; if a higher level alert should arise, more drastic remedial action would be invoked. To elucidate the implications arising when dropout rates reach various alerts, the following table estimates the power of the study for the primary hypotheses as the dropout rate increases above 20% (at which the study power is 88% for the primary hypothesis).

Dropout rate	20%	30%	35%	40%
Alert level	low	mid	high	extreme
Power available	88%	82%	76%	70%

The actions taken at each level of alert are given below:

- Mid-level alert = Conference call between study investigators to discuss approaches to minimize further losses to follow-up/dropouts.
- High-level alert = Conference call between investigators to determine further alterations of study protocol to complete the study with no further losses
- Extreme-level alert = In the unlikely event of a 40% dropout rate, study investigators would convene on a conference call to discuss the usefulness of continuing the study.

Participant Confidentiality:

As noted in the Human Subjects section, the mHealth platform is secure, firewall protected, and associated data are encrypted. All participant data will be treated as confidential. Records will be safeguarded according to the policies of HIPAA, the University of Connecticut, and Connecticut law. Data confidentiality will be protected through a multi-tiered approach including data collection, data transmission, data handling, and data distribution processes to ensure anonymity both during and after the study. Participant information collected by the research staff will contain only a non-identifiable study ID. A separate form linking study ID and participant identifiers (name, address, phone numbers, contacts' names and addresses) will be maintained in a separate, locked file. Hard data will be stored in locked file cabinets. Electronic data files will be de-identified, password protected, and stored on secure servers. Back-up copies of electronic data files will be updated immediately following the entry of new data. The backed-up version of the file will be kept in a separate location to protect against loss or damage. Furthermore, the network server upon which the main data file will be stored is backed up nightly to provide additional protection against loss.

Institutional Review Board:

Prior to commencing the study, IRB approval will be obtained. The IRB at the University of Connecticut, where the study will be conducted, will monitor the overall conduct of the study. Serious adverse events will be promptly reported to the IRB within 48 hours, which will provide immediate feedback and/or response.

Privacy/Confidentiality:

All participant data will be treated as confidential. Records will be safeguarded according to the policies of the University of Connecticut and Connecticut law. Participants will be assigned a three-digit identification code that reflects the number of participants in the study. Only these identification numbers will appear on the data collection documents. A master key matching participant names to identification numbers will be maintained in a locked secure location at UConn's Weight Management Research Group. The master key will be kept for 5 years after all data collection has ended. Only research staff will have access to the information or be able to associate identification codes with individuals. All raw data collected in paper form will be stored in locked filing cabinets. Electronic de-identified data will be retained in a database indefinitely. Audio recordings will be destroyed 5 years after data collection has ended All data will be reported in aggregate form only, in order to protect individuals' identities. Individual participants will not be identified in any reports, papers, presentations or other media. During the consent process, participants will also be asked if they can be contacted for future studies. Under these circumstances, their name and contact information would be stored separately from all personal health information (e.g., weight, survey data, etc.) in a password protected computer, in a password protected file, on a secure server. Participants who agree to be contacted for future studies would be contacted and, at that time, decide whether they wish to learn more about the new study. The study's project coordinator will work closely with the PI and study personnel to ensure the secure storage of all project databases and questionnaires. If necessary, data will be transmitted to study staff using password protected and de-identified files.

Participants will complete screening and assessment surveys online. Online questions will be administered using Qualtrics, a well-established service that is committed to keeping all participant data secure and confidential. All data is stored in a password protected database at a web hosting site that provides top of the line virtual and physical security. The web hosting facilities make use of firewalls, real-time security alerting using intrusion detection scanners, and 24-hour monitoring from their network operations center. The website itself is safeguarded against common hacker tricks. Physical security of database servers includes perimeter fencing, green field space, card access, biometric entries, and mantraps, 24-hour security guards and continuous camera surveillance inside and outside the facility's buildings. To prevent the possibility that data will be intercepted as it travels the internet, all data is encrypted in transmission, both when survey participants fill out surveys and when survey creators download their data. All electronic files will be password protected to protect the information from unauthorized access.

Our mHealth app is housed at UNC and is password protected, with each participant using a unique username and password. Data are stored in a password protected database at a web hosting site that provides top of the line security. The web hosting facilities make use of firewalls, real-time security alerting using intrusion detection scanners, and 24-hour monitoring from their network operations center. The website itself is safeguarded against common hacker tricks. All downloaded electronic files will saved on the secure UConn server, which is password protected to protect the information from unauthorized access. In the mHealth BE arm, participants will be asked to select pictures as "cues;" while research staff will not prompt participants to select pictures of themselves, it is conceivable that a participant may choose to do so (e.g., picture of previous thinner self). As noted in the consent form, participants are made aware of the privacy/confidentially limitations of pictures and all web-based / text correspondence.

Informed Consent

Participants will be initially screened through a secure portal on our lab website; any screener items that require follow-up information will be obtained by calling the interested individual via phone. All data on the website will be encrypted and accessed only by project research staff. If an individual is interested in

participating, (s)he will be invited to a virtual orientation session via Zoom. In the event of a virtual orientation sessions, all orientation documents will be sent to interested individuals prior to the session (including the consent form) and they will be encouraged to review these documents before the virtual session. During this session, interested individuals will be provided with detailed information about the study's purpose, risks/benefits, design, and requirements by study staff and be given an opportunity to ask questions. These sessions are interactive in nature. Once all procedures are explained and questions are answered (which takes approximately 1 hour), participants will be allowed to leave the orientation meeting if they are no longer interested. If the individual remains interested in participating, (s)he will provide oral/virtual consent via the audio, chat, and video functions of Zoom. Study staff will record all consented participants; these data will be stored on the UConn research drive in a locked file. After consent is provided, the participant will be officially enrolled in the study.

Documentation of Consent:
For the virtual consent process, participants will be sent the adult consent form prior to their Zoom / virtual consent meeting. During the virtual consent / orientation session, they will be asked to provide consent via hand raise, oral indication, or by sending a message to study staff using the chat function in Zoom. Study staff will record who provides consent. This information will be saved in a password protected file on the UConn research drive.

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