3/15/2019

IRB Protocol

Study Title: Grant Title: RELAX: A mobile application suite targeting obesity and stress

NCT02615171

IRB-1 Study Protocol

NCT02615171

Protocol Version # and/or Date: 03/15/2019 *[The protocol version must be revised each time a modification is submitted to the IRB to change the protocol.]*

Study Protocol Title: Grant Title: RELAX: A mobile application suite targeting obesity and stress
Alternate title for participant information form: A technology based weight loss program using mobile apps and Facebook

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.

Research Plan

Purpose/Introduction: *[State the reason for the study, the research hypothesis, and the goals of the proposed study as related to the research question(s). Provide a clear and succinct summary description of the background information that led to the plan for this project. Provide references as appropriate and, when applicable, previous work in animal and/or human studies. Provide previous UConn protocol number, if applicable.]*

Please note that this protocol is related to aims 2, 3, and 4 of the grant application. Some components of the methods have changed as well due to the lessons learned during the development phase of the project. The changes include: all study procedures being conducted online instead of in-person; and PCP's will not be included in the methods; and each participant will have a buddy help them during the pre-pilot intervention by providing feedback.

Disclosure: Dr. Pagoto is a paid Fitbit, Inc. Consultant.

SIGNIFICANCE. Mobile apps are innovative and promising weight loss tools. In our recent review of weight loss apps we discovered that the range of features offered in commercial weight loss apps is fairly limited relative

[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.

to the range of strategies used in lifestyle interventions.[1] Tracking and goal setting are the most common features, but patients who do not consistently track and/or meet their energy balance goals may achieve less benefit from apps. Research is needed to increase the sophistication of app-delivered behavioral strategies to help obese adults with lower adherence. Further, pairing mobile apps with traditional counseling may be the optimal treatment model as it takes advantage of technology while preserving the role of the provider. The purpose of this proposal is to develop and test mobile app-delivered stress and weight loss features in the context of a provider-delivered weight loss intervention.

Stress As A Predictor of Poor Outcome in Lifestyle Interventions. Stress is a major factor in weight loss treatment failure. Lifestyle intervention studies have shown that high stress (and/or depression) at baseline predicts worse outcomes,[2-4] which suggests that people with high stress do not adequately benefit from lifestyle interventions. Making matters worse, chronic stress was found to be related to a ~1.5-fold excess risk of developing coronary heart disease.[5] Stress has also been linked to the development of obesity, and specifically abdominal obesity. Stress may contribute to obesity and obesity treatment failure via its impact on eating behavior. In a recent study, stress was associated with disinhibited eating, binge eating, hunger, more frequent junk food consumption, and decreased intake of fruit, vegetables and whole grains.[6] Directly targeting stress in lifestyle interventions may be necessary to improve weight loss outcomes.

Adding Stress Management Can Improve Outcomes. Surprisingly few studies have incorporated stress management into a lifestyle intervention. Daubenmier et al[7] found that the diet, physical activity, and stress reduction components of a lifestyle intervention each contributed to reducing CVD risk independently and additively in the Multisite Cardiac Lifestyle Intervention Program. A small pilot trial found that adding stress reduction strategies to a lifestyle intervention for Black women gave it a marginal advantage on weight relative to a lifestyle intervention with no stress reduction component and a significant effect on cortisol.[8] A third study, also using a small sample, showed that a weight loss intervention that included classic stress management training (progressive muscle relaxation and diaphragmatic breathing) resulted in three times the weight loss as a condition that did not include stress management, a difference that was statistically significant.[9] These studies provide preliminary support the addition of stress management strategies to a lifestyle intervention.

Diet, Physical Activity, Stress and Stress-Induced Eating Are Key Treatment Targets. Another set of studies took a different approach, which is to test the effect of stress reduction strategies without dietary and physical activity counseling on weight and stress-induced eating. One study found that a mindfulness-based stress reduction intervention did not impact weight or stress-induced eating.[10] Two studies tested mindfulness-based interventions that directly targeted stress-induced eating. Both found reductions in stress-induced eating, but neither facilitated weight loss,[11,12] although one prevented weight gain compared to a wait list control group.[11] Altogether these studies suggest that stress reduction content should directly address stress-induced eating, but all four intervention components (diet, physical activity, stress, and stress-induced eating) seem necessary to generate weight loss.

Lower Intensity Lifestyle Interventions Are Needed. The implementation challenge of multi-component lifestyle interventions is that they have high cost and patient and provider burden, thereby reducing potential for dissemination and impact. The science needs to move towards the development of less intensive, more efficient interventions. The challenge historically with low intensity interventions (fewer, shorter visits) is that they have not been effective.[13-16] Another challenge is that people with significant motivational challenges (e.g., high stress, depression) need more, not less assistance. Mobile technology may provide solutions to these challenges with tools designed to reduce intensity (in terms of face-to-face visit time) and patient burden without neglecting the needs of patients who need help the most. The purpose of the present study is to develop a technology-assisted lifestyle intervention that targets a population with high rates of treatment failure while being less intensive than traditional models.

Technology-supported weight loss interventions are promising. Mobile phone use is high in the US and across socioeconomic groups with 285 million subscribers,[17] and some estimates show even higher rates of use among low SES groups.[18,19] Advantages of technology-supported weight loss interventions are the potential to reduce intervention intensity and burden, while making the intervention available 24/7 in participant's lives.[20] The literature on technology-supported weight loss intervention is still burgeoning but shows early signs of efficacy.[21-26] For example, technology-supported self-monitoring plus behavioral weight loss counseling was as effective or superior to behavioral weight loss counseling alone in two studies.[21,22]

In the pre-pilot trial, we propose to expand upon current mobile app delivered features by having the RELAX app provide intelligent feedback on behavioral patterns, such as the frequency, context, and influence of one behavior

on another (e.g., stress on caloric intake), as well as built-in stress reduction exercises that are cued during stress. None of the technology-supported weight loss interventions address stress or stress-induced eating and many are still web- not mobile-based.[23-25] On the other hand, we do not know if "more is better" in terms of the number of behavioral strategies in a mobile app. Too many strategies may be burdensome. For this reason, in the pilot trial we propose to compare the feasibility, usability, acceptability, and time and cost burden required with an app that includes diet and physical activity self-monitoring features to one that only includes very simplistic features of reporting stress eating, with the ultimate goal of understanding what type of features are associated with the highest usage and acceptability rates. This is a necessary question to move the field of mHealth for obesity forward given that the majority of apps include a narrow range of behavioral strategies.[27] More comprehensive mobile app-supported interventions are needed to target major barriers to weight loss, such as stress.

In the pilot trial, we propose to compare the feasibility of a potentially burdensome diet tracking app, MyFitnessPal, to a very simplistic stress eating app, Slip Buddy, during a weight loss intervention.

Aim 2: During a 6-week pre-pilot intervention, 24 participants will participate in an online weight loss intervention while using RELAX-App and RELAX-web. Quantitative and qualitative data will assess usability and acceptability and modify RELAX-App and RELAX-Web accordingly.

Aim 3: Pilot feasibility test. We will recruit 60 overweight and obese adults to participate in an online weight loss intervention while using a comprehensive diet tracking app versus a simplistic app. Feasibility outcomes are usage of app features, acceptability, adherence, clinical time burden, and retention. Exploratory outcomes include changes in weight, stress, and stress induced eating.

Specific Aim 4: Time and Cost Analyses. To determine the time participants and interventionists spend on the intervention as well as the cost.

For EACH Participant Population State the Number of Participants to be Enrolled and Screened*, if applicable: [State the total number of participants to be enrolled and, if enrolling more than one participant population, describe the total enrollment for each. Tip: consider attrition and the number of participants who may fail screening. Use of a range may provide flexibility.] Note that the range must be justified in the* ***Justification of Sample Size section below****.*

The total number of subjects that will be enrolled into the pre-pilot and pilot intervention will be 84. 24 participants for the pre-pilot and 60 participants for the pilot. It is estimated that we will screen 1075 participants to achieve this recruitment goal. Since the initial contact is via an online link, there will be many incomplete responses driving up the number of screened-out participants.

Justification of Sample Size*: [For qualitative and pilot studies, describe how the proposed sample size is appropriate for achieving the anticipated results. For quantitative studies, provide a power analysis that includes effect size, power and level of significance with references for how the sample size was determined. Explain the rate of attrition and possible number who fail the screening, with references as appropriate.]*

The intent of this grant is to use an iterative process to develop a mobile platform-based companion to a lifestyle intervention for obese individuals. Our main concern in determining sample size is to be consistent with published standards for usability and feasibility testing of mobile- and web-delivered tools. Our sample size of 24 for the pre-pilot intervention was based on a review on methodological aspects of usability testing that showed that serious problems were identified by 12-15 participants.[28] Our sample size of 60 pilot intervention participants was based on these studies as well as two pilot studies that used 24 subjects (12 in each group) and 23 in a single group design.[29,30] We sought a balance between including a sufficient number of individuals to assess the feasibility in a time- and cost-efficient way and the need to best position it to be tested in a fully powered randomized trial. The study is not powered to test efficacy of the RELAX and Slip Buddy mobile applications on weight loss, this is not our intent nor is it even appropriate to do so given the high probability of errant efficacy estimates in pilot trials as discussed in length by Leon and colleagues.[31]

For EACH Participant Population State Describe the Study Population(s)*: [Describe the participant population(s) including gender, ethnicity, income, level of education and age range.]*

We are recruiting obese individual of all ethnicities, income and education levels between the ages of 18 and 65 in the United States. Participants must current use a smartphone and have regular connectivity.

***Enrollment of UConn Students and/or Employees**: [Will UConn students be enrolled? If so, describe if these students include those who any key research personnel teaches, or for whom any key research personnel has responsibility. Will UConn employees be enrolled? If so, describe if these employees report to any key personnel. For each group, explain why this population is necessary to the study. Tip: convenience is not sufficient justification.]*

We will be recruiting overweight individuals between the ages of 18 and 65 from anywhere in the US. UConn students and employees may be enrolled if they meet eligibility requirements and are interested in completing the study. Since it is not essential that we recruit students and employees directly reporting to key personnel on this project, we will exclude them from participation.

***Enrollment of Key Personnel, Spouses or Dependents/Relatives**: Will study key personnel, spouses of key personnel, or dependents/relatives of any key personnel be enrolled in the study? If so, describe and provide justification.*

No

***For EACH Participant Population Describe Recruitment Methods:** [Specify each method and describe specific procedures for how participants will be identified and recruited. Attach copies of all advertisement/recruitment materials for IRB review. Describe how UConn Students/Staff and Key Personnel/Spouses/Dependents/Relatives will be identified and recruited, if applicable.]*

A survey link will be included with our recruitment materials. Participants will be instructed to complete the survey to be considered for the study and will be recruited using the following online strategies:

- Electronic recruitment: online, Facebook, Twitter, newsletters, intranet messages, emails;
- Connect with large businesses to get our ad and/or flyer e-mailed to their staff and students;
- Research Match (https://www.researchmatch.org/) volunteer database

***For EACH Participant Population Describe Screening Procedures, if applicable:** [Describe when participants will be screened and how this will occur. Include copies of all screening forms and related documents. Describe procedures to notify participants of the screening result. Tip: if screening will be conducted online or by phone prior to consent, be sure to request a waiver of signed consent, if appropriate. Provide a copy of the screening instrument.]*

Participants will complete screening procedures online and over the phone since they may be located anywhere in the US, not just local. We will post online recruitment ads which will contain a link to an online survey containing the initial screening questions. The survey will first have a description of the study and will then have the eligibility questions. If they are eligible to proceed they will be contacted by the study team to book a telephone screening call to review the consent form and provide contact information. The next step in the screening process is to complete an online survey including physical activity, medical history, weight history, quality of life, social networking use, and technology acceptance. We will not require PCP approval since we assess exclusionary medical conditions during the telephone screening and again during the screening survey. If conditions are reported, during either of these two assessments that might put the participant at risk during the intervention, they will be excluded.

Before participants are enrolled into the intervention, they must complete an orientation webinar. The purpose of the webinar is to educate participants about what research is, review study procedures and how to use the diet tracking app (either MyFitnessPal or Slip Buddy), review importance of participation of enrolled participants, and to allow participants another opportunity to evaluate if joining this study is the right choice for them. This webinar is being conducted to improve study retention. After completion of the webinar, participants will receive a final email asking if they are willing to participate in the intervention. The webinar moderator will record in REDCap tracking which participants completed the webinar.

Participants will need to complete the both screening surveys, telephone screening, and the orientation webinar before being enrolled into the intervention.

Design, Procedures, Materials and Methods: *[Describe the study design, including the sequence and timing of all study procedures. Experimental procedures should be clearly described and labeled as such. If the study uses control or experimental groups, or different treatment arms, clearly describe what participation will be like for each of the groups or study arms. Tip: describe procedures in the order conducted. The IRB strongly suggests that investigators incorporate flexibility into the study design to accommodate anticipated events (i.e. explain how missed study appointments can be made up by participants). If the research involves study of existing samples/records, describe how authorization to access samples/records will be obtained. If the study involves use of deception explain the reason why this is necessary. If applicable, describe the use of audiotape and/or videotape and provide justification for use. If this study offers treatment for the participants' condition, complete the Treatment Study Supplemental Form (IRB-1C) and attach it to this application for review. If the study includes measures, survey instruments and questionnaires, identify each and, if available, provide references for the measures. Describe what they intend to measure (relate to purpose/hypothesis) and their psychometric properties (e.g., reliability and validity). Identify any that were specifically created for the study.]*

Study design: Participation starts with an initial survey, telephone screening, and a 2nd screening survey. Eligible participants will then complete a webinar, 6-week (pre-pilot)/12-week (pilot) intervention, and an end-of-study focus group and follow/up survey. We will first recruit for a 6-week pre-pilot intervention and then the 12-week pilot intervention.

Intervention
The intervention includes social media-delivered DPP weight loss counseling and the use of RELAX (in the pre-pilot) or Slip Buddy vs MyFitnessPal (in the pilot). The intervention will last for 6 weeks for the pre-pilot participants and 12 weeks for the pilot participants. In the pre-pilot, we will recommend that they communicate with their buddy only through the RELAX app. Participants will also be encouraged complete diet and activity tracking using Fitbit. They may also share their diary with the interventionist to receive individualized feedback.

In the pilot:
In addition to the weight loss counseling, participants will be encouraged to use a diet tracking app. They will be randomized to a condition that uses MyFitnessPal or a condition that uses Slip Buddy. If they are assigned to the group that uses MyFitnessPal, they will enter everything they eat and do for exercise during the intervention period (12 weeks). They will receive a daily calorie goal directly from the app. If they are assigned to Slip Buddy, they will open the app any time they overeat to answer a few questions: what they were doing at that time (i.e watching TV, at a party, etc.), what they ate, stress level, and hunger level.

Participants will receive a Fitbit scale to take their weight weekly and at assessments. Weight is logged directly from the Fitbit scale to the participants' Fitbit account. Participants will be asked to set up a Fitbit account for the study and share login with the study staff so that the staff can record the weight taken. At the end of the study participants will be allowed to keep their scale and instructed to change their Fitbit password. If they already have a Fitbit account and choose not to create a 2nd one for the study, they may choose to share that login with the study staff. This method will allow for a standard weight measure for each participant with a higher level of accuracy than self-reported weight. If they choose not to share their login for the duration of the study, they will be allowed to email screenshots of their weight via the app.

<u>Focus Group Follow-up:</u>
A focus group will occur in the 7th week after the start of the intervention for pre-pilot participants and in the 13th week for pilot participants. The focus group will last for 60 minutes and will include a discussion about likes and dislikes of the intervention. Focus groups will be conducted via audio-recorded webinar. We will attempt to book about 5-10 participants per call, which will result in about 6-12 groups being conducted. Any participants who are unable to attend the webinar will receive the questions through an e-mailed survey link so that the survey may

be completed online. We will e-mail the survey link twice. At the time of the 2nd e-mail, we will also call them to let them know to check their e-mails. If there is no response from the participant after the 2nd e-mail, we will make no further attempts to contact them.

Participants will also receive an online follow-up survey during the 7th week after the start of the intervention for pre-pilot participants and in the 13th week for pilot participants, which will be a repeat of the screening measures and a feedback survey.

We will also inform participants that they are welcome to continue to use the study Facebook group, although it is not part of the study procedures. We will inform them that we will continue to monitor the Facebook group and collect Facebook use data from users for another 12 months for any participants who continue to use it. Coaches will not be participating or providing feedback to participants during this time. At the end of the intervention any participants still using the group will be asked if they would like to take over leading the group. We will continue to hold admin rights in order to extract data through 12 months, but at that time we will hand over administration rights to anyone who volunteers to take it on, and remove all study staff access.

At the end of the study, participants will no longer have access to the RELAX or Slip Buddy app. Access is granted by user login and when the study is over, the login for all participants will be deactivated. This is managed by the WPI team.

Measures

Data Collected	List of Measures	Baseline	During Intervention	F/up	Method
BMI	Height	X			REDCap
	Weight	X	X (weekly)	X	REDCap
Demographics	Income, employment, marital status, race/ethnicity, household composition*	X			REDCap
Medications	Brief Medication Questionnaire [32]	X		X	REDCap
Medical History	Assesses exclusionary medical conditions*	X			REDCap
Stress	Perceived Stress Scale[33]	X		X	REDCap
Emotional Eating	Eating Disorder Examination Questionnaire[34]	X		X	REDCap
App use	Data extraction		X		REDCap
Diet tracking (RELAX pre-pilot)	Data extraction from Fitbit		X		REDCap
Stress Eating	Data extraction from Slip Buddy				
Usability	System Usability Scale[35]			X	REDCap
Intervention Feedback	Acceptability, satisfaction, burden*			X	REDCap
Group engagement	Facebook data extraction		X		Facebook

* Investigator-derived items

Time Commitment:

Visit	Pre-Pilot Participants		Pilot Participants	
	Study Participants		Study Participants	Friend-Buddies
Initial Screening Survey (10 min)	10		10	n/a
Telephone Screening (20 min) (5 min study description for buddies)	20		20	5
Baseline (60 min total) Scale set-up (10 min) Online survey (50 min)	60		60	n/a
Webinar (60 min)	60		60	60
Intervention Pre-Pilot (6 wks): Participants: 35 min/week; Pilot (12 wks): Participants: 35 min/week; Buddies: 10 min/week	210		420	120
Follow-up (120 min total) Focus group (60 min) Online survey (60 min)	120		120	5
Total	480 min (approx. 8 hrs)		690 minutes (approx. 11.5 hrs)	180 minutes (approx. 3 hrs)

***Data Analysis**: [For all studies, specify the analytic techniques the researcher will use to answer the study questions. Indicate the statistical procedures (e.g. specific descriptive or inferential tests) that will be used and why the procedures are appropriate. For qualitative data, specify the proposed analytic approaches.]*

Pre-pilot: Responses to the usability survey based on the Systems Usability Scale will be summarized using descriptive statistics.

Pilot: Using t-tests, we will evaluate self-monitoring adherence, retention, attendance, burden, and intervention fidelity.

Specific Aim 4. The goal of the cost analysis is to compare the cost of delivering the intervention. The cost and effort of delivering the intervention will be tracked. As Ritzwoller[36] and colleagues recommend, we will perform sensitivity analyses to estimate the range of intervention costs after varying the inputs. For example, it may be difficult to accurately estimate time spent using the app by participants. Staff pay might also vary across settings, depending on which professionals are assigned as coaches (e.g., dietitians, health educators, psychologists). We will estimate a range of costs based on varying assumptions. We will evaluate total program costs per participant and total program costs per pound lost.

***Inclusion/Exclusion Criteria:** [List ALL inclusion and exclusion criteria. Any proposed exclusion criterion based on gender (women of childbearing potential), age, or race must include justification for the exclusion. Describe the conditions under which participants may be removed from the study, i.e., noncompliance with study rules, study termination, etc.]*

Inclusion Criteria: Participants must: (1) have a BMI of 27-45; (2) currently use an Android smartphone, (3) have cell phone connectivity at home and work, (4) and uses a smartphone every day.

Age justification: Weight loss interventions intended for ages outside of the range (<18 or >65) require individualized attention from a physician and will not be appropriate to use the DPP.

Exclusion Criteria:

1. Under the age of 18 and over the age of 65;
2. BMI under 27 or over 45;
3. Not interested in losing weight;
4. Does not currently own a smartphone;
5. Smartphone type and/or version not meeting app requirements;
6. No phone connectivity at home and work;
7. Unable to walk unaided for ¼ mile without stopping;
8. Has a condition that precludes dietary changes (i.e. ulcerative colitis, Crohn's disease, active diverticulitis, renal disease);
9. On a medication affecting weight;
10. Type 1 or 2 diabetes;
11. Had gastric bypass surgery;
12. Had or plans to have gastric bypass surgery during the study period;
13. Pregnant/lactating;
14. Has bipolar disorder, substance abuse, bulimia, or severe depression;
15. Lost 5% or more body weight in the last 3 months;
16. Has not experienced emotional eating over the last week;
17. On medication affecting weight;
18. Has concerns about being audiotaped;
19. Prisoner; or
20. Unable to provide consent;
21. Non-English speaking

Participants will be withdrawn from the study if: they drop from participation, do not complete all screening procedures, post inappropriate content on Facebook, or are disrespectful in the buddy system. Participants reporting that they would like to withdraw from the study will be given the option to: 1) withdraw from all intervention-related activity and contacts, but still complete the final assessment or 2) withdraw from the study completely with no additional study contact. If a participant becomes pregnant during the study, they will be withdrawn from the intervention, but will be given the option still complete the follow-up assessments.

Potential Harms/Risks and Inconveniences: *[Describe the potential risks to participants (and secondary participants, if applicable) and* ***steps taken to minimize risks*** *for each participant population. Assess the likelihood of the risk occurring and, if it were to occur, the seriousness to the participant. Types of risks to consider include, but are not limited to: physical, psychological, social, legal, employment, and financial. Also describe any anticipated inconveniences the participants may experience (time, abstention from food, etc.).]*

Possible risks for being in this study includes: Injury while exercising, breach of confidential information, and discomfort completing measures. The attempt to avoid risks to participants will be addressed by: suggesting moderate intensity exercise to avoid discomfort, pain, or injury. Participants reporting discomfort will be referred to their PCP. Injuries are unlikely to occur since we screen out medical conditions that could make someone prone to injury and we only suggest moderate activity. We also provide participants with information on exertion level and remind them to see medical attention if there is pain. Tracking data will be stored electronically in REDcap, a network secure data entry program; electronic data being collected from the website and app will be transmitted to WPI will be encrypted; any data on paper will be stored in a locked file cabinet; and participants will be informed that they may withdraw from the study at any time if they feel discomfort with any of the study procedures.

To maintain confidentiality, participants will be asked not to disclose that they are in a research study to protect confidentiality of other participants; posts from the participants will be continuously collected and monitored using computer programming and will address any issues related to privacy. We will do this by assigning a staff member to read and assess each interaction in the group on a daily basis. Any privacy-related problems will be brought to the attention of the PI immediately. During focus group calls, participants may share information given by other participants. To avoid this we'll ask that everyone on the call keeps the conversation confidential and if

they choose to use and alias during the call, we can assign one to them so that the study team knows who they are, but the others on the call do not.

Benefits: *[Describe anticipated benefits to the individual participants. If test results will be provided, describe and explain procedures to help participants understand the results. If individual participants may not benefit directly, state so here. Describe anticipated benefits to society (i.e., added knowledge to the field of study) or a specific class of individuals (i.e., athletes or autistic children). Do not include compensation or earned course credits in this section.]*

Participants may or may not benefit from participating in the study. Benefits that could occur are losing weight through the exercise and lifestyle intervention. Societal benefits include providing evidence to support an intervention delivery modality that is more conducive to settings like worksites, health plans, and clinics that serve large populations but have limited space, staffing, and resources for traditional in person interventions.

Risk/Benefit Analysis: *[Describe the ratio of risks to benefits. Risks to research participants should be justified by the anticipated benefits to the participants or society. Provide your assessment of anticipated risks to participants and steps taken to minimize these risks, balanced against anticipated benefits to the individual or to society.]*

The possible risks of the study (including injury during exercise, psychological discomfort, and breach of confidentiality) are minimal and are outweighed by the possible benefits to participants (weight loss).

Economic Considerations: *[Describe any costs to the participants or amount and method of compensation that will be given to them. Describe how you arrived at the amount and the plan for compensation; if it will be prorated, please provide the breakdown. Experimental or extra course credit should be considered an economic consideration and included in this section. Indicate when participants will receive compensation.]*

Economic burden to subjects includes the time needed for screening and study participation. There is no cost to participants for participating in the study. Depending on smartphone data usage plan for each participant, usage charges may incur due to increased use of mobile apps such as Facebook, Fitbit, Slip Buddy, and My Fitness Pal.

Participants will be paid in the form of online Amazon gift cards. Participants will receive $20 compensation for completing the baseline visit. Pre-pilot participants will receive $30 for completing the focus group and follow-up. Pilot participants will receive $50 for completing the focus group and follow-up. Participants will also be allowed to keep the study scale ($120 value).

Data Safety Monitoring: *[This is a prospective plan set up by the study investigators to assure that adverse events occurring during studies are identified, evaluated, and communicated to the IRB in a timely manner. Although the investigators initially propose a Data Safety Monitoring Plan (DSMP), the IRB must approve the plan and may require revision of the plan. A DSMP is required for all human studies at the University of Connecticut except for studies determined to be exempt from continuing IRB review. For studies that present more than minimal risk to participants, the IRB will review and determine on a case-by-case basis whether a data safety monitoring board is most appropriate. Please refer to the IRB's policy regarding data safety monitoring before completing this section - http://research.uconn.edu/policies-procedures.*

Issues that should be addressed in the DSMP include the following:

1. *frequency of the monitoring*
2. *who will conduct the monitoring (Under UConn policy a student cannot be the sole person responsible for monitoring the data and safety of the protocol procedures.)*
3. *what data will be monitored (include compliance with approved IRB protocol.*
4. *how the data will be evaluated for problems*

5. *what actions will be taken upon the occurrence of specific events or end points*
6. *who will communicate to the IRB and how communication will occur*
7. *describe procedures to inform the sponsor*

Sample response to issues listed above for minimal risk/slight increase over minimal risk – "Survey results will be monitored by the PI in conjunction with the student investigator once every two weeks (items 1, 2 and 3). Survey responses will be reviewed to monitor for clarity (i.e., the same question is skipped by 5 or more participants). In that case, the question will be revised and an amendment will be submitted to the IRB (items 4, 5 and 6)."

A DSMP is set up for this study and will include reports to the safety officer after each phase of the study. Reports will be produced by the program director and data manager. Reports will be reviewed by the principal investigator and a statistician then will be sent to the safety officers on the board.

Report type
Recruitment rates
Inclusion/exclusion
Demographics
Adherence to study protocols
Adverse events
Participant Retention/Engagement
Data review (completeness/outliers)

Qualifications and responsibilities of the Safety Officer
The safety officers for this project are Dr. Kristin Schneider, Assistant Professor at Rosalind Franklin University, North Chicago, IL. Dr. Schneider has a degree in clinical psychology, experience in exercise and weight loss interventions, and an understanding of the types and severity of injuries commonly experienced during weight loss trials.

Recruitment rates and adherence inclusion/exclusion criteria, and ethnic diversity goals:
Recruitment progress, inclusion/exclusion criteria, and diversity goals will be reviewed at each meeting. This review will ensure that project deadlines are being met, that participants meet eligibility criteria, and that the ethnic diversity goals outlined in the grant proposal are being met.

Adherence to study protocols:
The principal investigator will: direct creation of all study protocols and will be involved in trainings and supervision of all study staff. Quality control will be conducted in all phases of the project. The focus groups will be audio recorded. A 10% randomly selected sample of the recordings will be assigned to the independent coder and project director for review. A summary will be provided to the safety officers and a checklist will be completed for each review.

Adverse events:
Participants who report conditions during the screening phase that could create a safety concern while receiving the intervention will be excluded. Adverse events that occur during the intervention will be assessed, recorded, and followed up until resolved. Safety monitoring procedures will be documented in a standard protocol and overseen by the PI and program director. Any adverse events will be immediately reviewed by the program director. The safety officers will be informed during monthly reports for all adverse events. Serious adverse events will be communicated immediately to the safety officers. The NIH and UConn IRB be notified immediately in the event of serious adverse event. Any death of a study participant will be reported to the NIH and UConn IRB whether or not it appears to be related to the study.

The adverse event report will include a listing of adverse events including duration, severity, seriousness, relatedness, action taken, and resolution. This information will be presented unblinded. A significant increase in the rate of adverse events in one treatment group would be cause for concern for the safety of participants in the study.

Participant retention
Engagement will be recorded throughout the study. If a participant chooses to drop from the intervention, they will be given the option to skip the rest of the intervention visits, but still complete the final assessment. Engagement data will be provided in a report to the safety officers.

Data Security:
The databases will be maintained on UConn servers where security will be maintained through access controls. The program director will control the database and surveys and will allow access to necessary staff. Staff wanting access to identifiable data will need to: have prior IRB approval to be on the project, apply for a REDCap account, be approved by the program director, and utilize a password for login. Electronic data extracted from the app and website to WPI's servers will be encrypted.

Data review (completeness/outliers):
Data reports will be reviewed by the data manager, program director, statistician, and PI. Reports will include completeness of data (visits completed, online engagement, % of expected forms submitted, % of submitted forms passing edit); missed visits and missing information within visits; descriptive information for each endpoint (change in weight and physical activity) without statistical testing; and quality control analyses for primary outcome (change in weight).

Privacy/Confidentiality Part 1: *[Explain how the privacy interests of participants will be maintained during the study (note that **privacy pertains to the individual not to the data**). Describe how data will be coded. Do not use the any potentially identifiable information such as initials of participants as part of the code. If identifiable, sensitive information (illegal drug use, criminal activity, etc.) will be collected, state whether a Certificate of Confidentiality will be obtained. Be sure to state whether any limits to confidentiality exist and identify any external agencies (study sponsor, FDA, etc.) that will have access to the data. If participants will be screened, describe the plans for storage or destruction of identifiable data for those that failed the screening.]*

REDCap will be used for data entry and management. Digital recorders will be used for recording audio from the end-of-study focus groups. The database and recordings will be maintained on UConn servers where security will be maintained through access controls. Once recordings are saved on the server they are deleted from the recorder. Recordings are used for qualitative analysis. When the recordings are transcribed by study staff (RA's), the names of participants are replaced with ID numbers to anonymize the transcript. Files will be managed by the data manager and project director, who will control user access and rights. For each user, REDCap will require a REDCap profile, username and password to enter the program. Staff will only have access to the database if the data manager has given them access. UConn IRB and their representatives, and study personnel will have access to the research data, as will the study sponsor if requested. All participants will be assigned an ID number, which will link them to their study data. The ID number will be 3-4 numerical characters representing the number of participants in the study. PHI fields will be stored in a separate form from other data collection forms. Data will be completely de-identified once the last assessment is complete. At this time the link between ID number and study data will be destroyed. Study data in the form of hard copies will be stored in a locked file cabinet managed by the program director and will be destroyed 3 years after completion of the study.

Diet tracking data entered into Fitbit, will be transmitted from Fitbit to the WPI server using the RELAX app. RELAX app has been connected to the Fitbit dietary entries. Participants will be given login information to use to enter dietary data in Fitbit, which will pair the diet records to their RELAX app. Providing a log in to participants rather than then using their own login will allow data to be paired while still anonymous to WPI. Only UConn will hold the master key to the data and study ID numbers.

Data from ineligible participants:
Contact information will be stored in a file with an indication that they are not eligible. However the data collected from the screening, including reason ineligible, will be stored in a separate de-identified file.

***Privacy/Confidentiality Part 2: Complete the Data Security Assessment Form**: [**This form IS REQUIRED for ALL studies**. The form is available here - http://research.uconn.edu/irb/irb-forms-infoed/. This form will be used to assess procedures for protecting confidentiality of data collected during the study and stored after closure. It will also be used to assess plans for storage and security of electronic data in accordance with University Best Practices. Review the document proving tips to complete the form located at http://content.research.uconn.edu/pdf/storrs/rcs/irb/TipsDataSecurityAssessmentForm.docx.*

This form has been completed.

Informed Consent

As PI, you are responsible for taking reasonable steps to assure that the participants in this study are fully informed about and understand the study. Even if you are not targeting participants from "Special Populations" as listed on page 4, such populations may be included in recruitment efforts. Please keep this in mind as you design the Consent Process and provide the information requested in this section.

***Consent Setting:** [Describe the consent process including who will obtain consent, where and when will it be obtained, and how much time participants will have to make a decision. Describe how the privacy of the participants will be maintained throughout the consent process. State whether an assessment of consent materials will be conducted to assure that participants understand the information (may be warranted in studies with complicated study procedures, those that require extensive time commitments or those that expose participants to greater than minimal risk).]*

A signed consent waiver is being requested for this study. Participants will review an informational page before completing the initial survey screener. Ample time will be allowed for discussion or questions. Consent will be reviewed during the telephone screening by research assistants/coordinators trained in the consent process.

***Capacity to Consent:** [Describe how the capacity to consent will be assessed for participants with limited decision-making capacity, language barriers or hearing difficulty. If a participant is incapable of providing consent, you will need to obtain consent from the participant's legal guardian (please see the IRB website for additional information).]*

To be able to actively participate in the study, participants must be adults without impaired decision making ability that are able to speak and read English. The consent process will include a discussion of the participants understanding of what participating in research means including their rights as a research participant, the protocol, as well as risks and potential benefits to participating in the study. If research personnel obtaining consent believes there is a concern regarding a participant understanding participation will be discussed with the program director who will determine whether to exclude the participants on this basis.

***Parent/Guardian Permission and Assent:** [If enrolling children, state how many parents/guardians will provide permission, whether the child's assent will be obtained and if assent will be written or oral. Provide a copy of the script to be used if oral assent will be obtained.]*

N/A

***Documentation of Consent:** [Specify the forms that will be used for each participant population, i.e., adult consent form, surrogate consent form, child assent form (written form or oral script) or an information sheet. Copies of all forms should be attached to this application in the same format that they will be given to participants (templates and instructions are available on the IRB website).]*

An information sheet will be used for the study participants.

Waiver or Alteration of Consent:** [The IRB may waive or alter the elements of consent in some minimal risks studies. If you plan to request either a **waiver of consent** (i.e., participants will not be asked to give consent), an **alteration of

consent *(e.g., deception) or a* ***waiver of signed consent*** *(i.e., participants will give consent after reading an information sheet), please answer the following questions using specific information from the study:]*

Waiver (i.e. participants will not be asked to give consent) or alteration of consent (e.g. use of deception in research):

- *Why is the study considered to be minimal risk?*
- *How will the waiver affect the participants' rights and welfare? The IRB must find that participants' rights are not adversely affected. For example, participants may choose not to answer any questions they do not want to answer and they may stop their participation in the research at any time.*
- *Why would the research be impracticable without the waiver? For studies that involve deception, explain how the research could not be done if participants know the full purpose of the study.*
- *How will important information be returned to the participants, if appropriate? For studies that involve deception, indicate that participants will be debriefed and that the researchers will be available in case participants have questions.*

Waiver of signed consent (i.e. participants give consent only after reading an information sheet):

We are requesting a waiver of signed consent to be able to recruit participants across the US for an online study.

- *Why is the study considered to be minimal risk?*

  The survey is minimal risk because includes surveys and a weight loss intervention.

- *Does a breach of confidentiality constitute the principal risk to participants? Relate this to the risks associated with a breach of confidentiality and indicate how risks will be minimized because of the waiver of signed consent.*

  The ability to review the consent online will limit any risks of travelling to the study site needed to complete an in-person consent.

- *Would the signed consent form be the only record linking the participant to the research? Relate this to the procedures to protect privacy/confidentiality.*

  No. We also utilize contact information and Facebook names to communicate with participants throughout the study.

- *Does the research include any activities that would require signed consent in a non-research setting? For example, in non-research settings, normally there is no requirement for written consent for completion of questionnaires.*

  No.

References / Literature Review:

1. Pagoto S, Schneider K, Jojic M, Debiasse M, Mann D. Evidence-based strategies in weight-loss mobile apps. *Am J Prev Med.* Nov 2013;45(5):576-582.

2. Clark MM, Cargill BR, Medeiros ML, Pera V. Changes in self-efficacy following obesity treatment. *Obes Res.* Mar 1996;4(2):179-181.

3. Elder CR, Gullion CM, Funk KL, Debar LL, Lindberg NM, Stevens VJ. Impact of sleep, screen time, depression and stress on weight change in the intensive weight loss phase of the LIFE study. *International journal of obesity (2005).* Mar 29 2011.

4. Pagoto S, Bodenlos JS, Kantor L, Gitkind M, Curtin C, Ma Y. Association of major depression and binge eating disorder with weight loss in a clinical setting. *Obesity (Silver Spring, Md.* Nov 2007;15(11):2557-2559.

5. Steptoe A, Kivimaki M. Stress and cardiovascular disease: an update on current knowledge. *Annu Rev Public Health.* 2013;34:337-354.

6. Groesz L, McCoy S, Carl J, Saslow L, Stewart J, Adler N, et al. What is eating you? Stress and the drive to eat. *Appetite.* 2012;58(2):717-721.

7. Daubenmier JJ, Weidner G, Sumner MD, Mendell N, Merritt-Worden T, Studley J, et al. The contribution of changes in diet, exercise, and stress management to changes in coronary risk in women and men in the multisite cardiac lifestyle intervention program. *Ann Behav Med.* Feb 2007;33(1):57-68.

8. Cox TL, Krukowski R, Love SJ, Eddings K, DiCarlo M, Chang JY, et al. Stress management-augmented behavioral weight loss intervention for African American women: a pilot, randomized controlled trial. *Health Educ Behav.* Feb 2013;40(1):78-87.

9. Christaki E, Kokkinos A, Costarelli V, Alexopoulos EC, Chrousos GP, Darviri C. Stress management can facilitate weight loss in Greek overweight and obese women: a pilot study. *Journal of human nutrition and dietetics : the official journal of the British Dietetic Association.* Apr 30 2013.

10. Kearney DJ, Milton ML, Malte CA, McDermott KA, Martinez M, Simpson TL. Participation in mindfulness-based stress reduction is not associated with reductions in emotional eating or uncontrolled eating. *Nutrition research (New York, NY).* Jun 2012;32(6):413-420.

11. Daubenmier J, Kristeller J, Hecht FM, Maninger N, Kuwata M, Jhaveri K, et al. Mindfulness Intervention for Stress Eating to Reduce Cortisol and Abdominal Fat among Overweight and Obese Women: An Exploratory Randomized Controlled Study. *J Obes.* 2011;2011:651936.

12. Alberts HJ, Thewissen R, Raes L. Dealing with problematic eating behaviour. The effects of a mindfulness-based intervention on eating behaviour, food cravings, dichotomous thinking and body image concern. *Appetite.* Jun 2012;58(3):847-851.

13. McTigue K, Harris R, Hemphill MB, Bunton AJ, Lux LJ, Sutton S, et al. *Systematic evidence review. Screening and interventions for overweight and obesity in adults.* Research Triangle Park, NC: Agency for Healthcare Research and Quality
U.S. Department of Health and Human Services;2003. No. 21.

14. Harris MF, Chan BC, Laws RA, Williams AM, Powell Davies G, Jayasinghe UW, et al. The impact of a brief lifestyle intervention delivered by generalist community nurses (CN SNAP trial). *BMC Public Health.* Apr 22 2013;13(1):375.

15. McGorrian C, MC OH, Reid V, Minogue M, Fitzpatrick P, Kelleher C. A brief cookery skills intervention is no more effective than written information alone in reducing body mass index in overweight cardiac rehabilitation patients. *Health promotion international.* Apr 17 2013.

16. Jansson S, Engfeldt P, Magnuson A, Lohse G, Liljegren G. Interventions for lifestyle changes to promote weight reduction, a randomized controlled trial in primary care. *BMC Research Notes.* 2013;6(213).

17. CTIA. Wireless Quick Facts. 2009; http://www.ctia.org/advocacy/research/index.cfm/AID/10323. Accessed May, 2012.

18. Leena K, Tomi L, Arja R. Intensity of mobile phone use and health compromising behaviours: How is information and communication technology connected to health-related lifestyle in adolescence? *J Adolesc.* 2005;28:35-47.

19. Smith A. Mobile Access 2010. *Pew Internet & American Life Project* 2010; http://www.pewInternet.org/~/media//Files/Reports/2010/PIP_Mobile_Access_2010.pdf.

20. Riley WT, Rivera DE, Atienza AA, Nilsen W, Allison SM, Mermelstein R. Health behavior models in the age of mobile interventions: Are our theories up to the task? *Translational Behavioral Medicine.* 2011;1(53-71).

21. Polzien KM, Jakicic JM, Tate DF, Otto AD. The efficacy of a technology-based system in a short-term behavioral weight loss intervention. *Obesity (Silver Spring, Md.* Apr 2007;15(4):825-830.

22. Pellegrini CA, Verba SD, Otto AD, Helsel DL, Davis KK, Jakicic JM. The Comparison of a Technology-Based System and an In-Person Behavioral Weight Loss Intervention. *Obesity (Silver Spring, Md.* Feb 10 2011.

23. Tate DF, Wing RR, Winett RA. Using Internet technology to deliver a behavioral weight loss program. *JAMA.* Mar 7 2001;285(9):1172-1177.

24. Tate DF, Jackvony EH, Wing RR. Effects of Internet behavioral counseling on weight loss in adults at risk for type 2 diabetes: A randomized trial. *JAMA.* Apr 9 2003;289(14):1833-1836.

25. Tate DF, Jackvony EH, Wing RR. A randomized trial comparing human e-mail counseling, computer-automated tailored counseling, and no counseling in an Internet weight loss program. *Arch Intern Med.* Aug 14-28 2006;166(15):1620-1625.

26. Chambliss HO, Huber RC, Finley CE, McDoniel SO, Kitzman-Ulrich H, Wilkinson WJ. Computerized self-monitoring and technology-assisted feedback for weight loss with and without an enhanced behavioral component. *Patient Educ Couns.* Feb 2 2011.

27. Pagoto S, Schneider K, Jojic M, DeBiasse M, Mann D. How evidence-based are mobile apps? *Am J Prev Med.* in press.

28. Bastien Christian J. Usability testing: a review of some methodological and technical aspects of the method. *Int J Med Inf.* 2010;79(4):e18-e23.

29. Mulvaney SA, Anders S, Smith AK, Pittel EJ, Johnson KB. A pilot test of a tailored mobile and web-based diabetes messaging system for adolescents. *J Telemed Telecare.* Mar 2012;18(2):115-118.

30. Palmier-Claus JE, Rogers A, Ainsworth J, Machin M, Barrowclough C, Laverty L, et al. Integrating mobile-phone based assessment for psychosis into people's everyday lives and clinical care: a qualitative study. *BMC Psychiatry.* 2013;13:34.

31. Leon AC, Davis LL, Kraemer HC. The role and interpretation of pilot studies in clinical research. *J Psychiatr Res.* Oct 27 2011.

32. Svarstad BL, Chewning BA, Sleath BL, Claesson C. The Brief Medication Questionnaire: a tool for screening patient adherence and barriers to adherence. *Patient Educ Couns.* Jun 1999;37(2):113-124.

33. Cohen S, Kamarck T, Mermelstein R. A global measure of perceived stress. *J Health Soc Behav.* Dec 1983;24(4):385-396.

34. Fairburn C, Beglin SJ. Assessment of eating disorders: Interview or self-report questionnaire? *Int J Eat Disord.* 1994;16:363-370.

35. Brooke J. SUS-A quick and dirty usability scale. *Usability evaluation in industry.* 1996;189:194.

36. Ritzwoller DP, Sukhanova A, Gaglio B, Glasgow RE. Costing behavioral interventions: a practical guide to enhance translation. *Ann Behav Med.* Apr 2009;37(2):218-227.