7/24/2018

IRB Protocol

Study Title: Get Social: Randomized Trial of a Social Network Delivered Lifestyle Intervention

NCT02646618

# IRB-1 Study Protocol

***Protocol Version # and/or Date:*** *7/24/18 [The protocol version must be revised each time a modification is submitted to the IRB to change the protocol.]*

**Study Protocol Title:** Get Social: Randomized Trial of a Social Network Delivered Lifestyle 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.*

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.]*

Specific Aims section of the grant:

Lifestyle interventions have had established efficacy for over a decade but are still not widely disseminated, largely due to high cost and patient and provider burden.[1] Online social networks are an alternative way to deliver lifestyle counseling and delivery via this modality may virtually eliminate patient visits, the main source of cost and burden of traditional modalities. Interactions in online social networks are frequent, brief, and asynchronous because users login to their online communities during downtime during work and leisure time, or when they simply feel a need for social connection. As such, social media becomes embedded into people's daily lives. By using them we have a means to embed health behavior change agents into people's daily lives. Thus far in the

[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.

literature, existing online social networks have been used as component of web- or mobile app-based lifestyle interventions [2,3] but not as the primary modality for intervention delivery.

The purpose of the present study is to conduct a non-inferiority randomized controlled trial comparing a lifestyle intervention delivered entirely via private groups on the online social network Twitter to a traditional in-person group-based lifestyle intervention. We hypothesize that the Twitter-delivered intervention will not be inferior to the traditional intervention in weight loss at 12 months. We also hypothesize that the online social network delivered version will be less expensive. We performed three pilot studies of social network-delivered interventions using Twitter and Facebook and found that this approach was both feasible and acceptable.

Our pilot work reveals important potential advantages of social network delivered programs over traditionally delivered programs. **First,** online social networks overcome patient barriers such as scheduling, transportation, weather, and childcare. **Second,** this modality overcomes implementation barriers by not requiring space for visits, not limiting patient census due to daytime work schedules (e.g., traditional groups typically must be scheduled on weekday evenings or early mornings which limits the number of time slots available to treat patients in a week), and by more efficiently using counselor time (e.g., time commitment of 13 minutes per day for 12-15 patients). **Third,** online social networks are highly conducive to more immediate feedback. Counselors log in briefly twice daily which gives participants frequent opportunities for contact during the week. In focus groups, participants expressed that they liked daily albeit brief access to a counselor since they could get assistance on days they were struggling, rather than wait for weekly group meetings. Behavioral theory has long shown that the longer feedback is delayed, the less impact it has on behavior. **Fourth,** this modality may be more conducive to participants building a sustainable social network to support their weight loss journey after the intervention ends. Participants continue to be linked with each other on the social network after the study. Also, we will share content with them from online resources (e.g., weight loss blogs both peer and professional), which connects them to the informal weight loss community on Twitter. Finally, we will explore proposed predictors to determine for whom the online modality is best suited. Findings from this study may 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. If this efficacy trial is successful, we plan an effectiveness trial in a worksite setting to build upon our previous worksite interventions.[4]

**Aim 1: Efficacy.** Using a randomized trial (N=328), we will test whether a lifestyle intervention delivered via an online social network (Get Social) will result in a mean percent weight loss at 12 months that is not appreciably worse than the gold-standard in-person group-based lifestyle intervention (Traditional), i.e., the social network arm will not lose on average 2% less than the in-person arm. Secondary non-inferiority outcomes include weight loss at 12 months, and dietary intake and physical activity at 6- and 12-months.

**Aim 2. Cost Analyses.** To determine whether the lifestyle intervention delivered via an online social network will cost less per participant than in-person delivery. We hypothesize that the Get Social condition will cost less per participant than the Traditional condition.

**Aim 3. Predictors (exploratory).** We will test predictors of weight loss in the Get Social condition including engagement, age, sociability, neuroticism, openness, and smartphone and social network use. We hypothesize that people who are younger, more sociable, engage more on the social network, higher in neuroticism/openness, and heavier overall smartphone and social network users will lose more weight in the Get Social condition.

***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 recruited will be 328 randomized participants and 6 interventionists. It is estimated that we will screen 700 participants to achieve this recruitment goal.

***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 powered the study to be able to detect non-inferiority for the primary outcome, percent weight loss at 12 months. Thus detectable effect sizes for secondary outcomes (Aim 1), cost (Aim 2), and predictors of weight loss in the Get Social condition (Aim 3) are based on the N available to evaluate non-inferiority of the primary outcome. Interventionist sample size was determined based on the availability of the interventionist and a balance of conditions being led by each coach.

*Aim 1: Efficacy.* Our sample size estimates utilize methods developed specifically for non-inferiority trials.72 In a non-inferiority trial, the null hypothesis (H0) is that the new treatment is inferior to the standard treatment, and the alternative hypothesis (HA) is that the new treatment is not inferior to the standard treatment. "Not inferior to" is defined by the non-inferiority margin, δ. Here, we set δ = 2%, based on a clinically meaningful difference in average weight loss between the two treatment arms. This means that if the Get Social condition loses up to 2% less weight on average than the Traditional condition, we will consider the Get Social condition to be non-inferior to the Traditional condition. If the Get Social condition loses >2% less weight then it will be considered inferior to the Traditional condition. Thus, adequate power for clinical non-inferiority requires a sample size such that there is better than 90% probability that the lower limit of the confidence interval lies above –δ, if the true effect size is zero or above. We estimated SD=5.5% based on our previous, fully powered randomized trial.28 With alpha=0.05, and δ=2%, we have 90% power to conclude that the Get Social condition is not inferior to the Traditional condition with 131 participants per arm. Accounting for 20% attrition, we will enroll 328 participants total (164 per arm). We considered adjusting the sample for intraclass correlation but previous research shows that weight loss does not cluster among members of weight loss treatment groups.1 We do not believe that the social influence in online groups will be stronger in the Get Social condition. Studies of social influence suggest that team-based activities or recruiting relatives or friends can lead to weight loss clustering but we will not be using such an approach.1 That said, we do believe that after the intervention, peer-to-peer engagement may continue for longer because participants will continue to have a channel by which to communicate with one another. They will also have the opportunity to collect additional social ties outside of the intervention which may be the source of social support, but this is likely to vary greatly across participants (not within treatment groups) and we do not have evidence that such ties will exert social influence of the magnitude of team-based activities and closer ties (i.e., relatives, friends). Secondary outcomes. For the secondary outcomes, we calculated the non-inferiority margins so that we have 90% power to detect given N=131 per arm, setting α=0.05, and using observed SDs from the literature. For change in kcal/day energy intake at 12 and 18 months, we have 90% to detect that Get Social is not inferior to the Traditional condition with a non-inferiority margin of 182 kcal/day with SD=500 kcal/day.28,56 For change in moderate-to-vigorous intensity physical activity minutes per day at 6 and 12 months, the non-inferiority margin is 9.2 minutes/day with SD=25 minutes/day. For percent weight loss at 12 months, the non-inferiority margin is 2.2% with SD=5.5%.28 If weight losses are more variable at 12 mos than 6 mos, the detectable non-inferiority margin is 3.0% with SD=8.0%.57 Power calculations were conducted using PROC POWER in SAS.73,74

*Aim 2: Cost*. With N=131 available per arm (N=262 total) and α=0.05 we have 80% power to detect differences in mean cost per participant of 0.35 SDs. For example, if the SD for cost is $100, then we have 80% power to detect differences in mean cost per participant of $35.

*Aim 3: Predictors (exploratory).* With N=131 available per arm (N=262 total) and α=0.05 for continuous predictors we have 80% power to detect correlations of 0.243 with 12-month percent weight loss. With N=131 available per arm (N=262 total) and setting α=0.05, for categorical variables, detectable differences in mean percent weight loss depend on the proportion of the predictor in the sample. For a predictor with 50% prevalence (i.e., n=65 and n=66 with vs without the characteristic), we have 80% power to detect differences of 0.49 SDs. For predictors with 33% prevalence, we can detect differences of 0.52 SDs. For predictors with 20% prevalence, 0.62 SDs, and for predictors with 10% prevalence (i.e., n=13 vs n=118), 0.82 SDs. For estimated SD=5.5% for 12-month percent weight loss, this indicates differences of 2.7%, 2.9%, 3.4%, and 4.5% weight loss, respectively. Sample size calculations for Aims 2 and 3 were conducted using Stata.

***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 will be recruiting from a representative population of individuals that live or work around Worcester MA and Storrs CT. We are recruiting men and women of all ethnicities, income and education levels between the ages of 18 and 65. Thus far we have had less success recruiting minorities and men and have put additional effort towards that goal. We will recruit participants in 9 waves off set by 2-3 months each. Waves 1-6 were recruited and carried out at UMass and waves 7-9 will be recruited and carried out at UConn.

We will also collect intervention delivery and feedback data from the interventionists. Interventionists are trained in the delivery of the DPP and are set up as consultants.

***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 the local community. 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.]*

Participants will be recruited from the local community using the strategy below. Participants will be instructed to contact study staff via email or phone.

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

We will also do targeted recruitment for men given that men enroll in weight loss studies at lower rates than women. We will use ads that specifically request the participation of men and over select men in the patient research registry until we have met our 50% recruitment mark. Advertisements for the study will be submitted to the IRB for approval prior to use.

Interventionists are invited to take part in this study by the research staff from having been a previous interventionist or a collaborator on a different project.

***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.]*

**Telephone screening:**

Interested participants will either call the study office or be called after sending an email expressing interest in the study in order to complete an initial telephone screening call, which will provide details about participating and an initial eligibility assessment. Eligible participants will be invited to a 90-minute baseline visit. Ineligible participants will be notified of their ineligibility at this time as well. Eligible participants will receive an e-mail after the call to confirm the baseline visit date/time. We are requesting a waiver of consent to perform this telephone screening. After the call, participants will be emailed a consent form to review before attending the in-person baseline visit.

**Baseline Visit:**
Participants will receive a reminder e-mail 1 day before their visit. This visit will last 90 minutes and will include the consent process, weight/height measurement, blood pressure reading, binge eating disorder interview, surveys, three 24-hour diet recall interviews, and PCP approval. During this visit, study staff will also review a randomization agreement with the participant. This agreement will outline the differences of the two conditions and the importance of enrolling participants who are ok with being in both. We will ask the participant to complete the checklist and sign the document. We will also ask condition-specific questions in the baseline survey to allow participants to express concerns about either condition.

Blood pressure will be measured according to standards set by the American Heart Association (AHA) using an automated monitor. Participants will be sitting for a minimum of 10 minutes before blood pressure is taken. Two readings will be taken and an average of the two will be used for data analysis. Participants presenting with a reading 140/90 or higher will be given a letter recommending them to consult with their primary care doctor at their earliest opportunity. An ambulance will be called for participants presenting with a reading of 220/120 or higher.

Participants will receive an e-mail immediately after the baseline visit which will include the survey link. Additionally, an e-mail will be sent providing further instructions for 2$^{nd}$ and 3$^{rd}$ dietary recalls. Participants ineligible after the baseline visit 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. inability to get medical clearance, taking exclusionary medication, or expressing a preference for either condition). If the reason is sensitive (i.e. high depression score, suicidal ideation, presence of BED) staff will call them to let them know. In the conversation, staff will let them know that when depression is very high, it's best to focus on that first rather than focusing on multiple things such as depression plus weight loss. In the conversation for BED, we will let them know that the DPP is not an appropriate intervention because we don't provide psychological help in the intervention, and receiving professional help, specifically cognitive behavioral therapy, will be more beneficial to them. We will offer to send a list of local resources to these participants. If suicidal ideation is present, the program director will call to assess safety and suggest professional help if needed.

**Orientation Webinar:** During the baseline phase of the project, before participants are randomized, they must complete a 60-minute 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 an email with the group dates asking if they are able to attend most of them. The webinar moderator will record in REDCap tracking which participants completed the webinar.

Participants will need to complete the telephone screening, baseline visit, post-baseline items, 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:**
Participants will complete a telephone screening, an in-person baseline, and an online webinar (described above). Eligible participants will then be randomized to one of two 12-month weight loss interventions: online (Get Social) or in-person (Traditional). Follow-up assessments will occur at 6- and 12-months.

**Randomization:** Randomization will take place after the baseline procedures are complete once we've determined eligibility. Participants will be randomized to the Get Social or the Traditional condition. We will randomize 36-40 participants for each recruitment wave, for a goal of approximately 18 per condition. Participants 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. 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.

**Orientation ~~Visits~~:**

- Traditional participants: ~~This in-person group will last 1 hour and will include training on~~The first session of the intervention will be extended from 1.5 hours to 2 hours in order to provide time for the orientation which will cover: ~~-~~My Fitness Pal, an overview of their participation, and study goals. My Fitness Pal is an app that can be used to track diet and physical activity. It can be used on a computer or mobile app. Participants will receive their study goals for weight loss (1-2 lbs. per week), diet, and physical activity. The weight loss goal is approximately 7% weight loss over a 12 month period. This orientation may be completed on an individual in-person basis or phone for people unable to attend the group, though this option won't be encouraged. The weight loss goal is provided in the My Fitness Pal app. ~~–~~The orientation group is led by the interventionist~~, a post-doctoral fellow, and a research assistant.~~ and research assistants.

- Get Social participants: Each participant will be required to attend an in-person 1-hour individual orientation visit, led by a research assistant, to set up their Twitter account, receive a tutorial on Twitter, Android users will download the App Usage Tracker to record their time spent on Twitter during the intervention, and Get Social participants will sign up for the study website where articles posted on Twitter are accessed only by study participants.. Participants will be asked to follow the study staff and participants, on Twitter, set their account to "protected" and will review suggestions on how to engage in the Twitter group. They will be asked to tweet daily to get experience with Twitter functions and to bring any questions or concerns to the group orientation. Then, they will attend an in-person 2-hour group orientation visit with their smartphone or laptop to receive additional training/practice on Twitter, an introduction to My Fitness Pal, and an overview of their participation and study goals. Participants will receive their study goals for weight loss (1-2 lbs. per week), diet, and physical activity. The 2-hour orientation group is led by the interventionist and research assistants
~~, a post-doctoral fellow, and a research assistant.~~

**Intervention Phase:**

- All participants will receive weight loss counseling based on the Diabetes Prevention Program (DPP). The DPP was chosen given ample efficacy data for weight loss,[5,6] and our experience.[7-9] The DPP includes instruction in self-monitoring of food intake, diet/exercise counseling, and behavioral modification. The

DPP was chosen for this study because it's an evidence-based weight loss program focused on lifestyle changes. The goals for the intervention are 175 minutes of moderate physical activity per week and an overall weight loss of 7% over a 12 month period. Each participant will get an individualized calorie goal that would facilitate a 1-2 lbs. weight loss weekly. The group leader/online coach will counsel participants toward achieving and maintaining the study goals. Participants will be encouraged to use an app such as MyFitnessPal to track daily diet. Participants who were recruited at UMass during wave 1-6 will complete study procedures at UMass. Participants who are recruited at UConn during waves 7-9 will complete study procedures at UConn.

- Traditional participants will receive the DPP intervention during in-person group visits. Groups will include 18 participants each. During the first 6 months, groups will be held weekly for 8 weeks, then biweekly for 16 weeks. Groups will be held monthly between 6- and 12-months. There will be a total of 22 groups and each group will last 90 minutes (except for the first group which will be extended to 2 hours to accommodate the orientation) and each one will be audio recorded to track intervention-adherence. Participants will have weight taken in-person before the start of each group. During the weeks participants do not have a group, they will be encouraged to take their weight at home and e-mail it to study staff. Staff will e-mail them during these weeks asking for their current weight. The e-mail text wording is included in the measures attachment.

- Get Social participants will receive the DPP intervention in a "protected" Twitter group. Where participants and counselors will activate the "protected tweets" privacy setting so that the tweets are only viewable to each other. The DPP content has been restructured to deliver in an online context. The delivery includes a morning and evening post each day. The online coaches will log in twice daily to respond to questions, address concerns, and encourage engagement. Participants will receive an e-mail asking for their current weight, the minutes per week they used Twitter, and questions about treatment receipt. These e-mails will be sent during the same weeks that the Traditional participants have a group. The questions for this survey will all appear together accessible by one link. See measures attachment for survey. When reporting time on Twitter, participants with iPhones will reference the battery setting on their phone, which provides app usage times and participants will Androids will be asked to download an app called App Usage Tracker. This app is free and downloaded from the Play Store and tracks time spent on apps.

- Interventionists will be asked at to complete a survey at the 6 month timepoint. The survey link will be e-mailed at the 6 month time point in each wave. The survey will ask about their experience delivering the intervention. If they do not respond we will follow up with them via email or phone. Once they have delivered interventions to participants in both the Get Social and Traditional conditions the survey will also ask for their opinions comparing and contrasting their preferences for each condition.

**Follow up:**
Participants will complete follow-up visits at 6- and 12-months. The visit will last 1 hour and will include a weight measurement, blood pressure reading, three 24-hour diet recall interviews, and repeated baseline measures. The online survey containing the measures will be e-mailed to participants 1 week prior to the scheduled follow-up visits.

**Time Commitment:**

| Visit | GS Condition (in minutes) | TC Condition (in minutes) |
|---|---|---|
| Telephone Screening (20 min) | 20 | 20 |
| Baseline (210 min total)<br>Visit (90 min)<br>2 at-home dietary recalls (60 min)<br>Online survey (60 min) | 210 | 210 |
| Webinar (60 min) | 60 | 60 |
| Orientations | 180 | |

| | | |
|---|---|---|
| GS: individual orientation (60 min)<br>GS: group orientation (120 min)<br>TC: group orientation (60 min) | | |
| Intervention<br>GS: approx. 35 min/week 8 weeks, 14 min/week for 16 weeks, 8 min/week for 28 weeks (12.5 hrs)<br>TC: 22 1.5 hr groups (33 hrs) | 750 | 1980 |
| 6-month (150 min total)<br>Visit (30 min)<br>2 at-home dietary recalls (60 min)<br>Online survey (60 min) | 150 | 150 |
| 12-month (150 min total)<br>Visit (30 min)<br>2 at-home dietary recalls (60 min)<br>Online survey (60 min) | 150 | 150 |
| Total | 1520 minutes (approx. 25 hrs) | ~~2630~~ 2570minutes (approx. 4~~34~~ hrs) |

**Interventionist data collection:**
The interventionists provide the following information, some of which will be used in the analysis:

- Weekly timesheets for invoicing their time (these hours are used to calculate time/cost needed to deliver the intervention – aim 2).
- A 10 minute survey at the end of each 6-month phase for each wave used to gather interventionist feedback.

**Measures**

| Data Collected | List of Measures | Baseline | During Intervention | 6 Months | 12 Months | Method |
|---|---|---|---|---|---|---|
| BMI | Height | X | | | | REDCap |
| | Weight | X | X (weekly) | X | X | REDCap |
| Medications | Brief Medication Questionnaire [10] | X | | X | X | REDCap |
| Blood pressure | Blood Pressure | X | | X | X | REDCap |
| Demographics | Income, employment, marital status, race/ethnicity, household composition* | X | | | | REDCap |
| Medical History | Assesses exclusionary medical conditions* | X | | | | REDCap |
| Personality factors neuroticism/ openness | Ten-Item Personality Inventory (TIPI)[11] | X | | | | REDCap |
| Binge Eating Disorder | SCID Interview[12] for BED | X | | | | Interview |
| Physical Activity | Arizona Physical Activity Questionnaire[13] | X | | X | X | REDCap |
| Sleep Quality | STOP[14] | X | | X | X | REDCap |
| | Insomnia Severity Index[15] | X | | X | X | REDCap |
| | Pittsburgh Sleep Quality Index Questions[16] | X | | X | X | REDCap |

| | | | | | | |
|---|---|---|---|---|---|---|
| | History of sleep apnea diagnosis* | X | | X | X | REDCap |
| | Previous or current treatment for sleep apnea* | X | | X | X | REDCap |
| Depression | BDI[17] | X | | X | X | REDCap |
| Chronic Pain | Brief Pain Inventory[18] | X | | X | X | REDCap |
| Quality of Life | EQ-5D-3L[19] | X | | X | X | REDCap |
| Contamination | Weight-loss related social media use* | X | | | X | REDCap |
| Social media use | Social Media Use* | X | | X | X | REDCap |
| Dietary recall | 3 24hr recalls (ASA24-Automated Self-Administered)[20] | X (3) | | X (3) | X (3) | Online |
| Social support for weight management | WMSI[21] | X | | X | X | REDCap |
| Measure time spent on Twitter | Phone or app tracking | | X | | | REDCap |
| Group engagement on Twitter | Engagement in group | | X | X | X | Twitter |
| Treatment receipt | Questions each week related to intervention* | | X | | | REDCap |
| Intervention acceptability and burden | Questions given at 6m follow-up* and time spent data extraction from getsocial.com | | | X | X | REDCap |
| Interventionist Feedback (Interventionists only) | Interventionist Survey* | | | X | | REDCap |

* Investigator-derived items

***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.]*

**Preliminary analysis**

Baseline participant characteristics will be examined by condition. If groups differ on certain characteristics, these variables will be included as covariates in the primary analyses. Other preliminary analyses include assessing patterns of missing data, dropout rates, distributional properties of dependent measures, and correlations among outcome measures. A series of sensitivity analyses will be performed to examine the extent of potential bias by assuming the participants who dropped out are (i) missing completely at random (i.e., independent of the outcome), (ii) are responders to the intervention, or (iii) are non-responders to the intervention. Multiple imputation to impute missing data will be used if more than 5% of data are missing.

**Primary non-inferiority outcome**

We will model percent weight loss at 12 months using a linear regression model framework, with percent weight loss as the dependent variable and study condition as the independent variable. Test of the intervention condition indicator will provide a statistical test of the intervention effect and the estimated coefficient, along with the

estimated confidence interval. This analytic approach aims to test whether the Get Social condition is not appreciably worse than (i.e., not inferior to) the traditional condition by our a priori inferiority margin of 2%. The effect estimates will reveal clinical non-inferiority of the Get Social condition if the confidence interval lies completely above $-\Delta$ or clinical non-inferiority of the traditional condition if the confidence interval lies completely below $+\Delta$, i.e., 2%.

**Secondary non-inferiority outcomes**

Secondary non-inferiority outcomes (dietary intake and physical activity at 12 months) will be examined using the same approach as described for the primary outcome. Linear multivariable models will be used to estimate change in daily caloric intake at 12 months; such models are reasonable given the target sample size and that changes in these outcomes are approximately normally distributed. We anticipate using log transformation to estimate change in physical activity variables, given that physical activity data tends to be skewed. The distribution of secondary outcomes will be explored graphically and inform the primary outcome analysis; analyses will be modified as needed through transformation of the data.

**Cost**

We will compare total intervention costs per participant and total intervention costs per pound lost by treatment condition. We will conduct sensitivity analyses to estimate the range of costs after varying the inputs (e.g., time spent on Twitter by participants, staff pay across settings and based on qualifications and training). We will also examine administrative, interventionist, and participant costs by treatment condition. Assuming a normal distribution of total costs per participant, we will first compute t-tests comparing the average cost per participant across treatment conditions. We will test the null hypothesis of no difference between groups using a two-sided test and $\alpha=0.05$. If total cost per participant is not normally distributed, a non-parametric approach using the Mann-Whitney test for median comparisons will be used. If participant characteristics are found to differ according to treatment allocation/condition, multivariable models will be used to adjust for the potential confounding effects of these characteristics. Assuming a normal distribution of total costs per participant, multivariable linear regression models will be used. If not normal, we will identify appropriate transformations (e.g., logarithm, square root) for the cost variable.

**Exploratory outcomes (treatment retention, acceptability, and burden)**

We will compare treatment retention (percent retained in treatment, i.e., percent who has not dropped out of treatment) and ratings of acceptability and burden (measured on 5-point Likert scales) across treatment conditions using $\chi 2$ tests.

**Predictors of weight loss in the Get Social condition (exploratory)**

Bivariate associations between each potential predictor of weight loss (e.g., engagement, age, sociability, neuroticism, openness, smartphone and online social network use) and percent weight loss at 12 months will be examined among participants in the Get Social condition using linear regression models. Multivariable predictors of percent weight loss at 12 months will be estimated using linear regression models. Variables will be added to the model one at a time, in order of magnitude of the crude effect estimate (largest to smallest; $p<0.05$) associated with the outcome. The final model will be selected based on consideration of effect estimates, 95% confidence intervals, and Akaike information criterion (AIC).

***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.

Participants will be excluded if they:

1. Do not have a smartphone;
2. Are unable to get medical clearance from their PCP;
3. Have plans to move during study;
4. Are not interested in losing weight;
5. Have Type 1 Diabetes or uncontrolled Type 2 Diabetes (as determined by PCP);
6. Have medical conditions that would prevent increasing physical activity or making dietary changes;
7. Are pregnant/lactating or plans to become pregnant during study;
8. Are currently taking medication affecting weight;
9. Currently participating in a clinical weight loss program to assist them with weight loss (e.g. Weight Watchers, Sparkpeople, etc);
10. Unable to walk at least ¼ mile unaided without stopping;
11. Experienced a weight loss of 5% or more in past 3 month;
12. A history of/or plans on having bariatric surgery;
13. Did not complete the baseline measures;
14. Not willing to use Twitter, or if a current Twitter user, not willing to create an new account specifically for study purposes;
15. Participated in another weight loss study under the direction of the PI of this study;
16. Current smoker (smokes 3 or more cigarettes per day);
17. Unavailable to attend weekly group meetings;
18. Prefers one condition over another;
19. Score of 30 or higher on the BDI or endorsement of 2 or 3 on BDI #9 indicating suicidal thoughts;
20. Presence of binge eating disorder;
21. Did not complete the orientation webinar;
22. Are unable to provide consent due to mental illness or a cognitive impairment;
23. Does not speak English; or
24. Are a prisoner

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

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

Possible risks for being in this study includes: Injury while exercising, breach of confidential information, and discomfort completing measures. The attempt to avoid risks to participants will be addressed by: suggesting moderate intensity exercise to avoid discomfort, pain, or injury. Participants reporting discomfort will be referred to their PCP. Injuries are unlikely to occur since we screen out medical conditions that could make someone prone to injury, we obtain medical clearance, 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.

For Get Social participants only: To maintain confidentiality, participants will be asked not to use their real name, locations, or contact information for their user information or in there tweets ; they will be asked to only use user names when talking to other study participants; they will also be asked not to disclose that they are in a research study to protect confidentiality of other participants; tweets 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 and Co-I's 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. Societal benefits include providing evidence to support an intervention delivery modality that is more conducive to settings like worksites, health plans, and clinics that serve large populations but have limited space, staffing, and resources for traditional in person interventions.

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

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

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

Economic burden to subjects includes the time needed for screening and study participation. My Fitness Pal is freely accessible. Additionally, there is no cost to participants for attending study visits. Depending on smartphone data usage plan for each participant, usage charges may incur due to increased use of mobile apps such as Twitter and My Fitness Pal.

Participants will be paid in the form of online Amazon gift cards. Participants will receive $30 for completing the baseline procedures. If participants complete the 6 month assessment within the 2-week target window, we'll provide $40 compensation; otherwise we'll provide $30. If participants complete the 12 month assessment within the 2-week target window, we'll provide $60 compensation; otherwise we'll provide $45. Payment will be in the form of an online gift card paid after each assessment. The procedures for each assessment will need to be completed before providing compensation, including all 3 24hr recalls.

At each time point, gift cards will be purchased and sent to participants within two weeks of the final participant in each group completing the associated procedures to decrease administrative time.

***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 DSMB has been set up for this study and convene twice a year. DSMB reports are produced by the program director and data manager. Reports will be reviewed by the principal investigator and the study statistician then will be sent safety officers on the board. Recruitment reports are generated and emailed at the end of each recruitment wave and a full data report is generated and reviewed during a meeting twice a year:

| **Report type** | **Frequency of review** |
|---|---|
| Recruitment rates | Twice per year and at the end of each recruitment wave |
| Inclusion/exclusion | Twice per year and at the end of each recruitment wave |
| Demographics | Twice per year and at the end of each recruitment wave |
| Adherence to study protocols | Twice per year |
| Adverse events | Twice per year |
| Participant Retention/Engagement | Twice per year |
| Data review (completeness/outliers) | Twice per year |

**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 and Dr. Edward Stanek, Professor at University of Massachusetts Amherst. 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 will be reviewed at the end of each recruitment phase, which will occur 3-4 times per year. Inclusion/exclusion criteria and diversity goals will be reviewed twice per year. 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. All visits will be audio recorded. A 10% randomly selected sample of the recordings will be assigned to the co-investigator 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:**
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 during monthly reports for all adverse events. Serious adverse events will be communicated

immediately to the safety officers. The NIH, UConn, and UMMS IRB will be notified immediately in the event of serious adverse event. Any death of a study participant will be reported to the NIH, UConn and UMMS 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**
Attendance will be collected at all study visits. If a participant misses a group, materials will be sent to them and a make-up session will be offered. 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. Compliance information (number/percent of intervention visits attended; engagement in Twitter private group) will be provided in a report to the safety officers.

**Data Security:**
The databases will be maintained on UConn and UMass 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 directo, 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 groups. The database and recordings will be maintained on UMass and 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 only for quality control and will not be transcribed. Access to the files require permission from the program director, a UMass/UConn password, and IRB personnel approval. 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. UMass and UConn IRBs 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. PHI fields will be stored in a separate form from other data collection forms. Data will be completely de-identified once the last assessment phase 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).]*

The consent process will take place at the beginning of the baseline appointment. Ample time will be allowed for discussion or questions. Consent will be obtained by research assistants/coordinators trained in the consent process. To ensure that participants are given enough time as needed to review the consent form, they will be emailed the consent form prior to the baseline appointment.

The interventionists will receive an online survey at the 6-month time point of each wave. An information sheet appears on the first page in place of a signed consent form. They will as much time as needed to review the information sheet and email/call staff for questions. They may also decide not to complete the survey.

***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).]*

Adult consent form will be used for the study participants and an information sheet for the interventionists.

***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 administer a feedback survey to interventionists and to perform the telephone screening with participant. The screening involves minimal risk and will save staff and participant time in the event of ineligibility by allowing staff to assess criteria before an in-person visit.

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

  The survey is minimal risk because it lasts about 10 minutes and includes feedback related to the intervention delivery. We don't ask any sensitive questions. The telephone screening is minimal risk because it lasts about 15 minutes and includes a description of the study and initial eligibility-related questions.

- *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 complete the short survey online at their own comfort reduces the possibility of any discomfort of unnecessary travel to our location to provide in-person consent. During the telephone screening, we ask for permission to ask questions and indicate that they may choose not to answer.

- *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 have financial forms that are utilized to pay them for delivering the intervention and their first and last names are known to all study subjects. Performing a telephone screening will save staff and participant time in the event of ineligibility by allowing staff to assess criteria before an in-person visit.

- *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.*

  The interventionists are considered research subjects due to the need to gather and analyze feedback data about intervention delivery. This is done in a short survey.

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