Study Protocol and Analytic Plan:

A Non-Inferiority Trial Comparing Synchronous and Asynchronous Remotely Delivered Lifestyle Interventions

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Study Protocol

Background

Lifestyle interventions are efficacious but costly and have poor scalability.[4] Remotely-delivered lifestyle interventions, which leverage videoconferencing software, online platforms, and/or mobile apps, have increased potential for reach and scale. A systematic review concluded that remote lifestyle interventions are effective,[5] with largest effects in those that include human coaching. Some remote lifestyle interventions are *synchronous*, such that they are delivered via videoconferencing or phone. Other remote lifestyle interventions are conducted *asynchronously* via online platforms that allow for clinicians and patients to engage via text exchanges or online groups. Asynchronous interventions allow people to engage whenever it is convenient 24/7 which makes them conducive to 'in the moment' support, and this addresses a key barrier to lifestyle interventions which is the feasibility of attending numerous meetings. In this application we propose a non-inferiority trial comparing two remotely delivered lifestyle interventions: one that is delivered *synchronously* and one that is delivered *asynchronously*. Evidence for asynchronous interventions is needed because they may be a convenient alternative for many people, more scalable, and more sustainable. Further, for asynchronous telehealth to receive reimbursement, we need evidence for their efficacy relative to synchronous approaches.

While some evidence shows that remote and in-person lifestyle interventions produce fairly similar outcomes when delivered synchronously, we know less about how *asynchronous* remote interventions compare to *synchronous* ones. In a non-inferiority trial comparing an in-person (synchronous) lifestyle intervention to an asynchronous, remote lifestyle intervention, we found that the in-person condition lost more weight at 6 months, but due to greater weight regain in that condition, the groups were not significantly different in weight loss at 1 year. The asynchronous remote intervention also cost 18% less per pound lost. Interestingly, at the end of the trial, 64% of participants said the asynchronous remote intervention would be more convenient than the in-person intervention. We discovered another possible advantage of asynchronous remote lifestyle interventions which is that they may be more scalable than synchronous remote ones. In a trial of two asynchronous, remote lifestyle interventions—one with a group of 94 participants and one with a group of 40 participants,[6] we observed similar weight loss and acceptability between conditions. However, the larger group remained intact for longer. In the year following the intervention, we turned the groups over to participants to lead themselves, a period we

called the “peer-led maintenance phase.” We found that the larger group engaged for much longer during this phase. This suggests that larger groups may be more sustainable and have greater potential for long term weight loss maintenance. Our next step is to examine how an asynchronous remote intervention compares to a synchronous remote intervention, not only in short term weight loss, but also in engagement, scalability, sustainability, and weight loss maintenance. We are also interested in whether the asynchronous, remote condition, by giving people the opportunity to engage any time, will end up creating a higher functioning group, i.e., greater collective efficacy. Now that we’ve established the feasibility of large asynchronous, remote groups, we propose to randomize participants to large groups (n=82) in both conditions, which will allow us to compare synchronous to asynchronous interventions that are scaled to a level that pushes the field forward.

The proposed study is a randomized controlled non-inferiority trial. We will randomize 328 adults who are overweight or obese in one of two conditions. Participants in the asynchronous condition will receive lifestyle counseling via a private group on Facebook. Participants in the synchronous condition will receive a lifestyle intervention via videoconference group meetings. Two waves of 164 participants will each be randomized into two groups of 82 participants. Content in both conditions is based on the Diabetes Prevention Program Lifestyle Intervention. Assessments will be taken at baseline, 6-, 12-, 18-, and 24-months. Percent weight change at 6 and 12 months is the primary endpoint. Secondary endpoints include retention, engagement, cost, and sustainability, defined as engagement in the year-long post-intervention period.

We hypothesize that members in the asynchronous condition, by virtue of having more opportunities to engage (i.e., 24/7) will feel higher collective efficacy about their group than the synchronous condition where interactions are restricted to weekly or less frequent group meetings. Further, we hypothesize that the asynchronous condition will engage more in the post-intervention period because it is easier to do so than it will be in the synchronous condition where engagement will depend on how reliably the volunteer group leader arranges regular videoconference meetings and on the availability of group members to attend those meetings. We suspect collective efficacy may decline in the synchronous condition during the post-intervention period due to these participation barriers. Further, if few people show up to the initial group meetings in the synchronous condition, this may negatively impact attendance rates in subsequent meetings.

Total participants required to answer the study question

The total number of participants that will be enrolled into the intervention is 328. However, it is estimated that we will screen ~4,000 participants to achieve this recruitment goal. Since the initial contact is via an online link, there will be many incomplete responses driving up the number of screened-out participants.

How was sample size determined?

We powered the study to be able to detect non-inferiority for the primary outcome, percent weight loss at 6 and 12 months.

Aim 1: Our sample size estimates utilize methods developed for non-inferiority trials.[7] In a non-inferiority trial, the null hypothesis (H_0) is that the new treatment is inferior to the standard treatment, and the alternative hypothesis (H_A) 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 mean weight loss between the two conditions. 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 trial.[62] With alpha=0.05, and δ=2%, we have 90% power to conclude that the ASYNC condition is not inferior to the SYNC condition with 131 participants per arm. Assuming 20% attrition, we will enroll 328 participants (164 per arm).

Aim 2: Engagement, Cost. Engagement: We have 80% power to detect differences of ≥0.79 SDs in engagement (word count) between conditions. With N=164 available per arm (N=328 total) and α=0.05 we have 94% 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 94% power to detect differences in mean cost per participant of $35. In our previous non-inferiority trial comparing a synchronous in person lifestyle intervention to an asynchronous remote lifestyle intervention, the difference in cost per participant was $82.66. We suspect the difference will be less in this trial because travel costs contributed to the difference in our previous trial that used an in-person condition.

Aim 3: Maintenance and Sustainability. Maintenance will be tested in a longitudinal design, assuming 5 time points (including pretest, 6, 12, 18, and 24 months) clustered within individual. From the conservative perspective of the inferiority effect size, δ=2%, SD

=5.5%, with alpha=0.05, and ICC = 0.6, the study will have power of 97.6% to yield a statistically significant result with a sample size of 328 participants. Sustainability (engagement during the Peer Led Maintenance Phase): We have 80% power to detect differences of ≥0.79 SDs in engagement (word count) between conditions.

How are participants recruited?

Participants will be notified or approached about this research study through digital ads on various platforms (e.g., search engines, health websites, and social media platforms, etc.).

Recruitment methods we will use include strategies used in our previous remote trials. The recruitment messages will include a link to the REDCap survey where they can read the information sheet in full and complete the eligibility survey if they wish to. Online recruitment may be used with recruitment messages posted on Facebook groups throughout the US. We will also use Research Match which connects volunteers to research studies.[11,12] To meet our goal of reaching males, we may also recruit on Reddit, where 74% of users are male.[13] Facebook group recruitment consists of study staff posting recruitment messages in Facebook groups. We have met recruitment milestones in our weight loss trials (N=161;[14] N=240[15]; N=328[16]). Additional strategies that we may or may not use depending on recruitment flow include:

- Other online recruitment: Twitter, newsletters, intranet messages, listservs, Daily Digest, emails, and other online locations and platforms as needed.
- Connecting with large businesses to get our ad and/or flyer e-mailed to their staff and/or students.

To get a representative sample for this study, it is possible we will have to cap certain groups to allow room for other groups (e.g., stop enrolling white women to allow enrolling more males or other people of various ethnic/racial backgrounds). In that event, we will send participants generic wording via email (included in accompanying documents) letting them know that we are looking for people with specific characteristics and can only take a certain number of people who have similar characteristics. If they want a further explanation, we will refer them to email Dr. Pagoto to have a more detailed conversation about this decision. As per the grant, the goal of the participant sample is to recruit 50% female and 50% male and anticipate enrolling at least 30% minorities into the study. Given that we will be recruiting online, we will not be bound to the racial and ethnic diversity in

the local area. We will conduct online advertising in areas that have higher concentrations of ethnic minorities than the US generally so that we can meet our recruitment targets. Because recruiting a gender- and ethnically diverse sample for weight loss studies that do traditional local recruitment can be challenging, this study gives us an opportunity to hone an online recruitment strategy by evaluating the yields from ads in different geographical regions and cities.

How will participant privacy be respected?

During the recruitment process, we are unable to see who is viewing our advertisements on any platform, therefore their anonymity is respected. We may be able to see data such as how many people have clicked on an advertisement for example, but not the identity of who each person is. The entire process up until the eligibility screener is anonymous. We only email them to answer any questions they may have or respond about their eligibility status. Contact information is collected only after a participant reads through a simple information sheet and marks that they are interested in moving forward with the study. They do not have to provide the research team with any personal information until after they have decided after learning about the research study. Even if the participant takes the eligibility survey, they can choose to not provide contact information and exit out of the survey, but it will make them ineligible (since we will not be able to contact them to move forward with next steps). The contact information will be stored in a REDCap database and will only collect their contact information in REDCap if they decide to provide us with that information during the eligibility screening process.

With all above mentioned recruitment strategies, participants will be able to follow the link to the REDCap survey to complete the eligibility screening. They will click on a link that will bring them to a landing page and the screening survey in REDCap, which is HIPAA compliant. This eligibility survey will collect their contact information, so the research team has a way of contacting participants about eligibility. Participants will also be able email us as our lab email will be posted on the landing page or within the recruitment wording/images we post online.

Study Timeline

The study will last for approximately 5 years from July 2023 through June of 2028 from startup procedures, recruitment, intervention, follow-ups, and data analysis).

The timeline below is subject to change depending on various factors such as how quick the startup procedures are and how recruitment for each wave is moving forward.

	YR 1				YR 2				YR 3				YR 4				YR 5			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Start up	X	X	X	X																
Recruitment (Wave 1)					X	X														
Intervention (Wave 1)							X	X	X	X										
6-month Follow-up (Wave 1)								X												
12-month Follow-up (Wave 1)										X										
18-month Follow-up (Wave 1)												X								
24-month Follow-up (Wave 1)														X						
Recruitment (Wave 2)								X	X	X										
Intervention (Wave 2)											X	X	X	X						
6-month Follow-up (Wave 2)												X								
12-month Follow-up														X						

(Wave 2)																			
18-month Follow-up (Wave 2)																X			
24-month Follow-up (Wave 2)																	X		
Data cleaning/ analyses/ manuscript prep				X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Participant Time:

Participants will be in the study for 24-months, which will include the 12-month intervention, the 12-month peer-led maintenance phase, and the follow-up procedures at 6, 12, 18, and 24 months. Prior to that, participants will complete the screening and baseline procedures to be enrolled. See table below for approximate time details for this study. Please note: Times on this chart may vary greatly depending on how much time participants actually engage during the 12-month maintenance period; these are our best estimates.

Study Phase	**Approximate Time (min)**
<u>Screening</u> Initial Screening Survey (15 min)	15
<u>Baseline</u> Orientation Webinar (60 min) E-consent (10 min)	105

Scale set-up (10 min) Baseline survey (20 min) Randomized and oriented to respective condition (5 mins via email)	
Private Facebook Group ~165 min a month in Facebook group in first 12-months (1,980 mins) ~60 min a month in Facebook group in second 12-months (720) Videoconference Group 22 90-minute meetings in first 12-months (1,980 mins) 12 60-minute meetings in second 12-months (720 mins)	Private Facebook Group 2,700 Videoconference Group 2,700
6-Month Follow-up Weigh-in (~5 min) Online survey (~15 min) 12-Month Follow-up Weigh-in (~5 min) Online survey (~15 min) 18-Month Follow-up Weigh-in (~5 min) Online survey (~15 min) 24-Month Follow-up Weigh-in (~5 min) Online survey (~15 min)	80
Total	2,900 minutes (approx. 48 hours)

Methods

Study Design: Participation starts with reading a simple information sheet and doing an online eligibility survey. From there, those that are eligible will be scheduled for and complete an orientation webinar. Participants will be asked to keep video on during the webinar and answer a brief question to confirm webinar attendance. After that, they will be sent the E-consent, and if signed, they will be asked to complete another survey to collect baseline assessment data, and then be sent a scale. Eligible participants at this point will then be randomized and complete a 12-month intervention followed by a 12-month peer-led maintenance phase, and finally complete follow-up assessments at 6-, 12- 18-, and 24-month time points (survey and weigh-in).

Recruitment: We will post online recruitment ads that will contain simple study information with a link to an online survey containing the screening questions. Ads that are done with Research Match will lead interested individuals to the REDCap landing page that will give them some more information about the study and then will bring them to the survey. See the recruitment section (starting on page 7) for full recruitment details.

Inclusion Criteria

- 18-70 years old
- BMI 27-45 kg/m^2
- Wi-Fi connectivity at home
- Logs into Facebook at least 5 days per week over the past 2 weeks
- Has “liked”, posted, or replied on Facebook at least twice a week over the past month
- Has a smartphone
- Able to participate in the study in English
- Interested in losing weight
- Lives in United States

Age justification: Children under 18 require different programming for weight loss and maintenance given their developmental needs. Weight loss for elderly adults should be medically supervised, something this study does not offer.

Exclusion Criteria

- Under the age of 18 and over the age of 70
- BMI under 27 or over 45 at screening; then under 27 at the point of the first weight on scale
- Does not have Wi-Fi connectivity at home
- Does not have a Facebook account
- Does not log into Facebook at least 5 days per week over the past 2 weeks
- Does not "like"/post/reply on Facebook at least twice a week over the past month
- Not able to participate in the study in English
- Not interested in losing weight
- Does not live in the United States
- Pregnant/lactating or plans to become pregnant during study period
- Reports having bipolar disorder, substance abuse, psychosis, an eating disorder, or severe depression
- Had bariatric surgery or plans to have surgery during the study
- Currently taking medication affecting weight (e.g., neuroleptics/antipsychotics, mood stabilizers, weight loss medication, or tricyclic antidepressants)
- Has lost ≥5% of weight in past 6 months
- Is participating or intends to participate in another weight loss program during the study
- Chronic pain that interferes with the ability to exercise
- Type 1 Diabetes
- Type 2 Diabetes
- Unable to make dietary changes or increase physical activity due to digestive medical condition(s)
- Unable to walk ¼ mile unaided without stopping
- Unable to walk ¼ without experiencing chest pain or dizziness

- Had a previous myocardial infarction/heart attack
- Has a known coronary artery disease (not including hypertension)
- Has chronic kidney disease
- Has a heart valve abnormality
- Has a heart arrhythmia
- Currently smokes or vapes nicotine
- Meets criteria for severe depression on the PHQ-8 (score of >19)
- Participated in previous weight loss studies under the PI
- If UConn employee/student, has concerns about being in a Facebook group/meeting with other UConn faculty, staff, and students
- Had major surgery in past 6 months and have not been cleared by their doctor to resume physical activity and diet changes
- Plans to have major surgery during the study period
- Did not complete screening and on-board processes of study (screening survey, webinar, e-consent, baseline survey, scale set-up, etc.)
- Prisoner

Screening: Participants will complete screening procedures online since they may be located anywhere in the country. The screening survey will first have a description of the study and the data we will collect from them at that point (the simple information sheet). At the bottom of the information sheet, they can mark whether they are interested in participating or not interested. If they mark that they are interested, it will bring them to the screening questions to determine eligibility. The survey logic within REDCap will determine eligibility for participation based on participant responses. If they are ineligible, they will be notified after the survey is submitted. If they are eligible dates and times for webinars will be available for the participant to select a time to attend a live informational webinar.

We will not require PCP approval since we assess exclusionary medical conditions during the screening process. If conditions are reported that might put the participant at risk during the intervention, they will be excluded.

Webinar: The purpose of the webinar is to educate participants about what research is, review study procedures, how the intervention is going to work, review importance of participation of enrolled participants, and to allow participants to evaluate if joining this study is the right choice for them. This webinar is being conducted to improve study retention and explain study procedures. Participants will receive a link to access the webinar via WebEx (under UConn's WebEx license). Once the participants are logged into the webinar, staff will proceed with the slides. Toward the end of the slides, participants will have the opportunity to use the chat function to ask questions and discuss any concerns related to the program. The webinar moderator will record in REDCap tracking which participants completed the webinar. After completion of the webinar, participants will receive an email to go over any questions they may have had during the webinar and a link to the online consent form.

As a result of the COVID-19 Pandemic, our lab is working remotely. Therefore, any phone calls or texts made to participants while our team members are working from home will be conducted via Google Voice. This is an app that gives our staff a different phone number to protect their personal information. We will not be recording any phone calls with Google Voice. Participants will be able to reach out to investigators as easily as standard calling. Participants do not need the app to contact the lab. Researchers will retain the call history and text message exchanges for the duration of the study within the Google Voice app. Call history and text messages will be deleted once the study is over. If something sensitive is shared by a participant, we will delete it right away and save it in the One Drive or REDCap if it is relevant to the study. Team members using Google Voice to communicate with participants will ensure their phones are properly maintained during the study for security and privacy purposes. It is important to note that some information may be retained on Google's active servers temporarily for billing UConn staff or other business purposes, and residual copies may remain in Google's backup systems. Anonymized copies of call record information, with no personally identifiable information, will be retained on Google systems to meet reporting and auditing requirements. However, this is no different than any standard phone plan.

Baseline: Participants that decide to complete the online consent process will be sent a study scale. Participants who do not consent will be brought to a landing page thanking them for their time learning about the study, but they will no longer be eligible to participate beyond that point. Once the participants receive their scale, UConn staff will give the participant an option to set it up themselves or schedule a call to help them set up the scale and ensure that it is working, and we can access their data. UConn staff will then collect a baseline weight from participants to confirm their BMI for eligibility reasons.

After BMI has been confirmed and participants are still eligible at this point, the next step is for the participant to be sent the online baseline survey about demographics and depression.

Once all of that has been complete and the participant is still eligible, UConn staff will do a final eligibility check, going through all previous steps done by the participant and double-check to confirm that they are eligible. If they are not, UConn staff will notify them via email. If they are eligible, UConn staff will let them know they are eligible to participate in the study and will be randomized. Once randomized, we will notify them which group they are in and all necessary onboarding information for that group (e.g., getting into the Facebook group or schedule and link for group meetings, etc.).

Participants will need to complete both surveys (screening and baseline), webinar, consent, set-up the scale and provide the study team with a baseline weight to confirm BMI (done with scale we ship to them), before being randomized into the trial. Participants will be randomized into one of two groups.

Ineligible participants will be notified either automatically or by the research team via email that they do not meet criteria for the study. Staff will use a generic response about how their pattern of responses does not match our eligibility criteria (the examples are provided in additional documentation). If they want to know specifics as to why they were ineligible, staff will refer the participant to email the PI so they can have a more detailed discussion about eligibility. This is being done to avoid upsetting participants and letting Dr. Pagoto, a clinical psychologist, handle communication of more sensitive information. For participants who score a 20 or higher on the PHQ-8, they will be contacted via email to let them know they are ineligible and to provide them with a list of resources/support (attached in study documents) for their symptoms of depression if they want to utilize those options. It's important to note that a high score on the PHQ-8 only indicates the presence and severity of symptoms of depression, but not an actual diagnosis. Further, we will also provide mental health resources to those who express mental health struggles during the intervention or request mental health resources.

Intervention: Participants will be randomized into either the asynchronous or synchronous condition. Both programs are 12-month online weight loss interventions, with a 12-month peer led maintenance phase and are both based off the counselor-led Diabetes Prevention Program (DPP) lifestyle intervention. Breakdown of each condition and the two phases are below. The counselors in both conditions will be trained Lifestyle Coaches to deliver the National Diabetes Prevention Program. They will be trained by an organization called State

of Wellness, which is an organization who has signed an MOU with the CDC to train the DPP. The counselors will either be a member of our team, or we may hire dietitians for this role.

1. Asynchronous Remote Lifestyle Intervention

In the asynchronous group, the DPP lifestyle intervention will be delivered within a counselor-led Facebook group with twice daily pre-programmed posts as in our previous studies (see 4 sample posts below).[16,17,18,19] All Facebook groups will be on the "private" setting which means only group members can see the group and its content. Each week's content is based on the corresponding module of the DPP. The DPP assigns participants the goals of 1) calorie tracking to achieve a calorie goal based on amount needed to lose 1-2 pounds per week, 2) developing a healthy diet consistent with the American Heart Association guidelines, 3) engaging in 150-300 minutes per week of moderate/vigorous intensity exercise (i.e., brisk walk at 2.5-4 mph, bicycling, gardening, dancing, water aerobics, canoeing, playing doubles tennis. etc.) or 75-150 minutes of vigorous exercise (e.g., jogging at 6mph, soccer game, shoveling, playing a tennis singles game, etc.), 4) developing a strength training regimen consistent with the National Exercise Guidelines, and 5) losing 1-2 pounds per week. Goal setting happens on Mondays when the counselor posts diet and exercise goals with the group. The counselor will give the group different sets of 2 goals each week—a diet goal (e.g., reduce added sugar) and an exercise goal (e.g., add 15 minutes of moderate intensity exercise on 3 days) to help participants progress toward the overall program goals. On Fridays, the counselor posts a weigh-in post asking participants to reply with their weight change in pounds for the week. This ensures participants are weighing themselves weekly and allows an opportunity for problem solving for those not losing weight. Goal accountability happens each Sunday when the counselor posts asking participants to report how they did on the weekly goals. In between these recurring posts are posts that reflect the DPP module for the week (e.g., nutrition, making time for exercise). Many posts contain links to our Pinterest page which includes recipes, meal plans, and workouts tailored to dietary preferences (e.g., vegetarian) and cultural influences (e.g., African American, Latinx). Participants also have the opportunity to send their counselor private messages if they don't want to post in the group. Additionally, the coach or study team members may post periodic videos of themselves or study-related content to facilitate building a relationship with the participants and to assist with stimulating engagement. The counselors may attempt to re-engage any participants who stop commenting or reacting in the Facebook group by tagging them in a post, private messaging, emailing, or calling them.

2. Asynchronous Peer-Led Maintenance Phase

At the end of the 12-month intervention, the counselor will query their group for two volunteer moderators to take over the leadership role for the next 12 months. We plan to give the volunteer moderators a library of 182 posts (based on the DPP protocol) that they can draw from to start conversations. The library will include goal setting posts, weigh-in posts, problem solving posts, goal accountability posts, and additional content that emphasizes lessons learned from the DPP. We will also arrange a 30 minute orientation call with each volunteer moderator to discuss the posts, give them guidance on how to moderate a Facebook group, send them a video produced by Facebook on how to run a Facebook group (including guidance on privacy), advise them to post daily and encourage group members to post updates about their progress and ask the group their questions, and finally, we will advise them on how to secure a replacement moderator if and when they no longer want to moderate the group. Moderators will be instructed to limit the advice posted to only be from the content we provide to them from the DPP. Moderators may use the library as they wish and post whatever they and/or the group prefer. The counselor will exit the group when the maintenance phase commences. Study staff will remain in the group but will not post or engage unless any activity occurs that could indicate a breach of confidentiality or any other type of harm. Participants will be informed that study staff will continue to extract engagement data from the group during this phase.

3. Synchronous Remote Lifestyle Intervention

In the synchronous group, the DPP lifestyle intervention will be delivered by a counselor in weekly videoconference sessions via Webex. The 16 session Core of the DPP Lifestyle Intervention will be delivered over 6 months, typically following the pattern of weekly for 8 weeks and then bi-weekly for 16 weeks (however, this is subject to change due to holidays, counselor not being able to show up due to illness, and other like issues that may occur during the intervention). After the 16-sesion Core of the DPP, the meetings will change to monthly meetings for 6 months, for a total of 22 meetings by the end of the intervention. These meetings will last about 90 minutes each time.

4. Synchronous Peer-Led Maintenance Phase

At the end of the intervention period, the counselor will query their group for two volunteer moderators to take over the leadership role of the group for the next 12 months. The leadership role would entail hosting the videoconference sessions. UConn will schedule and send out the invites on behalf of the volunteers for privacy reasons. We will provide the group leaders with additional content from the DPP to use in the groups if they choose. Moderators will be instructed to limit the advice talked about in meetings to only be from the content we provide to them from the DPP. We will also arrange a 30-minute orientation call with each volunteer group leader to discuss the content, give them guidance on how to

lead a group, and advise them on how to secure a replacement group leader if and when they no longer want to lead the group. Group leaders may use the content we provide as they wish and/or run the group in whatever way they and/or the group prefers. The counselor will not attend the group meetings; however, a member from the study team will attend the group to record attendance and run the transcription software but will not engage unless any activity occurs that could indicate a breach of confidentiality or any other type of harm. Participants will be informed that study staff will save the chat data and be using transcription software to record the group conversation during this phase so that this data can be used for research purposes.

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

Weigh-Ins: Participants will receive a cellular based digital scale (such as Fitbit Aria Air Scale) that will be mailed to them. This will allow them to take their weight weekly and at assessments. Using a wifi digital scale will allow for a standard weight measure for each participant with a higher level of accuracy than self-reported weight. Scales are cellular based, meaning that all participants have to do is step on the scale and we will receive the data on the back end. From a participant perspective, minimal set up is required except unboxing their scale, and connecting the scale to their Wi-Fi for syncing purposes to Fitbit. Our staff will also send a generated invitation link to request permission for the use of Fitabase for data collection. Once the participant receives the link, they will need to click on the link which will prompt them to log in to their google account and authorize Fitabase to access their Fitbit data. Fitabase is a cloud-based platform that collects, manages, and analyzes data from Fitbit devices. This software will allow us to export data from the study scales without having to access participants accounts. From the perspective of the researchers, the weight data will be delivered immediately for accurate data collection. Study staff will be available through email/phone if for some reason they encounter difficulties with their scale. The study team will check all participants' BMI. If a participant has a BMI under 27, we exclude them from the study and allow them to keep their scale as compensation. At the end of the study participants will be allowed to keep their scale. If at any point the data is not being sent to us due to connectivity issues, we will ask participants to upload screenshots of their weight to a secure REDCap link. Study staff will delete the screenshot from REDCap once the weight has been logged into the record.

Follow-ups/Assessments: The follow-ups/assessments will occur at the 6-, 12-, 18-, and 24-month marks after the intervention has begun. At each time point, participants will receive a link to an online REDCap survey. This survey will be a repeat of some of the measures assessed at baseline (indicated in the measures table below) and questions to solicit participants' feedback on the program. The participants will also weigh-in at each time point. Participants will be compensated (compensation explained in Payment/Course Credit to Participants section) for completing these assessments.

Adverse Events: Adverse events will be documented during the intervention and assessments. AE's will be formally assessed during each survey at the 6-, 12-, 18-, and 24-month mark by asking questions in the REDCap survey. During the intervention, AE's will be documented when a participant reports it to the weight loss counselor or posts it in the Facebook group. If it is reported during the intervention, the counselors will notify a research coordinator within 24 hours of learning of the event. The study team will then report it to the IRB (immediately or at the time of annual renewal depending on the AE). If participants gain 5% or more weight during the intervention, this will be treated as an adverse event. The participant will receive a phone call from a research coordinator, and they will be asked questions to figure out the cause of their weight gain. We will also assess Binge Eating Disorder (BED) at this time. If BED is present, we will treat it as a study-related AE. We will only assess BED once, even if there are multiple AEs for weight gain. Participants will not be removed from the intervention if they have 5% or more weight gain. If a participant is losing twice the weekly goal, which is 4 pounds of weight loss a week, consistently for 3 or more weeks in a row, then we will contact them to find out how they are accomplishing that and determine whether they are doing anything that is unsafe. If it is determined that they are losing weight in an unsafe manner, we will record that as an AE and the PI will have a discussion with them privately about healthy weight loss and how to do so in a safe manner moving forward. If after that conversation, they are still consistently losing 4 pounds of weight loss a week (for another 3 weeks or more in a row), we will remove them from the study and refer them to the National Eating Disorders Association helpline (https://www.nationaleatingdisorders.org/help-support/contact-helpline).

Measures: See table below.

Data Collected	List of Measures	Screening/ Baseline	6-Month	12-Month	18-Month	24 Month	Method

Inclusion/Exclusion criteria	Initial screening survey*	X					REDCap/ Qualtrics
BMI	Height	X					REDCap
	Weight	X	X	X	X	X	Fitbit/Fitabase
Demographics	Marital status, education race/ethnicity, sexual orientation, work status, household income, household members*	X					REDCap
Binge Eating Disorder	SCID Eating Disorder Examination Questionnaire[22]		X**	X**	X**	X**	REDCap
Depression	Patient Health Questionnaire (PHQ-8[23])	X					REDCap
Food/Drink Intake	MyFitnessPal Entries		X	X	X	X	MyFitnessPal
Collective Efficacy	Online Collective Self Efficacy Scale[24]		X	X	X	X	REDCap
Engagement	Facebook Engagement / Webex transcription		X	X			, REDCap, and Word Count (LIWC-22)

Sustainability	Engagement during peer-led phase, same method as row above				X	X	REDCap, LIWC-22
Counselor Time	Done via Facebook and tracking through phone			X			REDCap
Cost	Tracking costs associated with intervention			X			REDCap / Accounting System
Usability Feedback	Contamination, Satisfaction, burden*		X	X	X	X	REDCap

* = investigator derived

** = as needed for AEs

Psychometric information / General measure information

Demographic data: We collect demographic data and then we report the data in our manuscripts so that readers can gauge the generalizability of our data. This is very important in clinical trial research.

SCID Interview for BED: The SCID is an assessment of Binge Eating Disorder. We would use the SCID on an as needed basis for those who gain more than 5% of their weight during the intervention. The SCID's severity scales demonstrated substantial internal consistency (all Cronbach's alphas >.80), test-retest reliability, concurrent, and predictive validity.[22]

Patient Health Questionnaire (PHQ)-8: The PHQ-8 is an 8-question measure like PHQ-9 (with the omission of one question). Cronbach's α for the PHQ-8 was 0.88 which demonstrates good reliability and a Spearman coefficient of 0.616 which demonstrates good convergent validity when compared to the PHQ-9.48 Together, this data shows the PHQ-8 is as valuable as the PHQ-9.[23]

The Online Collective Efficacy Scale: The Online Collective Efficacy Scale is a 35-item validated scale designed to assess the degree to which members of an online group feel they are able to contribute to the group and the degree to which they perceive a fit between their goals and abilities and those of other members of the group.[24] This measure has 3 subscales: social presence, engagement, and collaboration and augmentation. Convergence validity resulted in significant moderate correlations between this scale and other related instruments.[24] Further, Using McDonalds' Omega, the study found satisfactory reliability for the subscales.

Engagement: For the *Asynchronous condition,* we will manually extract Facebook data. Will collect data on number of Facebook reactions (e.g., like, care, wow, etc.), replies, posts, and polls per participant during the program. *For the Synchronous condition*, we will use the transcription feature in Webex software to record and transcribe the group meetings. Each participant's words spoken and typed (in the chat of the meeting) will be exported into a separate file and analyzed with LIWC-22 as described above.

Analytic Plan

Sex As A Biological Variable. We will strive for a sample that is balanced by sex but acknowledge this is very difficult to achieve in behavioral weight loss trials in that a greater number of women than men attempt to enroll. We will stratify randomization by sex and include sex as a covariate in all models. We will conduct exploratory analyses of sex differences in outcomes by condition.

Aim 1: Non-Inferiority. Reporting and data analyses of this trial will follow the recommendation of the 2012 JAMA article "Reporting of Noninferiority and Equivalence Randomized Trials Extension of the CONSORT 2010 Statement".[28] We will use intention to treat, meaning all randomized participants will be included in the model in their originally randomized conditions. Preliminary analyses and evaluation of missingness. First, we will evaluate comparability of baseline characteristics by condition. If groups differ, these variables will be used as covariates in the primary analyses. Other preliminary analyses will include assessing patterns of missing data, dropout rates, distributional properties of dependent measures, and correlations among outcome measures. Attrition in weight loss studies may not be random.[29,30] We will perform a series of sensitivity analyses to understand the extent of potential bias by assuming the subjects 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. We will have quality checks to make sure our missing data is minimal but if we have more than 5% data missing, we will

use multiple imputation.[31] Assessment of non-inferiority. We will model percent weight loss at 6 and 12 months using a general or generalized (depending on outcome distribution characteristics) linear regression model framework, with percent weight loss as dependent variable and study condition indicator as an 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 will provide the estimate of the intervention effect. Our analytic approach aims to test whether the ASYNC condition is not appreciably worse than (i.e., not inferior to) the SYNC condition by our a priori inferiority margin of 2%. The effect size reveals clinical non-inferiority of ASYNC if the confidence interval lies completely above the non-inferiority margin (2%).

Aim 2: Engagement, Cost. Engagement. We will compare conditions on word count and proportion of the 4 language dimensions (analytical thinking, clout, authenticity, and emotional tone) using the same approach as described for the primary outcome. We will graphically explore distributional assumptions and adapt the analyses if necessary, fitting the most appropriate distribution. We hypothesize that mean word count part participant will be higher in the ASYNC condition at 1 year and at 2 years. Exploratory analyses will compare conditions on the 4 language dimensions at 1 and 2 years as well. Cost. As previously described, the costs of delivering each condition will be tracked throughout the entire study. Intervention and participant costs per participant will be computed and average costs will be compared across conditions. As Ritzwoller[32] recommends, we will perform sensitivity analyses to estimate the range of intervention costs after varying the inputs. We will estimate a range of costs based on varying assumptions. We will compare conditions on total program costs per participant and total program costs per pound lost. 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, general or generalized multivariable methods will be used to adjust for the potential confounding effects of these characteristics. Assuming a normal distribution of total costs per participant, multivariable general linear regression models will be used. If not normal, generalized linear models will be used. We hypothesize that the asynchronous condition will cost less per participant (and less per pound lost) than the synchronous condition.

Aim 3: Maintenance and Sustainability. Weight loss maintenance at 18 and 24 months will be analyzed using the same approach described for aim 1. Sustainability (engagement

during the peer-led maintenance phase), will be analyzed in the same way as engagement data in Aim 2 above.

Weight change. We will calculate absolute and percent weight change.

Collective Efficacy. Using the same models as for the primary outcome, we will compare conditions on total and subscale scores.

Engagement. LIWC-22 will be used to determine the total words spoken in the group by each participant and the proportion of words that reflect each of the 4 dimensions of language (analytical thinking, clout, authenticity, emotional tone).

Sustainability. Sustainability is defined as engagement during the peer-led maintenance phase. Engagement will be measured in words in the same fashion as described in the engagement section.

Counselor Time. Counselor time will be measured in each condition so that cost can be calculated. Asynchronous. Counselors will be given a study phone to use exclusively for counseling and will create a unique Facebook account for the study and only use it for their designated group. The time a user spends on Facebook each day can be found in Settings under 'Your Time on Facebook.'[33]Counselors will enter the minutes spent each day into a REDCap database. Synchronous. Counselors will enter the minutes spent preparing for and conducting the group meetings in a REDCap database.

Cost. We will systematically track costs associated with delivery of both intervention conditions, capturing information on the costs that would be required to implement each intervention in practice (i.e., outside a research context).[32] Intervention costs will be distinguished from costs associated with research and development costs (e.g., recruitment). We will create an accounting system that captures administrative and intervention for both conditions. As described in Ritzwoller,[32] we will use cost capture templates to evaluate staff time (described above). National salary data will be used to calculate costs including administration (e.g., staff time to schedule intervention posts) and intervention delivery (e.g., counselor time) costs.

Study Removal

Participants will be removed from the study if: 1) they do not complete all screening, baseline, and on-boarding procedures (two surveys, consent, webinar orientation, scale set-up, join the Facebook group, etc.), 2) become pregnant during the study period, 3) post inappropriate content in the Facebook group or be inappropriate during group meetings for synchronous condition (e.g., bullying/harassment of others, hate speech, violent/graphic content, violating privacy of others etc.), and 4) if they choose to withdraw their

participation from the study. Participants reporting that they would like to withdraw from the study and those that become pregnant will be withdrawn from the intervention but will be asked to complete the follow-up assessments.

Potential risks

Potential risks for being in this study include injury or cardiovascular events from exercising, accidental exposure of personal information, and discomfort with study procedures (e.g., feeling uncomfortable with some questions asked on a survey or someone says something they perceive as uncomfortable in a group meeting for those in that condition). The attempt to avoid risks to participants will be addressed by focusing mainly on suggesting moderate intensity exercise to avoid discomfort, pain, or injury. We do provide guidance on vigorous activity for those participants who prefer that type of exercise and/or are already doing it prior to joining the study in accordance with the National Exercise Guidelines. We also provide images or links on how to do exercises properly to avoid pain or injury. Participants reporting discomfort will be told to go see their PCP. Injuries are unlikely to occur since we screen out medical conditions that could make someone prone to injury. To avoid accidental exposure of personal information, tracking data will be stored electronically in REDCap, a network secure data entry program, in the UConn-supported R drive, or OneDrive which is secure. Only those who have IRB approval to work on the study will have access to the R drive and REDCap database for this study. To avoid discomfort during study procedures, participants will be informed that they may withdraw from the study at any time if they feel discomfort with any of the study procedures or if they don't want to answer a question on a survey, they can skip it. If someone says something in a group meeting (for those in that condition) they are free to leave the meeting and let the counselor know (if they wish) about what made the uncomfortable so the counselor can make sure it doesn't happen again if that step is needed. The likelihood of each of these risks happening is rare since we take steps to prevent these from happening and if they were to happen, the severity would be likely be minor.

Potential Benefits

Participants may or may not benefit from participating in the study. Benefits that could occur are losing weight through exercise and lifestyle changes and improvements in mental, physical, social, and emotional health. Through interacting with other participants and the counselor, participants may also feel supported in their behavioral change efforts. Participants will also receive weighing scales that they are able to keep at the end of the study.

Societal benefits include providing evidence to support ways to help people achieve healthy lifestyle goals and improve the outcomes of their health in a way that could be less burdensome than other programs that are commercially available.

The possible risks of the study are minimal. If injury during exercise was to occur, it would likely be minimal because we screen out those at risk for injury or pain. Even then, injury can still happen, therefore we suggest activities where injury is unlikely and/or would be minor (e.g., playing tennis may result in feeling minor pain/discomfort which should subside in a few days; and soreness may decrease over time as the body adjusts to the increase in movement). We also encourage a slow build-up of exercise in their daily routine to avoid any injuries. Any discomfort during the study can be mitigated because participants can stop participating or skip any questions they don't want to answer at any point. Accidental exposure of personal information is unlikely as steps are taken to prevent it (e.g., password protected UConn computers, only using secure websites or servers like the R drive and REDCap, only having approved personnel that are trained via CITI handle data). All these risks are outweighed by the possible benefits to participants (weight loss and enhancements in mental, physical, social, and emotional health) because it could improve their health and quality of life. Costs to Participants

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.

Payment to Participants

Participants will be paid electronically in the form of research debit cards (Clincards). Participants will receive $40 for the 6-month assessment, $50 at 12 months, $40 at 18 months, and $50 at 24 months. Participants who complete both assessments (weigh in and survey) at all time points will receive a bonus of $50 for completing everything. The procedures for each assessment will need to be completed before providing compensation. Additionally, participants may keep the study scale provided to them.

Data Safety Monitoring

Because of this low-risk status, the data safety monitoring (DSM) plan for this trial focuses on close monitoring by the principal investigator (PI) in conjunction with a safety officer, along with prompt reporting of excessive adverse events and any serious adverse events to the NIH and to the IRB at the University of Connecticut.

Although there are additional reports to be produced by the study coordinator as a result of this DSM plan, there are no substantive changes to the study protocol that might require review by the NIDDK. Safety reports will be sent to the study statistician, the PI,

and the safety officer. The Project Coordinator and Data Manager will be responsible for assembling the data and producing these reports, as well as assuring that all parties obtain copies of these reports.

The frequency of data review for this study differs according to the type of data and can be summarized in the following table:

Data type	Frequency of review
Subject accrual (adherence to protocol regarding demographics, inclusion/exclusion)	At the end of each recruitment wave (monthly at the beginning of the study)
Adverse event rates (injuries)	As they occur
Compliance to treatment	Quarterly
Out of range laboratory data	Yearly
Stopping rules report regarding statistical power implications of drop outs and missing data	Yearly

Qualifications and responsibilities of the Safety Officers

The safety officers for this trial will be Drs. Kristin Schneider and Joanna Buscemi. Dr. Schneider has a PhD degree, experience with lifestyle and exercise intervention trials including statistical analyses, and an understanding of the types and severity of injuries commonly experienced in lifestyle interventions. Dr. Buscemi is an expert in lifestyle interventions for minority populations. Safety Officers will review the reports sent by the study coordinator (at the frequency outlined above) and will use the checklist attached to this document to determine whether there is any corrective action, trigger of an ad hoc review, or stopping rule violation that should be communicated to the study investigator, the UConn IRB, and the NIDDK. In addition, the safety officer may comment on whether the study investigator needs to report any specific out of range data to the participant.

Measurement and reporting of subject accrual, adherence to inclusion/exclusion criteria

Recruitment rates and milestones, including baseline characteristics, will be reviewed weekly within the study team. This review will ensure that project deadlines are being met, that participants meet eligibility criteria, and that the gender and racial/ethnic diversity goals outlined in the grant proposal are being met. If recruitment falls behind

gender and racial/ethnic diversity targets, we will discontinue recruiting individuals of genders and racial/ethnic groups that are already filled and focus on recruiting those we still need. We will also seek consultation from Dr. Buscemi on our recruitment strategy. A report will be provided to the safety officers each year that recruitment is active.

Measurement and reporting of adverse events

We plan to collect data on injuries and medical conditions from the treatment and control groups yearly. The adverse event report will include a listing of all adverse events including duration, severity, seriousness, relatedness, action taken, and resolution. Adverse events are documented throughout the intervention and at the follow-ups. An adverse event report will be provided each year. All adverse events will be evaluated within 72 hours and all serious adverse events within 24 hours. Any study-related serious adverse events reported to the IRB will also be reported to NIDDK within 2 weeks. In the event of a serious adverse event, the safety officers and UConn IRB will be notified immediately. The data presented for a complete year will be blinded as there is no reason to expect one group to have higher rates than the other as both groups will receive the same intervention but via a different modality. We plan to present blinded adverse events data to the study statistician, the PI, and the safety officer throughout this trial. The adverse event form will be used by the study staff to report injuries or other adverse events caused by the lifestyle intervention. There is some level of injury that could be expected from starting an exercise regimen. The injury rate observed in the general population in those who report involvement in exercise over the past 30 days was 3-4%. The study statistician, the principal investigator, and the safety officer will review adverse event rates yearly. Most exercise injuries are mild in nature and allow a complete return to the same activities after slowly working back up to pre-injury levels. Participants who cannot exercise as a result of an injury may stay in the intervention and focus on the dietary component until they are ready to resume exercise.

Measurement and reporting of participant compliance (engagement) to treatment protocol

Once participants have started the intervention, data on participant engagement will be collected weekly by research staff and reviewed quarterly by the study investigator, the study statistician, and the safety officer. Participant engagement in the asynchronous intervention will be defined as any type of measurable engagement in the Facebook group (e.g., reactions, replies, posts, poll votes), and participant engagement in the synchronous intervention will be defined as attendance at videoconference meetings. If participants did not engage for one week, the interventionist will reach out to them via direct messaging (asynchronous condition) or email (synchronous condition). In the event of no response, research staff will phone the disengaged participant in attempt to re-engage them.

Stopping rules

In this minimal risk lifestyle intervention trial, it is more likely that drop-outs or difficulty in recruiting adequate numbers of participants will require stopping the trial than that excess adverse events will occur and require stopping the trial. However, as outlined elsewhere, we will monitor injury rates in all participants and the safety officer, together with the study investigators, will alert the IRB and the NIH if a larger than reasonably expected injury rate. Other issues relating to stopping rules for this trial include:

New Information

It is exceedingly unlikely that any new information will become available during this trial that would necessitate stopping the trial.

Limits of Assumptions

It is possible that baseline differences between the groups, excessive study dropouts and/or missing data by the interim measurement time point will limit the value of data analysis of measurements at 1 year. Baseline differences will be evaluated after the first measurement time point and effects on the power to detect differences in the primary outcome will be evaluated and communicated to the PI, safety officer and NIDDK. Given the monitoring plans outlined elsewhere in this document, it is exceedingly unlikely that there will be baseline differences between groups of any magnitude to threaten the validity of the study.

In contrast, excessive drop-outs could occur. In the grant proposal, we allowed for a 20% dropout in the recruited numbers. With 20% dropout rate in both groups, the primary hypotheses are testable at 5% Type I error and 90% power to establish non-inferiority. Dropout rates higher than 20% would be of concern, so we propose to monitor the dropout rate quarterly. Alert points are set at dropout rates of 20% (low alert), 30% (mid-alert), 40% (high alert) and 50% (extreme alert). With early alerts to problems, action would be taken to avoid higher level alerts; if a higher-level alert should arise, more drastic remedial action would be invoked. The actions taken at each level of alert are given below:

> *Mid-level alert* = Conference call between study investigators to discuss approaches to minimize further losses to follow-up/dropouts.
> *High-level alert* = Conference call between investigators to determine further alterations of study protocol to complete the study with no further losses
> *Extreme-level alert* = In the unlikely event of a 50% dropout rate occurs prior to the 1-year measurement time point, study investigators would convene on a conference call to discuss the usefulness of continuing the study. However, if 50% dropout rate occurred during the 2nd year of follow-up, it might still be of interest to continue the study; study investigators would convene on a conference call to discuss whether to complete the study.

Outline of safety reports

Below is an outline for a safety report for this trial. Tables and figures to be included in this report are included in the appendix.

I. Table of Contents
II. Narrative/ Trial Summary
    A. Summary of Main Findings (if available)
    B. Discussion of Issues or Problems
    C. Report Preparation Procedures
III. Study Description
    A. Project Organizational Chart, Personnel
    B. Brief Statement of Purpose of Trial
    C. Projected Timetable and Schedule
IV. Study Administration
    A. Recruitment Status
        1. Enrollment by Month
        2. Comparison of Targeted to Actual Enrollment
    B. Retention Status
        1. Overall Subject Status
        2. Individual Subject Status
V. Study Data Reports/Tables or Figures
    A. Generic Information
        1. Enrollment (Table 1, Figure 1)
        2. Status (Table 2)
        3. Demographics (Table 3 and 4)
    B. Safety Assessment
        1. Treatment Duration for All Subjects (Table 5)
        2. Treatment Duration for Subjects who Discontinue Treatment (Table 6)
        3. Adverse Events (Table 7)
        4. Serious Adverse Events (Table 8)
        5. Deaths (Table 9)
        6. Frequency of Specific Symptoms (Table 10)
        7. Other situations that might be of safety concern

Privacy/Confidentiality

For the initial screening survey, participants can answer the questions at their own place and in an environment of their choice since it is done via a link online. If they do not want to finish, they can exit out of the survey whenever they would like. We also provide a simple information sheet prior to the survey so they can decide if they even want to move forward with doing the screening survey.

During the webinar process, UConn staff will go over all the details of the study and what it means to be a participant to give them a thorough description of what they can expect and what the study is so they can decide if this study is a good fit for them. During the webinar, they turn their video and audio off and choose where they view the webinar.

Most contact is done online so participants can control where they are and how they answer on their own time. They will have ample time to decide if they want to participate or not and ask UConn staff any questions they may have. Consent will also be done online so they can control where they are when reading the form as well as the amount of time they have to read through the form before deciding.

Participants will be informed in the consent form that they are able to withdraw from the study at any time for any reason without any consequences. They can skip questions during baseline and follow-up assessments if it makes them uncomfortable as well.

The participant can control when, where, and how often they use the Facebook group or choose where they view and if they attend the virtual group meetings, depending which group they are in. We will encourage them throughout the study to attend the meetings / engage in the Facebook group as directed, but we only do so when it seems like they may be falling behind and if they do not reply to our contacts, we do not bother them about it again.

Most communications are done on an individual basis to respect their privacy. For the webinar, they can request a one-on-one if they prefer, or we have alternate methods to help respect their privacy (e.g., turn off video/audio during webinar).

All communications and data collections are done only for necessary research purposes. Participants can specify preferred and non-preferred communication methods (e.g., calls, texts, emails) that staff will honor and only use non-preferred communication if needed (e.g., participant prefers phone calls, but staff needs to send a survey link, we would then email them).

Participants will likely interact with each other in the Facebook group/Virtual meetings and see each other's names and profile picture/video, but we make sure during the webinar and in the consent that they are aware of that so all enrolled participants will be comfortable with sharing with others they may or may not know. Participants are free to change their Facebook name or profile picture if they wish or attend any group meeting without sharing their actual name or showing their face. Any participants will be marked ineligible during screening/baseline if they do not wish to use Facebook/ Webex for the study and any that become uncomfortable with it are free to withdraw at that point.

All data from participants is collected on an individual basis. Surveys are provided to them through secure links via REDCap that is unique to each participant.

Confidential Data Storage

The data will be maintained on UConn servers (R Drive, REDCap, and OneDrive) where security will be maintained through access controls. Files will be managed by the project coordinators, who will control user access and rights. For each user, REDCap will require a REDCap profile, username, and password to enter the program. Staff will only have access to the database, OneDrive, and R drive if the data manager or coordinator has given them access. The only staff who will have access to data are those approved on the IRB personnel and completed necessary CITI training. All participants will be assigned an ID number, which will link them to their study data. The ID number will be 2-4 numerical characters representing the number of participants in the study (e.g., the first person who fills out an eligibility screener would be ID 1). We may use Otter.ai transcription software to produce transcripts in the event the Webex automatic transcriptions are not sufficient for data analyses. Otter.ai retains no ownership rights to the recordings or transcripts. Staff will verify and edit the transcripts and then save the de-identified transcripts to the research drive on the UConn servers and delete the recordings from the drive and the Otter.ai platform. Please refer to these two sections of the terms of service and privacy policy: Terms of Service; Section 9 and specifically Section 9.3: https://otter.ai/terms: In summary, research team retains right to audio recordings and controls how the content is processed, transported, and distributed on the otter.ai platform. Once we delete the recordings from our trash, they are permanently deleted from platform. And from Section 2 of Privacy Policy: https://blog.otter.ai/privacy-policy/ “We train our proprietary artificial intelligence technology on aggregated, de-identified audio recordings. Only with your explicit permission will we manually review certain audio recordings to further refine our model training data.”. PII fields will be stored in a REDCap form. Any data with PII in the R Drive will be minimal and only what is necessary for data management and analysis. It will be marked as such. Data will be completely de-identified once we have our master dataset saved in our R drive (which will be fully de-identified). At this time, the link between ID number and PII will be destroyed.

Plans for data of participants who fail screening

The data collected from the screening will be stored in a form in REDCap under their study ID and will be kept until the end of the study. We will de-identify everything once we have the master dataset finalized.

Informed consent process

Participants will first read through a simplified information sheet prior to doing the eligibility screener. This will contain information about the study in general, next steps, and what data we will collect from them at this point. After reading through it, they will mark if they are or are not interested in participating in the study. If yes, they will go through the screening survey. From there, participants will then do an online webinar to learn more about the study and decide if this is a right for them, and then after that they will be sent the e-consent via a REDCap link where they will read through the consent from and consent online and then they will be sent a copy of the signed consent via email.

Who, on the study team, will obtain consent:

The research assistants/coordinators will obtain consent by sending a link via email to the e-consent form for participants to read and sign (if they choose).

Where will consent be obtained:

REDCap.

How much time participants will have to decide to be in the study:

Participants will be given ample time. At both the eligibility screener phase and informed consent phase, they will be given as much time as they would like. They will have our contact information if they want to reach out to ask any questions. They will have up until recruitment closes to make that decision.

Will an assessment be made of the participant's capacity to consent?

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