2/3/2021

IRB Protocol

Study Title: “Facebook and Friends” Developing an Effective Online Social Network for Weight Loss

NCT02656680

IRB-1 Study Protocol

Protocol Version # and/or Date: 12/28/2020

Study Protocol Title: Developing an Effective Online Social Network for Weight Loss

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 the aim for this protocol falls under aim 3 in the grant application. Furthermore, this aim has had an NIH-approved revision since the original application. Dr. Pagoto is a paid consultant for Fitbit, Inc.
In addition, this protocol aligns with all 160 randomized participants in aim 3.

Evidence-based lifestyle interventions are intensive, requiring multiple face-to-face visits over the course of 6-months up to 2 years.[1,2] Unfortunately, such interventions have not been widely implemented due to intensity and expense. Research shows that reducing intervention intensity (i.e., the number of visits/contact time) inevitably reduces weight loss outcomes.[3] Inexpensive means of reducing intensity while *preserving efficacy* are needed to make a brief counseling model work.

[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.

Technology-Based Solutions: Promising But More Data Needed In recent years, technology has been leveraged in various ways to change health behavior.[4] Mobile technology is being applied to weight loss, although commercialization is far ahead of the science. In a systematic review of mobile phone-based weight loss interventions, only 4 randomized trials were found.[5] Three utilized text-messaging as an adjunct to other features including websites, counseling, and print materials. The two trials that integrated text-messaging with counseling had larger weight losses (4-4.5 kg) than the one that did not (1.5 kg), suggesting that technology may not entirely take the place of personal contact. The fourth trial tested a mobile phone-based dietary game designed to teach people about nutrition and weight loss. Findings revealed very modest weight loss (1.9 kg). Surprisingly few NIH-funded studies of mobile-based weight loss interventions are underway. More research is clearly needed to determine how to utilize mobile technology (beyond text messaging) to reduce the intensity of effective lifestyle interventions.

Commercial Mobile Applications are Plentiful But Reflect A Narrow Range of Behavioral Strategies. According to our recently published systematic review,[6] commercial mobile apps for weight loss primarily include self-monitoring and goal-setting (see Preliminary Studies section), but lack other key strategies frequently employed in behavioral weight loss interventions, such as stimulus control, nutrition education, problem solving, reducing negative thinking, stress management, social support, and relapse prevention.[7] The focus of commercial weight loss apps on self-monitoring might limit their ability to improve upon traditional methods given a recent study showing that using mobile phones for dietary self-monitoring is no more effective at reducing caloric intake than paper-and-pencil methods.[8] Without more interactive and "intelligent" capabilities that help patients overcome weight loss challenges, commercial apps are likely only going to benefit highly motivated individuals. Additional features may be needed for individuals who do not respond to self-monitoring and goal setting alone.

Why Self-Monitoring Is Not Enough In a Mobile Application. We tested a mobile application that includes self-monitoring of diet/weight/physical activity, goal-setting, and social support. We found that such a mobile application when combined with a brief behavioral weight loss intervention did not improve upon the efficacy of a weight loss intervention that used traditional approaches to these strategies (e.g., paper and pencil diet records) (See Preliminary Studies section). We found that groups were alike in terms of the quantity and quality of problems they encountered as they tried to lose weight and the mobile application did not offer anything unique in terms of addressing the problems that arose. We then surveyed 11 professionals with experience delivering weight loss interventions, asking them to name the top weight loss challenges their patients report. The 3 most highly cited challenges were: finding time to exercise, resisting temptations, and stress. Of 77 responses, only 1 pertained to self-monitoring difficulties, which suggests that a mobile application that addresses a broad range of challenges could be useful.

Which Behavioral Strategies Are Conducive to Technology Delivery? Stimulus control, problem solving, and social support are three behavioral strategies that have high potential for technology delivery. **Stimulus control** involves awareness and control of cues that trigger problematic behavior. Mobile technology can assist in this process by helping to identify cues and delivering intervention when cues are present. **Problem solving** is a systematic, iterative process by which 1) the patient is asked to identify problems that arise in relation to a particular goal, 2) solutions are brainstormed, 3) a solution is selected by the patient, 4) a plan is made to attempt the solution, and 5) the outcome is evaluated and other solutions are tried if necessary until the problem is solved. Mobile technology may be programmed to facilitate this process. Social networks may also assist problem solving by giving participants a venue in which to voice problems and share solutions at any time of the day or week. Finally, **social support** can be facilitated via social networks to the extent that users are connected to others who share common goals and experience.

This study has several innovations that have the potential to shift current research and clinical paradigms forward. Online social networking in general is a novel, understudied weight loss tool. The 3 aims of the grant explore 3 approaches to delivering these traditional behavioral strategies via technology. This current protocol represents aim 3: We will conduct two pilot randomized trials of 80 overweight and obese participants each to test the feasibility of a behavioral weight loss program delivered entirely via Facebook. The trials will be iterative, with findings from the first informing the intervention for the second. In the first, participants will be randomized to a condition which allows them to invite their Facebook friends who want to lose weight to the group if they so

choose, or a condition that only includes the original study participants. Feasibility outcomes include engagement (frequency of likes/posts/comments, number of completed days of tracking), retention, acceptability, number of friends invited and weight loss. Post-intervention focus groups will gather feedback on the program. Baseline measures of gender, age, social media/technology experience, depression, and social anxiety will be used to predict social network acceptability, usage rates, and weight loss in the social networking condition.

The PI has extensive experience with behavioral weight loss interventions. In addition to 3 large RCTs she successfully adapted the DPP into a clinical program at UMass. She also implemented a behavioral weight loss program in a community mental health setting.

Lifestyle Intervention in Co-Morbid Obesity and Depression. (R01 MH078012-02; PI: Pagoto). This randomized trial compared the effect of behavioral activation for depression plus behavioral weight loss intervention (BA) to behavioral weight loss intervention alone (BWL) on weight loss in 161 women with co-morbid depression and obesity. Analyses revealed no differences between conditions in weight change at 6-months (BA= -3.0%, SE= 0.66%; BWL= -3.6%, SE =0.62%; p =0.51) or 12-months (BA= -2.6%, SE=0.78%; BWL= -3.0%, SE=0.74%; p=0.71). However, the BA condition evidenced greater improvement in Beck Depression Inventory-II scores at 6-months (BA mean change= -12.5, sd= .8; BWL mean change= -9.2, sd= .8; p=0.004) and 12-months (BA mean change= -12.6, sd= 1.0; BWL mean change= 9.6, sd= .9; p =0.045). Retention rates at 6-months and 12-months were 90% and 85%, respectively.

Translating the DPP Lifestyle Intervention into a Hospital-Based Weight Loss Program. Dr. Pagoto helped launch a group-based clinical weight loss program based on the DPP that has now been running for 7 years. The first 118 consecutive patients enrolled in the 16-week Core phase of the program lost an average of 4.5% (sd = 3.5). Mean attendance rate was 82%.

We plan to conduct a pilot randomized trial of a behavioral weight loss intervention with and without the social network to evaluate feasibility. Social network interactions will be content analyzed to identify the types that predict adherence and weight loss. We will also determine which individual difference factors predict who is most/least likely to benefit from online social networks. Finally, we will build a theoretical model of social support by evaluating to what extent 4 different social processes are associated with weight loss. We are comparing 2 conditions per wave in this study (there are 2 waves). Wave 1 includes randomization to: Facebook plus Friends (FB+friends) and Facebook without Friends (FB w/o friends). Wave 2 includes randomization to Facebook plus (FB+) and Facebook without (FB w/o).

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 intervention will be 160. If each of the 40 participants randomized to FB+Friends condition invite 10 friends each that will increase the enrollment number to 560, however it is impossible to predict how many invites will come from each person since it is unlimited. It is estimated that we will screen 2000 participants to achieve the initial enrollment goal. Since the initial contact is via an online link, there will be many incomplete responses driving up the number of screened-out participants. The number of friends that these participants invite to the group is unknown since some may not invite any at all while others may invite as many as they wish. The FB+ condition will have a subset of approximately 70 participant allowed into the group post-randomization. Given the 2000 participants needed to screen in order to achieve 160 randomized, the approximation of 400 invited friends and up to 70 post-randomized participants the total enrolled could be 2,470.

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 sample size was determined based on a balance between having a sufficient number of individuals to assess the feasibility of the intervention and resources allotted for the grant mechanism.

***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 men and women overweight or obese of all ethnicities, income and education levels between the ages of 18 and 65 in the United States.

***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, as well as any other volunteer databases that are discovered during recruitment.

The friends that are invited to join the FB+friends Facebook group by their friends will be invited via a Facebook invite button.

***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. The next step in the screening process is to complete a set of online screening surveys including weight, height, physical activity, and social networking use. We will not require PCP approval since we assess

exclusionary medical conditions in the initial 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 randomized, they must complete an orientation webinar. The purpose of the webinar is to educate participants about what research is, review study procedures, 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. For the post-randomized participants in the FB+ condition, they will listen to the webinar during the screening call to expedite the process of getting them into the Facebook group. They will then receive the final email after they have completed their baseline survey. This will be mandatory in order to enter the group. The webinar moderator will record in REDCap tracking which participants completed the webinar.

Participants will need to complete the initial screening survey, telephone screening, a baseline survey, and 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 screening surveys. Eligible participants will then complete a webinar, 16-week intervention, and an end-of-study focus group and follow/up survey.

Randomization: Upon completion of all screening measures and webinar, participants in wave 1 will be randomized either: 1) a Facebook group allowing the invite of their friends (FB+friends); or 2) a Facebook group including only study participants (FB w/o friends). Participants in wave 2 will be randomized to either: 1) a Facebook group allowing additional participants between the weeks of 1-8 (FB+); or 2) a Facebook group including only the original group of 40 participants (FB w/o). The participants added during the weeks of 1-8 will not be randomized. They will follow the same screening process, but will be automatically assigned to FB+. Participants in wave 1 will be randomized 1:1 to the two study conditions in randomly permuted blocks of size 4 and 6 using the ralloc program in Stata Randomization and will be stratified by gender (male vs. female) and baseline BMI (27.0-34.9 vs. 35.0-45.0). The randomization list was generated at the start of the study before randomization. The list is managed by the program director. Wave 2 will be randomized using the same stratification, using REDCap. Once a participant has been determined to be eligible, the program director will assign each participant to the next open assignment on the list. The program director will then tell the research assistant who will reach out to participants to inform them via e-mail of the condition assignment.

FB+friends invite details: If they are assigned to the group including their friends, they have the opportunity to invite their friends to participate in the weight loss group if they are interested in losing weight as well. They will not have a limit as to how many friends they can invite. Facebook has a feature which will allow anyone to invite friends into a group. The private group for this condition is set to only let the admin (study staff) approve the friend-invite request. The friends that are invited will not undergo the same procedures as the FB+friends study participants, but we will provide them with an informational sheet and collect minimal data from them.

First, the participant will invite their friend into the group using the Facebook invite feature. Next, approval will remain pending until the admin e-mails the friend a survey that includes: an informational sheet, demographics, interest in losing weight, and a self-reported weight. Email is obtained by messaging the invited friend for their email. If that doesn't work we will ask the friend who invited the participant. Once the survey is received, the admin will approve the invite. The admin will only e-mail the friend once to limit intrusion if they are not interested in joining the group.

The data that we'll collect from friends includes: demographics, interest in losing weight, self-reported weight when they join and at the end of the study, and their engagement data in the group. They will not complete the same measures as the other conditions, or report weekly weight, or attend a focus group.

Intervention (16 weeks):

Participants will receive a Fitbit scale to take their weight weekly and at follow-up. 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 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.

All participants will receive weight loss counseling based on the Diabetes Prevention Program (https://www.cdc.gov/diabetes/prevention/lifestyle-program/curriculum.html) lasting 16 weeks and delivered online in a private Facebook group. The DPP content has been adapted to be delivered in an online setting. Participants will receive tips and guidance related to the intervention through Facebook posts in the private group. The goals for the intervention are a 7% weight loss and 175 minutes of moderate physical activity per week. Each participant will get an individualized calorie goal that would facilitate a 1-2 lb weight loss weekly. The Facebook group privacy settings will be set to the "secret" setting. The group leader/coach will also counsel participants toward achieving and maintaining the exercise goal.

We will also offer some optional fun activity-related activities such as: notifying participants of virtual walks, races, and health fairs; or staff sending out "challenges" for participants to try such as running a 5K race. Staff will post a "featured participant" each week if participants volunteer to be a featured participant. We would have a post with the participant's picture and their story about why they want to lose weight, what they like, and anything else they would like to share.

Participants will also be encouraged complete diet and activity tracking using a tracker of their choice, such as MyFitnessPal. They may also share their diary with the interventionist to receive individualized feedback.

Focus Group Follow-up:

A focus group will occur in a conference call setting in the 17th 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 conference call including 1-5 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.

Participants will also receive an online follow-up survey in the 17th week, 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.

Measures

Data Collected	List of Measures	Screening Call	Baseline	During Intervention	F/up	Method
BMI	Height		X			REDCap
	Weight		X	X (weekly via Fitbit)	X	REDCap
Demographics	Employment, marital status, race/ethnicity, household composition*		X			REDCap
	International Physical Activity Questionnaire[9]		X		X	REDCap
Depression	PHQ-9		X			REDCap
Binge Eating Disorder	SCID Interview[11] for BED	X				Interview
Social support for weight management	WMSI[13]		X		X	REDCap
Social media use	Social Media Use*		X		X	REDCap
Group engagement	Facebook data extraction			X		Facebook
Invited friends questions	Survey questions*			X		
Intervention Feedback	Survey questions*				X	REDCap

* Investigator-derived items

Time Commitment:

Visit	Study Participants	Invited Friends
Initial Screening Survey (10 min)	10	5
Telephone Screening (20 min)	20	n/a
Baseline (35 min total) Scale set-up (10 min) Online survey (25 min)	35	n/a
Webinar (60 min)	60	n/a
Intervention Approx. 35 min/week for 16 weeks (approx. 10 hrs)	600	0-600*
Follow-up (85 min total) Focus group (60 min) Online survey (25 min)	85	5
Total	810 minutes (approx. 14 hrs)	10-610 minutes

*The length of intervention participation depends on when the friend got invited to the group.

***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.]*

Social network participation analyses include frequency of tweets/per day. Repeated measures ANOVA will be conducted (baseline to 4-months) to determine if participant's mean engagement per month changed over time. Descriptive analyses will assess acceptability at 4-months. Conditions will be compared on social support for weight loss at baseline and 4-months using mixed models (SAS PROC mixed). Sensitivity analyses will be performed for missing data. Participants' comments will be content analyzed to identify the types of interactions that occurred, which will then be used to predict weight loss. All comments made by participants will be exported from Facebook for qualitative analysis. Separate mixed models will be used to examine whether the identified themes predict group adherence or weight loss.[25, 26] Separate mixed models will be conducted to examine whether demographic factors, social media/technology experience, depression, and social anxiety predict: 1) acceptability, 2) participation, and 3) weight loss. Potential covariates include: age and gender. We will not be testing whether social constructs mediate differences in weight loss between conditions in this feasibility study. ***Exploratory Aim*.** We will explore trends and condition differences at 4-months. Linear mixed models will be used to test the condition x time (baseline vs. 4-month) effect on weight, social support constructs and Facebook participation.

***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.]*

Smartphone users ages 18-65 with a BMI 27-45 will be recruited for this study. Participants must log into a social media platform on a daily basis and engage (like, reply, post) at least 4 days per week.

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.

Inclusion Criteria: Participants must: be 18-65 years of age; have a BMI 27-45; and have daily internet access.

Exclusion Criteria:

1) Not posting on Facebook at least once per week;
2) Comments on someone else's on post on Facebook less than once per week;
3) Does not currently use a smartphone;
4) Is not familiar with using phone apps;
5) Pregnant/lactating;
6) Meets criteria for severe depression on the PHQ-9 (score of ≥20)
7) Had bariatric surgery or plans to during the study;
8) Condition that precludes lifestyle changes (i.e. a condition that prevents physical activity increase or dietary changes);
9) Medications affecting weight;
10) Incapable of walking ¼ mile without stopping;
11) Type 1 or 2 diabetes;
12) Participated in previous weight loss studies under the PI
13) Unable to attend the orientation webinar;
14) Has concerns about being audiotaped
15) Inability to provide consent;
16) Prisoners;
17) Non-English speaking
18) Has concerns about being in a Facebook group with other UConn faculty, staff, and students
19) Meets the criteria for Binge Eating Disorder

20) Has had a weight loss of 5% or greater within the last 3 months
21) If they do not have Wi-Fi and cannot send us a picture of their weight from the scale

Invited Friends of the subjects participating in the FB+friends condition: Must be: at least 18 years old, BMI of 25 or over, and have an interest in losing weight.

Participants will be withdrawn from the study if: they drop from participation, do not complete all screening procedures or post inappropriate content on Facebook. 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. If a participant is withdrawn, their invited friends will not be withdrawn unless they post inappropriate content on Facebook.

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; 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. 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.

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.

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.

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). 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.

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 and My Fitness Pal.

Participants will be paid in the form of online Amazon gift cards. Participants will receive $40 for completing the study. Payment will be in the form of an online gift card paid after the follow-up survey. The procedures for each assessment will need to be completed before providing compensation. Additionally, participants may keep the study scale provided to them (value of $120).

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 will be set up for this study and will convene before and after each recruitment wave. DSMP 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. Dr. Stanek has expertise in inference, mixed models, sampling, longitudinal data analysis, and cluster randomized 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 an 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. p to the safety officer.

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.

Data review (completeness/outliers):
Data reports will be reviewed by the data manager, project 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.

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. At the beginning of the telephone screening, staff will review the informational page and ample time will be allowed for discussion 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, 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 and an information sheet will be used for the invited friends.

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. We will use approved institutional data security procedures to protect this information.

- *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:

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