IRB-1 Study Protocol

Protocol Version # and/or Date: 12/7/2021

Study Protocol Title: Proof-of-Concept Study of an Integrated Mobile and Social Network Weight Loss Intervention

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.

No.

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

[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.

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 aim 1 of the grant application and includes a 6-week usability testing phase.

Obesity and Cardiovascular Disease. Obesity affects 39% of US adults[1] and is a significant risk factor for cardiovascular disease (CVD).[2] Lifestyle interventions such as the Diabetes Prevention Program have shown strong efficacy for reducing CVD risk[3,4] but have not been well-disseminated due to the expense of the clinic-based model.[5] Technology is changing how we deliver behavioral interventions by allowing patients to receive behavioral support in new ways. In spite of the promise, few fully-powered randomized trials have been conducted to test the efficacy of technology-based lifestyle interventions. This application is the culmination of several years of work by a team who has designed multiple technologies for obesity management.

Technology-Delivered Interventions Fill An Important Treatment Gap. A recent systematic review of 21 technology-delivered lifestyle interventions based on the Diabetes Prevention Program (13 of which were randomized trials) revealed that efficacy is promising, but weight loss is less than that observed in clinic- delivered programs.[6] The most common form of technology utilized in these programs was web-based platforms, but videoconferencing, interactive voice response phone calls, text messaging, and mobile applications were also used in some programs. This review concluded that studies including human counseling produced greater weight loss than fully automated programs and that participant engagement was a strong predictor of outcomes.[6] Increasing participant engagement may be key to improving outcomes, however it risks increasing counselor time which has implications for scalability. To advance this body of work, we aim to integrate technologies we developed to create a comprehensive technology-based weight loss program that maximizes meaningful participant engagement *without increasing counselor time*. Accomplishing this will require two things: 1) giving participants more technology-based assistance in behavior change strategies and 2) teaching participants how to mentor each other.

Popular Mobile Technology Approaches to Weight Management Have Low Compliance. Although commercial weight loss apps have proliferated, systematic reviews have revealed they include very few evidence-based features[7,8] and lack efficacy data.[8] The cornerstone feature of most weight loss apps is self-monitoring (i.e., calorie tracking).[7] A major problem with calorie tracking is compliance. In one study that prescribed a commercial weight loss mobile app to 212 primary care patients, more than half (56%) didn't use it in the first month and by six months only 16% were still using it.[9] While studies routinely show that consistent use is associated with greater weight loss, consistent users are few and predictors of consistent use are high health literacy and being white, which has implications for health disparities.[10] Mobile apps that assist users *the many other behavioral strategies* found in the DPP could be useful toward the goal of providing participants more assistance as they attempt to change their lifestyle behaviors. Our work shows that problem solving and stimulus control are two behavioral strategies that are amenable to mobile technology delivery.

Problem Solving: A Staple Behavioral Strategy. Studies have established that problem solving is not only an active ingredient of behavioral weight loss interventions,[11,12] but it is effective as a standalone intervention for weight loss maintenance[13] and it is a strong predictor of weight loss outcomes.[14] Problem solving is a counseling technique used to help patients identify barriers to behavior change and generate solutions to be iteratively attempted until barriers are overcome.[15]

In practice, the counselor works through 5 steps with the patient, including 1) identifying a barrier to behavior change, 2) brainstorming a list of solutions for overcoming the barrier with the patient, 3) having the patient select a solution he/she would be willing to try over the next week, 4) making a plan to attempt the solution, and 5) evaluating the outcome and trying additional solutions until the problem is solved. At the end of every session of lifestyle interventions, patients are asked to identify barriers that are likely to arise as they attempt the homework assignment and they are then assisted in making plans to overcome those barriers.[16] Additionally, an entire session of the DPP is devoted to problem solving skills.[17] Given the systematic process of problem solving, it is conducive to being facilitated via mobile app.

Peer Coaching: A Cost Saving Behavioral Strategy. Online social media platforms have frequently been used to deliver group-based behavioral weight loss interventions. Typically the way these work is that a social media platform's private group function is used to convene a group and deliver a feed based on a behavioral weight loss program.[18] Using the social media platform most popular with the target population is a way to get intervention content to people without requiring them to log into a novel platform or website. Using commercial social media platforms is also much cheaper than developing a novel platform. For example, the company Omada Health has raised $73M in 2019 for their online group-based counselor guided platform that delivers the DPP Lifestyle Intervention.[19] Two meta-analyses revealed modest effects of online social network delivered weight loss interventions.[20,21] In spite of the advantages of this modality of intervention delivery, participant engagement reported in studies is highly variable, with mean participant engagement ranging from once to 11 times per week.[22-29] The latter was our study which was unique because our group was facilitated by a counselor who posted conversation threads from the DPP twice a day and hosted activities such as weekly goal setting, weigh-ins, and progress reports. Participant engagement in these studies appears to be related to 1) whether the online platform was the sole intervention modality (vs just a place for participants to socialize) and 2) counselor activity, with studies reporting the lowest engagement posting only a single update per week.[24,28] Studies reporting the highest engagement had the counselor posting updates daily or near daily.[23,25-27] Even when the platform is the main intervention modality and counselors are very engaged, no studies have given participants direct guidance on how to best support and help each other.

Conceptual Model. We now know that simply providing a means for participants to engage with each other in an online platform may not be enough to generate the type of interaction that facilitates behavior change. In traditional group therapy, a counselor actively guides the group in activities like brainstorming, problem solving, and sharing experiences. Online group-based interventions should apply principles of group psychotherapy to facilitate practice of behavioral strategies and group cohesion. For this reason, our proposed intervention has conceptual underpinnings in the group therapy literature. An APA Task Force conducted a review of specific elements of the therapeutic process[30] concluded group cohesion is a key element in group therapy.[31] Group cohesion is a reliable predictor of both retention and outcomes in cognitive behavioral group psychotherapies.[31] To the extent that group members have the opportunity for in-session practice of behavioral skills with one another, group cohesion can be strengthened.[30] We know little about how to engage group members in skills practice in an online platform given the uniqueness of online interactions. Our mobile app and peer mentor training is specifically designed to prompt participants to practice problem solving skills with the group. Data from our previous work show that more frequent participant engagement of this type is associated with greater weight loss.

Overall, obesity is a serious risk factor for cardiovascular disease[2] but few people have access to behavioral treatments.[32] Technology-delivered weight loss programs have the potential to

increase reach and early studies reveal modest impact.[20] Less impressive outcomes have been produced by commercial weight loss mobile apps perhaps because they focus mostly on self-monitoring which in spite of being an essential component of behavioral weight loss interventions, has poor efficacy as a standalone intervention.[7,8] Comprehensive technology-based weight loss programs typically use online platforms to provide 1) technology supported dietary self-monitoring, 2) counseling in behavioral strategies, and 3) access to a peer group. In these models, the only technology-supported *behavioral strategy* is usually self-monitoring. The remaining behavioral strategies are the responsibility of counselors who provide personalized feedback. Technology that can assist people in the implementation of a wider range of behavioral strategies could increase the efficacy of technology-supported interventions. In separate studies, we developed and tested the feasibility of an online weight loss intervention and two mobile apps that help participants implement two behavior change strategies (problem solving and stimulus control).

The goal of this study is to merge these technologies into a comprehensive technology-delivered weight loss intervention and add new features that were suggested during our user-centered design process. Aim 1 is the pre-pilot phase. The objective is to conduct a one-arm pilot of a 6-week version of an online weight loss intervention paired with the Habit app and will evaluate the usability of the intervention in 20 adults with obesity. Usability is defined as use, acceptability, and burden of the mobile app features (dietary self-monitoring, slip tracker, and problem solving), and participant engagement in problem solving and peer mentoring.

We hypothesize that the online weight loss intervention, by prompting group practice of behavioral skills, will result in greater peer-to-peer interactions, increased weight loss related problem solving skills, and greater group cohesion, which will in turn, produce greater weight loss relative to a standard online weight loss intervention.

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: [State the total number of participants/records 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 6-week usability testing phase is 20. It is estimated that we will screen 800 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.]

We based the sample size of 20 on the number needed to allow sufficient diversity of participant experiences to identify usability issues.[33] This number also is a critical mass for an online group-based weight loss intervention to produce reasonable engagement, based on our experience. This sample size is consistent with recent pilot studies of similar interventions.[23,34] No statistical

comparisons are being made which precludes the need to calculate a sample size estimation based on effect sizes.

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.]

UConn students and employees may be enrolled if they meet eligibility requirements and are interested in completing the study. Students and employees directly reporting to key personnel on this project will be excluded 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 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, if applicable. Provide a copy of the screening instrument.]

We are recruiting overweight and obese individuals of all races and ethnicities, income, and education levels between the ages of 18 and 65 years in the United States. Participants must have regular home Wi-Fi connectivity.

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 via REDCap containing the initial screening questions. The survey will take 5 minutes. Participants will first be shown the information sheet and can elect to move on to the screening questions if they are interested. From there, they will then have the eligibility questions to complete. If they are eligible to proceed after completing the initial survey, they will be contacted by the study team to schedule a 15-minute telephone screening call to review the consent form, get screened for Binge Eating Disorder (BED), and provide contact information. We will not require PCP approval since we assess exclusionary medical conditions during the screening survey and again during the telephone screening. If conditions are reported, during either of these two assessments that might put the participant at risk during the intervention, they will be excluded. The next step in the screening process is to complete a set of online baseline surveys including demographics and depression severity lasting 20 minutes.

Before participants are enrolled, they must next complete a 60-minute orientation webinar. The purpose of the webinar is to educate participants about what research is, review study procedures, how the intervention is going to work, 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 eligibility is determined from the screening call and baseline survey, participants will receive a link to access the webinar. Once the participants are logged into the webinar, the research coordinator will proceed with the slides. Toward the end of the slides, participants will have the opportunity to use the chat function to ask questions and discuss any concerns related to the program. The webinar

moderator will record in REDCap tracking which participants completed the webinar. After completion of the webinar, participants will receive a final email asking if they are still willing to participate.

Participants will need to complete the initial screening survey, telephone screening, baseline REDCap survey, set-up the scale and log their first weight, and attend the orientation webinar before being enrolled into the 6-week usability testing intervention.

Ineligible participants will be notified by the research assistant or coordinator that they do not meet criteria for the study. This will be communicated via e-mail if the reason is not sensitive (i.e. taking exclusionary medication). If the reason is sensitive (i.e., high depression score, presence of BED) staff will call them to let them know. In the conversation, staff will use a generic response about how their pattern of responses is not a match to our eligibility criteria (the examples are provided in additional documentation). If they want to know specifics as to why they were ineligible, staff will refer the participant to email the PI so they can have a more detailed discussion about eligibility. This is being done to avoid upsetting participants and letting Dr. Pagoto, a clinical psychologist, handle communication of more sensitive information.

Once eligibility is determined after completing all screening procedures (initial screening survey, telephone screening call, baseline survey, and webinar), study staff will mail them a scale and then call to help them set up the scale and the apps, if they participant so wishes; they will also have the ability to set up the scale on their own.

Study staff will use Google Voice to communicate with the study participants (our lab is still working remotely so we do not have access to our lab phones). This is an app that gives our staff a different phone number to protect their personal information due to their inability to divert UConn phone lines to personal phones. We will not be recording any phone calls with Google Voice. Participants will be able to reach out to investigators as easily as they can using standard calling. Participants do not need the app in order to contact the lab. It is important to note that some information may be retained on Google's active servers temporarily for billing UConn staff or other business purposes, and residual copies may remain in Google's backup systems. Anonymized copies of call record information, with no personally identifiable information, will be retained on Google systems to meet reporting and auditing requirements. However, this is no different than any standard phone plan. All information in the app pertaining to each participant is deleted after the study is over (text messages or call history).

Anticipated Study Time Frame: [Describe the estimated time frame of the study from anticipated start to anticipated finish. If the study will occur in more than phase include these in the time frame. Use of a table is often helpful.]

Project Time Frame:
Aim 1 of this study, including recruitment, intervention, data cleaning and analysis will last for approximately 9 months.

Participant Time:
Participants will be in the study for approximately 8 weeks, which will include the screening phase, a 6-week intervention, and the follow-up survey, weigh-in, and focus group.

Study Phase	Approximate Time
Initial Screening Survey (5 min)	5

Telephone Screening (15 min)	15
Baseline (90 min total) Online survey (20 min) Orientation Webinar (60 min) Scale set-up (10 min)	90
Intervention Use of Facebook and diet entries (6 wks)/15 min/day (630) Optional weekly breakout sessions 45 min/week for 6 weeks (270) Weekly self-report app usage survey 5 min/week for 6 weeks (30)	930
Follow-up: Weigh-in (5 min) Online survey (30 min) Focus group (60 min)	95
Total	1,135 minutes (approx. 19 hrs)

Design, Procedures, Materials and Methods: [Describe the study design, including the sequence ll 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, where they will be conducted and how long they will take to complete. 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 this study offers treatment for the participants' condition, complete the Treatment Study Supplemental Form (IRB-1C) and attach it to this application for review. Use of a table is often helpful here.

Study design. Participation starts with an initial survey, telephone screening, and a baseline survey. Eligible participants will then complete an on-boarding process, which includes an orientation webinar and scale and app set-up. Participants will then complete the intervention for 6-weeks. Finally, there will be a follow-up period starting after the intervention ends which includes a final weigh-in, online survey, and a focus group call with the study staff.

Recruitment. As in our previous remote trials,[35] online recruitment will be used with ads posted in Facebook groups and Craigslist throughout the US and Research Match which connects volunteers to research studies.[36,37] To attract males we will also recruit on Reddit, where 74% of users are male.[38] Study staff will post recruitment messages in large, public Facebook groups in cities and towns around the country with even distribution in urban, suburban, and rural areas. To bolster male recruitment we will recruit more aggressively on Reddit via paid ads and via relevant subreddits.

A survey link will be included with our recruitment materials. Participants will be instructed to complete the survey to be considered for the study. Additional strategies that we may or may not use depending on recruitment flow include:

- Electronic recruitment: online, Twitter, Instagram, newsletters, intranet messages, daily digest, emails and other online sources as we come across them;
- Connecting with large businesses to get our ad and/or flyer e-mailed to their staff and students;
- Qualtrics recruitment panel: Participants on the Qualtrics panel meeting inclusion criteria will be recruited for this study.

- On the first page of the survey, they will read a brief introduction about this project and if they complete the survey, they will receive Qualtrics incentives regardless of participation in this trial.
- If they decide to hear more, they will click forward to the next page, which will be our information sheet.
- If they would like to participate in the trial after reading that sheet, they will click forward to the next page and start the survey.
- Participants who provide their email will be contacted by the study team for the telephone screening.

To get a representative sample for this study, it is possible we will have to cap certain groups in order to allow room for other groups (i.e., stop enrolling white women in order to allow enrolling more males or other people of various ethnic/racial backgrounds). In that event, we will send participants generic wording via email (included in accompanying documents) letting them know that we are looking for people with specific characteristics and can only take a certain number of people who have similar characteristics. If they want a further explanation, we will refer them to email Dr. Pagoto to have a more detailed conversation about this decision.

Screening. Please see the previous Screening Procedure section on page 5 and 6.

Intervention. This 6-week online weight loss intervention involves 5 major components: 1) peer mentoring, 2) counselor-led DPP lifestyle intervention delivered via private Facebook group, 3) commercial app supported diet self-monitoring (MyFitnessPal), and the Habit app which includes slip tracking and problem-solving features, 4) Habit app integration with the Facebook group to stimulate peer-to-peer engagement, and 5) weekly weigh-ins.

1. Peer Mentoring

During the 6-weeks of the intervention, the program will have weekly breakout sessions for participants to join within the Facebook group. Each week, the counselor and/or study staff will schedule a 45-minute event within the Facebook group that will allow participants to RSVP to, if they so wish. When they click on the event on the day/time it was scheduled for, they will be brought to a video chat room within Facebook where everyone who joined can video chat together. The counselor and/or staff member will be leading each group. Each week will be based on a topic around achieving a healthy lifestyle (or barriers to achieving a healthy lifestyle). The participants will pick the topic for each week. In the beginning of each breakout session, the participants will introduce themselves. Then, the counselor will pose discussion questions related to the topic of the week to facilitate a discussion. The participants will then respond to questions and can take notes. At the end, the counselor will review the top solutions/responses that came up. The meeting will be recorded and posted in the Facebook group for those who missed. Facebook requires all attendees in the event to confirm they are okay with the recording. If they do not wish to be recorded, they will be able to leave the meeting and watch the video after it is posted in the group. The breakout sessions are optional. The point of these breakout sessions is for group members to peer mentor each other, connect on a topic, do some brainstorming, and get to know each other better.

2. Facebook Group

Participants will be asked to join a private Facebook group where they will receive weight loss counseling based on the Diabetes Prevention Lifestyle Intervention (DPP). The group leader will counsel participants toward achieving and maintaining the exercise and diet goals to lose weight.

The participants will also be asked to participate in the Facebook group by reading and engaging with the posts from the counselors. Additionally, they will be asked to engage with their fellow participants through comments, reactions, and posts. By interacting with other participant's, they will be able to exercise the peer mentor training that they receive prior to the start of the intervention. The participants will be able to privately message their counselor if they do not want to share something with the group. A detailed description of the how the Facebook group will operate is below.

The counselor will post twice a day in the private Facebook group. Each week's content is based on the corresponding module of the traditional, in-person DPP (https://www.cdc.gov/diabetes/prevention/lifestyle-program/curriculum.html). The DPP assigns participants the goals of calorie tracking to achieve a calorie goal based on amount needed to lose 1-2 pounds per week, developing a healthy diet consistent with the American Heart Association guidelines, engaging in 150-300 minutes per week of moderate intensity exercise (i.e. brisk walk at 2.5-4 mph, bicycling, gardening, dancing, water aerobics, canoeing, playing doubles tennis. etc.), developing a strength training regimen consistent with the National Exercise Guidelines, and losing 1-2 pounds per week. Goal setting happens on Mondays when the counselor posts asking participants to share their diet and exercise goals with the group. The counselor will suggest 2-3 goals each week—a behavioral goal (e.g., self-monitoring, slip tracking, problem solving), a diet goal (e.g., reduce added sugar) and an exercise goal (e.g., add 15 minutes of moderate intensity exercise on 3 days) to help participants progress toward the overall program goals. Weigh-ins happen on Fridays when the counselor posts asking participants to reply with their weight change in pounds for the week. This ensures participants are weighing themselves weekly and allows an opportunity for problem solving for participants not losing weight. Goal accountability happens each Sunday when the counselor posts asking participants to report how they did on the weekly goals. In between these key posts are posts related to the topic of the week (e.g., nutrition, making time for exercise) and posts relevant to the behavioral strategy of the week (e.g., slip tracking). On the first day in the group the counselor will post a 5-minute problem solving video that teaches the process of problem solving, how the online weight loss program will help them implement this process, and their responsibility as a peer mentor. Additionally, the coach may post periodic videos of themselves or study-related content to facilitate with building a relationship with the participants and to assist with stimulating engagement.

3. Mobile Apps

Participants will be instructed to track their diet and exercise using MyFitnessPal for the first two weeks to achieve a negative energy balance at a level that produces 1-2 lbs of weight loss per week. They will then switch to the slip tracker within the Habit app for two weeks to gain an understanding of their diet and exercise slips and the contextual factors driving those slips. After that, they will then switch to the problem solver within the Habit app for the final two weeks to solve the problems they observed during slip tracking. This schedule was selected to avoid app fatigue and to give participants time to focus and practice each behavioral strategy without getting overwhelmed. However, if participants want to use the other features on unassigned weeks they may do so.

MyFitnessPal.
Participants will be given a calorie goal based on their BMI, gender, and activity level to produce a weight loss of 1-2 lbs per week. They will be asked to use MyFitnessPal to enter all of the food and beverages they consume and their exercise with the purpose of staying under the calorie goal.

Habit App.

Slip Tracking Feature. The slip tracker helps participants identify triggers of diet and exercise lapses that they can address with the problem solver. For diet slips, the user hits a button when they have a trigger and/or slip and then completes stress and hunger ratings and enters foods eaten and what they were doing at the time. At the end of the day, the user receives a notification asking if they missed recording any slips to ensure all slips were recorded. There will also be an exercise slip tracking feature. It will work such that at the beginning of the week, participants are asked to mark the days they plan to exercise on a calendar in the app. Then, the end of the day notification will ask the user if they exercised that day. If they did not exercise it counts as a slip and they will be asked to pick a day to reschedule. The user will also be asked the time they had planned to exercise and the activity that occurred instead (e.g., sleep, work, sedentary leisure activity). When participants browse their Exercise Slip History they can look for patterns in terms of when they are likely to skip exercise, the role of stress and poor sleep, and which activities they tend to do instead of exercise. This provides insights into what is obstructing their exercise intentions.

Problem Solving Feature. Participants will be asked to do problem solving on Mondays of the assigned weeks. Once the user selects diet or exercise on the home screen, the next screen will ask them to identify a problem and then they will answer 3-4 questions before receiving tailored solutions. Once a solution is selected, they will schedule days and times to try it.

Weekly Check-ins. The weekly check-in is part of the problem-solving feature. Participants report their weight and if they accomplished scheduled solutions. They can continue working on original solutions and/or to select new ones. Those wanting new solutions are brought to the list of solutions. Participants who lost no weight will be prompted to try a new solution. Participants who have lost no weight but have accomplished their solutions will be prompted to select a new problem to work through. This will prevent participants from putting more energy into solving problems that are not resulting in weight loss and to nudge them toward problems that are obstructing weight loss. If a participant hasn't lost weight and has not executed their chosen solutions, they will be prompted to change the scheduling of the solution or to change the solution. This will help dislodge participants who are stuck. It might also prevent them from abandoning the app when a plan isn't working by guiding them on what to do when stuck. The essence of problem solving is to keep iterating solutions until something works, so the app, like a therapist, keeps the participant moving through that process.

4. Mobile App Integration with the Facebook Group

Problem Sharing in the Group. When participants select a problem from the app but do not find a desirable solution, the app will provide an option for them to share the problem in the Facebook group. The prompt will provide language the user can edit as she/he sees fit: "*I am working on [night time snacking]! I welcome ideas! Thanks!"* If so much problem sharing occurs in the Facebook group that it overwhelms the feed in the pre-pilot, we will place a limit on how often the app allows the user to share a problem.

Sharing Plans to Implement Solutions in the Group. Participants can also share their chosen solution with the Facebook group by clicking a button that brings up a dialogue box to edit: "*I plan on [bringing my lunch to work] this week. My reminders are set for [7pm Sunday – Thursday]. Ask me how I'm doing this week!")*. Making a commitment in the group increases

accountability. To prevent the feed from getting flooded with such posts, the app will only allow the user to share one plan per week.

Sharing Successes in the Group. In the Habit app, when participants have successfully solved a problem and lost weight, they will have the opportunity to click a button to share to the Facebook group.

5. Weigh-ins.

Participants will receive a Fitbit Aria scale mailed to them by the study team. This will allow them to take their weight weekly and at assessments. Weight is logged directly from the scale to the Fitbit app. Using a Wi-Fi scale will allow for a standard weight measure for each participant with a higher level of accuracy than self-reported weight. 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. Study staff help the participants set-up their Fitbit scale if they need it and check their BMI once the scale is working. If a participant has a BMI under 25, we exclude them from the study, and allow them to keep their scale as compensation. 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. If they choose not to share their login for the duration of the study, they will be allowed to upload screenshots of their weight to a secure REDCap link. Study staff will delete the screenshot from REDCap once the weight has been logged into the record.

Follow-ups. Follow-ups are completed after the intervention ends. Participants will receive a link to an online REDCap follow-up survey during the 7th week after the start of the intervention. This survey will be a repeat of some of the measures assessed at baseline (indicated in the measures table below) and questions to solicit participants' feedback on the program and app. The participants will also weigh-in one final time during the 7th week. Finally, the participants will schedule and attend a focus group call lead by study staff to get their feedback on their experience in the intervention.

Adverse Events. Adverse events will be documented during the intervention and follow-up phases. AE's will be formally assessed at follow-ups by asking a question in the REDCap survey. During the intervention AE's will be documented when a participant reports it to the weight loss counselor or posts in the Facebook group. If it is reported during the intervention, the counselor will notify Kaylei Arcangel at UConn within 24 hours of learning of the event. UConn will then report it to the IRB (immediately if it's serious, or at the time of annual renewal). If participants gain 5% or more weight during the intervention, this will be treated as an adverse event. The participant will receive a phone call from a UConn RC and they will be asked questions about what might be going on with their weight gain. We will also re-assess Binge Eating Disorder (BED) at this time. If BED is present, we will treat it as a study-related AE. We will only re-assess BED once after the telephone screening, even if there are multiple AE's for weight gain. Participants will not be removed from the intervention if they have 5% or more weight gain.

[Describe study procedures for use of interviews or focus groups if applicable. Include details such as how long each procedure will take to complete, who will be asked to participate in these procedures and where these procedures will be conducted. Provide copies of interview and focus group questions/topic areas.]

Focus groups. A focus group will occur in a WebEx setting starting in the 7th week after the start of the intervention. The focus group will last for approximately 60 minutes and will include a discussion about likes and dislikes of the intervention. All focus groups will be conducted via WebEx including 1-4 participants on each call. Any participants who are unable to attend the

focus group will receive the focus group questions through an e-mailed survey. We will e-mail the survey 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. The focus groups will be recorded on WebEx and then will be transcribed using Otter.ai, a web-based transcription software.

After the study is over, we will be removing all members and all content from the Facebook group.

[If the study includes *measures, survey instruments and questionnaires (including the collection of demographic data)*, 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 and attach a copy for IRB review.]

See below.

Data Collected	List of Measures	Baseline	6-week usability	F/up	Method
Inclusion/Exclusion criteria	Initial screening survey*	X			REDCap or Qualtrics
BMI	Height	X			REDCap
	Weight	X		X	REDCap
Demographics	Income, employment, marital status, race/ethnicity, household composition*	X			REDCap
Binge Eating Disorder	SCID Eating Disorder Examination Questionnaire[39]	X			REDCap
Depression	Patient Health Questionnaire (PHQ-8[40]	X			REDCap
Weight Loss Problem Solving Skills	Social Problem Solving Inventory-Revised (Modified for weight loss)	X		X	REDCap
Problem Sharing and Peer Mentoring	Facebook Engagement		X		Grytics into REDCap
App use	App use data*		X		WPI server and REDCap
Diet tracking	Data extraction*		X		MFP records
Usability Feedback	Acceptability, satisfaction, burden*, and user engagement			X	REDCap and interview

***investigator derived**

Psychometric properties for non-investigator derived measures:

SCID Interview for BED: The SCID's severity scales demonstrated substantial internal consistency (all Cronbach's alphas >.80), test-retest reliability, concurrent, and predictive validity.[39]

PHQ-9: The internal consistency reliability (Cronbach's alpha 0.89) and inter-rater reliability (intra class correlation coefficient, 0.94; 95% CI, 0.86-0.95) were high. PHQ-9 has good reliability and at cut off score ≥9, it has good validity to identify depression in primary care. Similarly, the PHQ-8, similar to PHQ-9 (with the omission of one question) is as useful as the PHQ-9 with strong validity and reliability [44, 45]

Social Problem-Solving Inventory-Revised: The internal consistency reliability (Cronbach's α 0.95) was high. The SPSI-R score was significantly associated ($p < .05$) with various subscales from calories, exercise, distress, and quality of life suggesting concurrent validity.[43]

The User Engagement Scale Short Form (UES-SF): The UES-SF has shown to be statistically reliable ($\omega = 0.88$). Furthermore, each subscale highly correlates with the remaining items in the scale. This suggested that each subscale was suitable to accurately represent the value of the overall components from which the subscales were derived. Accordingly, these items were defined to be the UES-SF and were taken forward for evaluation.[46]

[If applicable, describe the use of audiotape and/or videotape, provide justification for use and indicate if this is a requirement of participation.]

The recording feature on WebEx webinars will be used for recording audio for the end-of-study focus groups. The recorded audio is necessary in order to turn the information said by participants into a transcript for analysis. This grant has an iterative process. The information we receive from participant's feedback through the focus group help to inform the future phases of this study. The recordings are deleted once the transcription is finished. The transcription is anonymous and their names, if spoken during the call, are replaced with their REDCap ID number. We ask them to only say their first name if there are multiple people on the call in order to decipher who is saying what. If they are uncomfortable with using their name, we will provide an alias. During the initial screening, we will ask if they are comfortable being audio-recorded during a focus group call. If they select no, they will be excluded from the study. More information about the privacy/confidentiality of the recordings will be provided in the applicable section.

[If the study involves use of *deception* or *incomplete disclosure*, explain the reason why this is necessary to answer the research question(s). Complete the alteration of consent section below]

N/A

[Describe opportunities provided to participants to ask questions in order for them to make an informed decision regarding participation.]

Participants are able to ask questions during the telephone screening and the webinar. They may also email the study team at any time.

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.]

Proportion of participants meeting app use, engagement, acceptability, and burden targets will be calculated. We will summarize burden ratings as mean (SD). We will conduct thematic analyses[42] of interview data regarding likes/dislikes for each feature and the overall program. Drs Sherry Pagoto and Ran Xu will develop a codebook based on themes emerging during an initial review. The team will finalize themes before final independent coding and consensus. We will calculate inter-rater reliability and will reach consensus via discussion. We will summarize frequency of themes. We will use NVivo 12 (QSR International, Melbourne, Australia) to manage and analyze qualitative data and SAS 9.4 (SAS Institute Inc., Cary, NC) to analyze quantitative data.

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.]

Inclusion Criteria

- 18-65 years old;
- BMI 27-45 kg/m^2;
- Wi-Fi connectivity at home (for Wi-Fi scale);
- Logs into Facebook at least 5 days per week over the past 2 weeks;
- Has posted/replied on Facebook at least twice a week in the past 2 weeks;
- Able to participate in the study in English; and
- Interested in losing weight

Age justification: Children under 18 require different programming for weight loss and maintenance given their developmental needs. Weight loss is often not indicated for elderly adults and should be medically supervised.

Exclusion Criteria

- Under the age of 18 and over the age of 65;
- BMI under 27 or over 45 at screening; then under 25 at the point of the first Fitbit Aria weight;
- Does not have Wi-Fi connectivity at home;
- Does not have a Facebook account;
- Does not log into Facebook at least 5 days per week over the past 2 weeks;
- Did not post/reply on Facebook twice a week over the past 2 weeks;
- Not able to participate in the study in English;
- Does not live in the United States;
- Pregnant/lactating or plans to become pregnant during study period;
- Bipolar disorder, substance abuse, psychosis, bulimia, binge eating disorder, or severe depression;
- Had bariatric surgery or plans to have surgery during the study;
- Currently taking medication affecting weight;
- Chronic pain that interferes with the ability to exercise;
- Type 1 Diabetes;
- Type 2 Diabetes;
- Unable to make dietary changes or increase physical activity;
- Unable to walk ¼ mile unaided without stopping;
- Currently smokes or vapes nicotine;

- No phone connectivity at home and work;
- Has a condition that precludes dietary changes (i.e. ulcerative colitis, Crohn's disease, active diverticulitis, renal disease);
- Meets criteria for severe depression on the PHQ-8 (score of >19) ;
- Not interested in losing weight;
- Does not currently own a smartphone;
- Smartphone type and/or version not meeting app requirements;
- Participated in previous weight loss studies under the PI;
- Unable to attend the orientation webinar;
- Did not complete baseline survey;
- Has concerns about being in a Facebook group with other UConn faculty, staff, and students;
- Had major surgery in past 6 months;
- Has an implanted cardiac defibrillator or pacemaker
- Did not complete screening and on-board processes of study;
- Not willing to be audiotaped for focus groups;
- Prisoner; or
- Unable to provide consent

[Describe the conditions under which participants may be removed from the study, i.e., noncompliance with study rules, study termination, etc.]

Participants will be withdrawn from the study if: they choose to drop from participation, do not complete all screening/on-boarding procedures, post inappropriate content on the social network, or post inappropriate content during peer mentoring. 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.

Possible risks for being in this study includes: Injury while exercising during the intervention, breach of confidential information during the intervention or focus group, and discomfort completing measures during the intervention or assessments, or using the app during the intervention. 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. Moderate-level physical activity is 3.0 - <6.0 METs, which includes activities such as brisk walk at 2.5-4 mph, bicycling, gardening, dancing, water aerobics, canoeing, playing doubles tennis. etc.). If participants were to be injured, the likelihood that the injury would be serious is also rare and unlikely. We also provide participants with information on exertion level and remind them to see medical attention if there is pain. Tracking data for the screening, intervention, follow-ups, and focus groups will be stored electronically in REDCap, a network secure data entry program;

electronic data being collected from the app will be transmitted to WPI will be encrypted. During the focus groups participant may not keep what others say confidential. At the start of the group, we will remind participants that they may skip anything that they do not want to answer. Additionally, participants will be given the option to complete an individual interview in place of a focus group if they prefer more privacy. Participants will be informed that they may withdraw from the study at any time if they feel discomfort with any of the study procedures. We will use Otter.ai transcription software to produce transcripts. Otter.ai will not have access to identified data and will retain no ownership rights to the recordings or transcripts**.** Any privacy-related problems will be brought to the attention of the PI immediately.

[Describe any anticipated inconveniences the participants may experience (such as: their time, abstention from food, etc.).]

Participants will be asked to dedicate about 14 hours of their time over the course of 8 weeks to participate in this study.

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. 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 changes as well as learning about peer mentoring. Through interacting with other participants and the coach, participants may also feel supported in their behavioral change efforts.

[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).]

Societal benefits include providing evidence to support an intervention delivery modalities that are 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 completing measures and using the app, 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 provided. 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, study participation, and follow-up procedures. 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.

Participants will be paid in the form of online Amazon gift cards. Participants will receive $75 for completing the study. Payment will be in the form of an online gift card paid after the follow-up procedures are completed (weigh-in, survey, focus group). The procedures for each assessment will need to be completed before providing compensation. Additionally, participants may keep the study scale provided to them

Participants who complete the Qualtrics initial screening survey, whether or not they participate in this study, will receive Qualtrics incentives. Their incentives are based on a points system. Respondents accumulate points as they take surveys and then trade in points for E-gift cards to anywhere of their choice (amazon, walmart, target, etc.). The compensation Qualtrics provides is separate from the compensation for participating in the baseline and follow-ups of this trial.

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 reviewed under the Exempt Criteria. 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 will 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)."

The Data and Safety Monitoring Plan will include monitoring the study for the progress of recruitment and retention, and the occurrence of adverse events (both serious and otherwise), inclusion/exclusion criteria, adherence to study protocols, and data review (completeness/outliers).

1. Frequency of monitoring

The data report for the 6-week pilot intervention phase will be sent to the two safety officers once follow-ups have been completed. Recruitment is monitored daily during the recruitment phase. All

surveys are monitored once submitted to REDCap within 48 hours. The Facebook group is monitored daily. Weigh-in submissions are monitored weekly. App usage is monitored weekly.

2. Safety Monitoring Committee

The two safety officers for this project will include faculty independent from the research team with expertise in clinical psychology, exercise and weight loss interventions, and an understanding of the types and severity of injuries commonly experienced during weight loss trials. The two safety officers will review the reports sent by the project director will use a checklist to document any corrective actions that should be communicated to the principal investigators, the University of Connecticut IRB, and the NIH. In addition, the safety officers may include documentation on whether the principal investigators should provide follow-up to a participant.

3. What data will be monitored:

Recruitment rates and adherence to inclusion/exclusion criteria, and ethnic diversity goals:
Recruitment progress, including baseline characteristics, will be reviewed. 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. Recruitment progress is monitored weekly and a final report will be provided in the DSMB report.

Adherence to study protocols:
Quality control will be conducted in all phases of the project. The Facebook group will be monitored daily for intervention protocol adherence. A final report will be provided in the DSMB report.

Adverse events:
The adverse event report will include a listing of all adverse events including duration, severity, seriousness, relatedness, action taken, and resolution. Adverse events are documented throughout the intervention and at follow-up. A final AE report will be provided in the DSMB report. In the event of a serious adverse event, the safety officers will be notified immediately.

Participant retention
Engagement will be tracked during the intervention, and completion of follow-ups will be documented. Participants will be reminded of upcoming study assessments. If a participant chooses to drop from the intervention, they will be given the option to skip the rest of the intervention, but still complete the follow-up. Retention is reviewed and discussed weekly throughout the study and at follow-up. A final retention and engagement report will be provided in the DSMB report.

Data review (completeness/outliers):
Reports will include completeness of data (visits completed, % 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). Data will be cleaned at the end of each phase (screening, intervention, and follow-up). A final data review reports will be provided in the DSMB report.

4. Data evaluated for problems
   Data reports will be reviewed by the data manager, program director, statistician, and PI.

5. Actions taken during certain occurrences

Baseline participants who report conditions 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 of all adverse events during data review. Serious adverse events will be communicated immediately to the PI and safety officers. The NIH and UConn IRB will 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.

6. IRB Communications
   The program director and research coordinator will communicate with the IRB. Communication will occur through emails, phone calls, and/or InfoEd as necessary.

7. Informing sponsor procedures
   The sponsor will be notified within 48 hours for serious events that the IRB recommends we report.

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. Explain how long data will be kept in an identifiable format and how long de-identified data will be retained. Explain how long the master key or audio or video recordings obtained, will be kept. Consider whether keeping de-identified data will be retained indefinitely and whether participants may be contacted for a follow-up study (explain procedures to retain identifiable contact data is kept.]

REDCap will be used for data entry and management. The database will be maintained on UConn servers where security will be maintained through access controls. Files will be managed by the data manager and research coordinators, 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 2-3 numerical characters representing the number of participants in the study. PHI fields will be stored in a separate REDCap form from other data collection forms. We will provide participant emails to our co-investigator at WPI. We will email the co-investigator a list of participant email addresses. Emails are needed to allow participants access to download the study app onto their phones. Emails will not be attached to the data that participants enter into the app. The participant accounts in the app will be attached to a unique app ID that the UConn staff can link to the REDCap study ID. WPI will not have access to the REDCap study ID, therefore app data will remain unlinked for WPI. Once participants download the app and confirm to the staff that it is downloaded and they can access the app, we will inform WPI to delete the list of email addresses from their records. WebEx recordings will be used to record the audio from the focus groups at the end of the study. The recordings will be maintained on UConn servers where security will be maintained through access controls. We will use Otter.ai transcription software to produce transcripts. Otter.ai retains no ownership rights to the recordings or transcripts. Staff will verify and edit the transcripts and then save the de-identified transcripts to the research drive on the UConn servers and delete the recordings from the drive and the

Otter.ai platform. Please refer to these two sections of the terms of service and privacy policy: Terms of Service; Section 9 and specifically Section 9.3: https://otter.ai/terms: In summary, research team retains right to audio recordings and controls how the content is processed, transported, and distributed on the otter.ai platform. Once we delete the recordings from our trash, they are permanently deleted from platform. And from Section 2 of Privacy Policy: https://blog.otter.ai/privacy-policy/ "We train our proprietary artificial intelligence technology on aggregated, de-identified audio recordings. Only with your explicit permission will we manually review certain audio recordings to further refine our model training data.". When the recordings are transcribed by study staff (RA's), the names of the participants are replaced with ID numbers to anonymize the transcript. 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 5 years after completion of the study.

Data from ineligible participants, including those excluded for having an exclusionary BMI from the Fitbit scale:
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 form and will be de-identified at the end of the study.

If identifiable, sensitive information (illegal drug use, criminal activity, etc.) will be collected, state whether a Certificate of Confidentiality will be obtained.

N/A

Be sure to state whether any limits to confidentiality exist (e.g. mandated reporting) and identify any external agencies (study sponsor, FDA, etc.) that will have access to the data.

Worcester Polytechnic Institute (WPI) will see participant emails and the app use data that is entered into the Habit app. Additionally, study staff from WPI will join the Facebook group to assist participants with any Habit app issues. They all have had CITI training at WPI, will be approved personnel, will not have access to study tracking/survey data, and will not have a link to study ID. Also, it is possible that participants in this study know each other.

If participants will be screened, describe the plans for storage or destruction of identifiable data for those that failed the screening.]

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 form and will be de-identified at the end of the study

Privacy/Confidentiality Part 2: Complete the Data Security Assessment Form

: [**This form IS REQUIRED for ALL studies**. The form is available here - https://ovpr.uconn.edu/services/rics/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.

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/permission Setting: [Describe the consent/permission process including *who* will obtain it, *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.

A signed consent waiver is being requested for this study. Participants will review an informational page before completing the initial survey screener. At this point, they are able to contact the study staff with any questions they may have before continuing. Also, during the telephone screening, staff will review the informational page and 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.

State whether an assessment of consent/permission 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).]

We will not perform an assessment to ensure participants understand the information, however we will conduct an interactive webinar to discuss any concerns or questions.

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, when 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. For longitudinal studies, assent may happen at several points during the study.]

N/A

Documentation of Consent: [Specify the forms that will be used for each participant population, i.e., adult consent form, surrogate consent form, parental permission sheet. 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/incomplete disclosure 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.
- Explain why the research could not be practicably carried out 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.
- Explain why the research could not be practicably carried out without using identifiable private information and/or identifiable biospecimens.
- 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.
- Indicate if the waiver/alteration as noted above is applicable to the entire study or to a portion of the study.

Waiver of ***signed*** consent (i.e. , no signature, participants give consent only after reading an information sheet). Tip: if the investigator will obtain information through oral or written communication with the prospective participant or if the investigator will obtain private identifiable information or identifiable biospecimens by accessing records, then a waiver of signed consent is NOT required.,:

This is being asked to conduct the initial survey online.

- Why is the study considered to be minimal risk?

  The study is minimal risk because it includes surveys and a weight loss intervention. The weight loss intervention is commercially available.

- 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 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.

- Describe if the participants or their legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to subjects and there is an appropriate alternative mechanism for documenting that informed consent was obtained. Not applicable to FDA Regulated Studies.

  N/A.

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