Study Protocol and Analytic Plan

for Building Habits Together Online Weight Loss Program

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Study Protocol

Background

Technology-delivered weight loss programs have the potential to increase reach and early studies reveal modest impact.[3] Less impressive outcomes have been produced by commercial weight loss mobile apps perhaps because they focus mostly on self-monitoring which in spite of being an essential component of behavioral weight loss interventions, has poor efficacy as a standalone intervention.[4,5] Comprehensive technology-based weight loss programs typically use online platforms to provide 1) technology supported dietary self-monitoring, 2) counseling in behavioral strategies, and 3) access to a peer group. In these models, the only technology-supported behavioral strategy is usually self-monitoring. The remaining behavioral strategies are the responsibility of counselors who provide personalized feedback. Technology that can assist people in the implementation of a wider range of behavioral strategies could increase the efficacy of technology-supported interventions. In separate studies, we developed and tested the feasibility of an online weight loss intervention and two mobile apps that help participants implement two behavior change strategies (problem solving and stimulus control).

Aims

The goal of this study is to merge these technologies into a comprehensive technology-delivered weight loss intervention and add new features that were suggested during our user-centered design process. Aim 2 of this grant is the pilot feasibility randomized trial. The goal is to evaluate feasibility of a program where participants will all receive an online weight loss program delivered via a private Facebook group led by a professional counselor but be randomized to the Habit app which we developed or commercial calorie tracking app. These apps would serve as a tool to participants during the intervention (we are not assessing the efficacy of the app on participants weight loss). Feasibility outcomes are recruitment, retention, app use, engagement, acceptability, burden, group cohesion, and contamination at 6 months. Our goal is to evaluate whether we meet our targets for these outcomes.

The total number of participants that will be enrolled into the 6-month feasibility trial is 70. It is estimated that we will screen ~1,700 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 based the sample size of 70 for this pilot feasibility trial on necessities for examining feasibility. This sample size allows us to recruit online groups of 35 which we have demonstrated in an ongoing study is feasible and breeds regular engagement. Our previous work with smaller online groups (i.e., n=12)[33,34] showed that presence of a few quiet participants can result in a fairly rapid decline engagement among entire group.[33,34] We plan on enrolling waves of 70 participants (35 participants in each treatment condition), thus the feasibility trial allows to pilot recruitment procedures and assess feasibility of recruitment and engagement in the Facebook groups.

Retention: With n=35 per treatment condition, the 95% confidence interval (CI) for the estimated retention rate in each condition will be within ±11.8% if the observed retention is 85%. Thus, given n=35 per condition, the lower limit of the 95% CI for the observed retention rate in either treatment condition should not be lower than 73.2%. App use: With n=35 per treatment condition, the lower limit of the 95% CI for observed proportion of 80% of participants meeting targets for app use in either treatment condition should not be lower than 66.7%. Acceptability: Assuming 85% retention, with n=30 available per treatment condition, the lower limit of the 95% CI for observed proportion of 80% of participants providing high acceptability ratings in either treatment condition should not be lower than 65.7%. Exploratory outcomes: We propose 6-month change in weight, 6-month change in weight loss problem solving, counselor time, and group cohesion at 6 months as exploratory because a true test of efficacy will require a fully powered trial informed by the refined procedures that will result from this feasibility study. Since the primary focus of this pilot trial is to assess feasibility to inform the design of the subsequent efficacy trial and the trial was powered to assess feasibility, not demonstrate efficacy, we only have 80% power to detect differences far larger than we expect to find in the subsequent efficacy trial. For example, taking an intent-to-treat approach, we have 80% power to detect differences of ≥0.68 SDs in weight change and the other exploratory outcomes. For example, if the SD=6.0%10,11 weight loss, we only have 80% power to detect differences in percent weight loss ≥4.1%, a difference 1.5-4 times larger than observed in previous research.

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). One method we may use will be in collaboration with a company called Build Clinical. Build Clinical is a technology company that enables academic researchers to engage the exact populations needed for a given study.[38] Build Clinical will create the advertisements and landing page as well place the digital ads on the various platforms across the Internet. Participants will learn about the research study through these digital ads that will appear

on the platforms they are on. If they are interested, they will click on the ad which will bring them to a landing page that will give them some more information about the study. From there, they can click on the link from the landing page which will bring them directly to survey where they can read the information sheet in full and complete the eligibility survey if they wish to.

Build Clinical's privacy policy states that they utilize managerial, physical, and electronic safeguards intended to protect the data that they gather (Personal Data) from unapproved access, use or dissemination. They use Secure Socket Layer (SSL) for authentication and encrypted communications to ensure users' trust and confidence in their Website and Services and are HIPAA compliant.[39]

Other recruitment methods we may use include strategies used in our previous remote trials.[40] Similar to Build Clinical, with these strategies, 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 in Facebook groups throughout the US. We will also use Research Match which connects volunteers to research studies.[41,42] To meet our goal of reaching males, we may also recruit on Reddit, where 74% of users are male.[43] 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;[44] N=240[45]; N=328[46]). 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
- Qualtrics recruitment panel: Participants on the Qualtrics panel meeting inclusion criteria will be recruited for this study.
    - On the first page of the survey, they will read a brief introduction about this project and if they complete the survey, they will receive Qualtrics incentives regardless of participation in this trial.
    - If they decide to hear more, they will click forward to the next page, which will be our information sheet.
    - If they would like to participate in the trial after reading that sheet, they will click forward to the next page and start the survey.

- Participants who provide their email will be contacted by the study team for the telephone screening.

With all above mentioned recruitment strategies, participants will be able to follow the link to the REDCap survey to complete the eligibility screening, except for BuildClinical. They will click on a link that will bring them to a landing page and the screening survey hosted by BuildClinical, 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.

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.

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 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 made an informed decision after learning about the research study. The contact information will be stored in a REDCap database. If a prospective participant decides to email us before going through the REDCap link, we do not collect that information. We will simply reply to their email(s). If they request to have those emails removed from our inbox, we will delete all correspondence with them and only will collect their email address in REDCap if they decide to provide us with that information during the eligibility screening process.

Study Timeline

This study will last for approximately 9-months from December 2022-August 2023 (3 for recruitment and on-boarding, 6 for the intervention, and 1 for follow-up assessments).

Timeline subject to change (depending on how long app refinements take prior to recruitment and how recruitment goes).

	Dec	Jan	Feb	Mar	Apr	May	Jun	July	Aug
Recruitment	X	X	X						
Intervention			X	X	X	X	X	X	
Follow-ups								X	X
Data management and analyses	X	X	X	X	X	X	X	X	X

Participant Time:

Participants will be in the study for 8-months, which will include the screening/onboarding phase, a 6-month intervention, and the follow-up survey, weigh-in, and focus group.

Study Phase	**Approximate Time (min)**
Screening Initial Screening Survey (15 min)	15
Baseline Orientation Webinar (60 min) E-consent (10 min) Baseline survey (20 min) Scale and app set-up (10 min)	100
Weight Loss Program Online weight loss group and mobile app use (6-months)/15 min/day (2,730) Monthly breakout sessions 45 min/month for 6 months (270)	3,000

Follow-up Weigh-in (5 min) Online survey (30 min) Focus group (60 min)	95
Total	3,210 minutes (approx. 54 hours)

Methods

Study Design: Participation starts with a simple information sheet, online eligibility survey, orientation webinar, e-consent, and then another survey to collect baseline assessment data. Eligible participants will then complete an on-boarding process, which includes app and scale set up. Participants will then be randomized and complete a 6-month intervention, and a 6-month follow-up assessment after the intervention ends (survey, focus group, and weigh-in).

Recruitment: We will post online recruitment ads that will contain a link to a simple information sheet and an online survey containing the screening questions. Ads that are done with Build Clinical will lead the participant to a landing page that will give them some more information about the study and then will have the link to bring them to the simple information sheet and survey. See recruitment section (starting on page 8) for full recruitment details.

Screening

Inclusion Criteria

- 18-65 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 posted/replied on Facebook at least once a week in the past 2 weeks

- Able to participate in the study in English
- Interested in losing weight

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

Exclusion Criteria

- Under the age of 18 and over the age of 65
- 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
- Did not post/reply on Facebook once a week over the past 2 weeks
- Not able to participate in the study in English
- Does not live in the United States
- Not interested in losing weight
- 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
- Has lost ≥5% of weight in past 3 months
- Is participating or intends to participate in another weight loss program during the study that provides coaching or problem solving
- Chronic pain that interferes with the ability to exercise

- Type 1 Diabetes
- Type 2 Diabetes
- Unable to make dietary changes or increase physical activity
- Unable to walk ¼ mile unaided without stopping
- Currently smokes or vapes nicotine
- No phone connectivity at home and work
- Has a digestive disorder/condition that precludes dietary changes
- Meets criteria for severe depression on the PHQ-8 (score of >19)
- Does not currently own a smartphone
- Smartphone type and/or version not meeting app requirements
- Participated in previous weight loss studies under the PI
- Unable to attend the orientation webinar
- If UConn employee/student, has concerns about being in a Facebook group 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 in the next 6-months
- Has an implanted cardiac defibrillator or pacemaker
- Did not complete screening and on-board processes of study (screening survey, webinar, e-consent, baseline survey, app set-up, scale set-up, etc.)
- Not willing to be audiotaped for focus groups
- Prisoner; or
- Unable to provide consent

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 that 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. BuildClinical also had logic to determine eligibility. If they are ineligible, they will be notified after the survey is submitted. If they are eligible to proceed, they will be contacted by the study team via email to book 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.

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. Participants will receive a link to access the webinar via WebEx (under UConn's WebEx license). Once the participants are logged into the webinar, the research coordinator/assistant 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 due to their inability to divert UConn phone lines to personal phones. We will not be recording any phone calls with Google Voice. Participants will be able to reach out to investigators as easily as standard calling. Participants do not need the app to contact the lab. It is important to note that some information may be retained on Google's active servers temporarily for billing UConn staff or other business purposes, and residual copies may remain in Google's backup systems. Anonymized copies of call record information, with no personally identifiable information, will be retained on Google systems to meet reporting and auditing requirements. However, this is no different than any standard phone plan.

Baseline

Participants that decide to complete the online consent process will be immediately sent the online baseline survey about demographics, depression, and weight loss problem

solving skills. 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.

After the baseline survey is completed, for those that are still eligible, UConn will ship a study scale to the participant. 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 the BMI has been confirmed, 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 engage in a series of emails with the participants to help them set-up the study apps and confirm they are working. If the participant prefers, the set-ups can be done over the phone as well.

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), and set-up all study apps 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 assistant/coordinator via email that they do not meet criteria for the study. Staff will use a generic response about how their pattern of responses is not a match to our eligibility criteria (the examples are provided in additional documentation). If they want to know specifics as to why they were ineligible, staff will refer the participant to email the PI so they can have a more detailed discussion about eligibility. This is being done to avoid upsetting participants and letting Dr. Pagoto, a clinical psychologist, handle communication of more sensitive information.

Intervention

Participants will be randomized into the Habit app or calorie tracking app program. Both programs are 6-month online weight loss interventions and involve these major components: 1) monthly group meetings, and 2) counselor-led Diabetes Prevention Program (DPP) lifestyle intervention delivered via private Facebook group. The Habit condition use the Habit app and the calorie tracking condition will use a commercial app for calorie tracking.

1. **Monthly Group Meetings**

During the 6-months of the intervention, the program will have monthly breakout sessions for participants to join via WebEx or within Facebook "rooms." Each month, the counselor and/or study staff will schedule a 45-minute event within the Facebook group that will allow participants to RSVP to, if they so wish. When they click on the event on the day/time it was scheduled for, they will be brought to the events tab in the Facebook group where they can click on the WebEx link and/or internal Facebook link to bring them to the breakout session. The counselor and/or staff member will be leading the sessions. Each month will be based on a topic around achieving a healthy lifestyle (or barriers to achieving a healthy lifestyle). The participants will have the option pick the topic for each week if they'd like. If not, the study team will pick a topic. The counselor will talk about the topic of the month and will promote discussion between participants. As needed, the counselor will pose discussion questions related to the topic of the week to help facilitate the discussion. The meetings will be recorded and posted in the Facebook group for those who missed. If they do not wish to be recorded, they will be able to leave the meeting and watch the video after it is posted in the group or turn their video off. The point of these breakout sessions is for group members to connect on a topic, do some brainstorming, and get to know each other better.

2. **Facebook Group**

Participants will be asked to join a private Facebook group where they will receive weight loss counseling based on the Diabetes Prevention Lifestyle Intervention (DPP). The Habit and calorie tracking app conditions will each have their own Facebook group. The group leader will counsel participants toward achieving and maintaining the exercise and diet goals to lose weight. The participants will also be asked to participate in the Facebook group by reading and engaging with the posts from the counselors. Additionally, they will be asked to engage with their fellow participants through comments, reactions, and posts. The participants will be able to privately message their counselor if they do not want to share something with the group. A detailed description of the how the Facebook group will operate is below.

The counselors in both groups will post at least two times a day in the private Facebook groups. Each week's content is based on the corresponding module of the traditional, in-person DPP (https://www.cdc.gov/diabetes/prevention/lifestyle-program/curriculum.html). The DPP assigns participants the goals of calorie tracking to achieve a calorie goal based on amount needed to lose 1-2 pounds per week, developing a healthy diet consistent with the American Heart Association guidelines, engaging in 150-300 minutes per week of moderate intensity exercise (i.e., brisk walk at 2.5-4 mph, bicycling, gardening, dancing, water aerobics, canoeing, playing doubles tennis. etc.), developing a strength training

regimen consistent with the National Exercise Guidelines, and losing 1-2 pounds per week. Goal setting happens on Mondays when the counselor posts asking participants to share their diet and exercise goals with the group. The counselor will suggest 2-3 goals each week—a behavioral goal (e.g., self-monitoring, problem solving), a diet goal (e.g., reduce added sugar) and an exercise goal (e.g., add 15 minutes of moderate intensity exercise on 3 days) to help participants progress toward the overall program goals. Weigh-ins happen on Fridays when the counselor posts asking participants to reply with their weight change in pounds for the week. This ensures participants are weighing themselves weekly and allows an opportunity for problem solving for participants not losing weight. Goal accountability happens each Sunday when the counselor posts asking participants to report how they did on the weekly goals. In between these key posts are posts related to the topic of the week (e.g., nutrition, making time for exercise) and posts relevant to the behavioral strategy of the week (e.g., slip tracking). Additionally, the coach may post periodic videos of themselves or study-related content to facilitate with building a relationship with the participants and to assist with stimulating engagement. We will also have a staff member from WPI in the Facebook group to assist with any technical issues that participants may have with Habit app. The counselors may attempt to re-engage any participants who stopping commenting or reacting in the Facebook group by tagging them in a post, private messaging, emailing, or calling them.

3. **Mobile Apps**

Calorie tracking participants will be instructed to track their diet and exercise using a commercial mobile app (MyFitnessPal) to achieve a negative energy balance at a level that produces 1-2 lbs. of weight loss per week. Habit participants will use the Habit app throughout the program.

MyFitnessPal App.

In the calorie tracking app condition, participants 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 use enter all the food and beverages they consume and their exercise with the purpose of staying under or at the calorie goal.

Habit App.

Daily weighing. Participants will receive a notification each morning to remind them to enter their weight for that day. Participants can edit the notification time if they choose to.

Slip Tracking Feature. The slip tracker helps participants identify triggers of diet and exercise lapses that they can then later address with the problem solver feature. For diet

slips, the user hits a button on the main screen when they have a trigger and/or slip and then completes a series of questions about the slip (e.g., where they were, what time, what they were doing, how hungry they are etc.). Once a day (participants can choose what time their daily notification pops up on their phone), the user receives a notification asking if they missed recording any slips to ensure all slips were recorded.

Exercise Planner: The exercise planner works such that at the beginning of the week, participants are asked to mark the days they plan to exercise on a calendar in the app. Then, the daily notification will ask the user if they exercised that day. If they did not exercise, it counts as a slip. The user will also be asked if they want to reschedule the exercise and the activity that occurred instead (e.g., sleep, work, sedentary leisure activity).

Insights: Participants can browse their Exercise, Weight, and Diet Slip History. They can look for patterns in terms of when they are likely to skip exercise, or slip in terms of their diet, the role of stress and poor sleep, and which activities they tend to do instead of exercise, where, when, and what time, they are more likely to have a diet slip. This provides insights into what is obstructing their exercise and diet intentions.

Problem Solving Feature. Participants will be asked to do problem solving. The participants will click on the 'problem solving' tab on the main screen and then selects 'solve a diet problem or 'solve an exercise problem', the next screen will ask them to identify their biggest problem with diet/exercise and then they will answer a series of questions to help the app provide tailored solutions to the participants. Participants will then pick a solution to work on for that week. They can access their current solution they are working on as well and set a reminder and access previous solutions worked on under the 'problem solving' tab in the app.

Weekly Check-ins. Participants will report their weight and if they accomplished scheduled solutions in the weekly check in. They can continue working on the same problems and solutions and/or select new ones. Participants who lost no weight will be prompted to try a new solution. Participants who have lost no weight but have accomplished their solutions will be prompted to select a new problem to work through. This will prevent participants from putting more energy into solving problems that when solved do not result in weight loss and to nudge them toward problems that when solved will result in weight loss. If a participant hasn't lost weight and has not executed their chosen solutions, they will be prompted to change the solution. This will help dislodge participants who are stuck. It might also prevent them from abandoning the app when a plan isn't working by guiding

them on what to do when stuck. The essence of problem solving is to keep iterating on new solutions until something works, so the app keeps the participant moving through that process.

Habit App Integration with the Facebook Group

Problem Sharing in the Group. When participants select a problem from the app but do not find a desirable solution, the app will provide an option for them to share the problem with others. The prompt will provide language the user can edit as they see fit (e.g., "I am working on [nighttime snacking]! I welcome ideas! Thanks!"). This will be copied onto the clipboard on their phone and then the participant can go into the Facebook group and post it.

Sharing Plans to Implement Solutions in the Group. Participants can also share their chosen solution with the Facebook group by clicking a button that brings up a dialogue box to edit (e.g., "I plan on [bringing my lunch to work] this week. My reminders are set for [7pm Sunday – Thursday]. Ask me how I'm doing this week!"). They can then press the "share" button which will copy the sentences from the dialogue box onto their clipboards on their phones. They can then go into the Facebook group and paste and post the language that was curated in the Habit app.

Sharing Successes in the Group. In the Habit app, when participants have successfully solved a problem and lost weight, they will have the opportunity to click a button to edit and then copy the wording in the Habit app onto their clipboard on their phone to share to the Facebook group.

Weigh-ins.

Participants will receive a Fitbit Aria scale mailed to them by the study team. This will allow them to take their weight weekly and at assessments. Weight is logged directly from the scale to the Fitbit app. Using a Wi-Fi scale will allow for a standard weight measure for each participant with a higher level of accuracy than self-reported weight. Weight is logged directly from the Fitbit scale to the participants' Fitbit account. Participants will be asked to set up a Fitbit account for the study and share login with the study staff so that the staff can record the weight taken. Study staff help the participants set-up their Fitbit scale if they need it and check their BMI once the scale is working. If a participant has a BMI under 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 and instructed to change their Fitbit password. If they already have a Fitbit account and choose not to create a 2nd one for the study, they may choose to share that login with the study staff. If they choose not to share their login for the duration of the study, they will be allowed to upload

screenshots of their weight to a secure REDCap link. Study staff will delete the screenshot from REDCap once the weight has been logged into the record.

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

Focus groups. A focus group will occur in a WebEx setting starting the week after the end of the intervention. The focus group will last for approximately 30-60 minutes (depending on how many participants are in attendance) and will include a discussion about likes and dislikes of the intervention as well as their opinion on various features of the app and intervention. All focus groups will be conducted via WebEx including 1-4 participants on each call. Any participants who are unable to attend the focus group will receive the focus group questions through an e-mailed survey. We will e-mail the survey twice. At the time of the 2nd e-mail, we will also text them to let them know to check their e-mails. If there is no response from the participant after the 2nd e-mail, we will make no further attempts to contact them. The focus groups will be recorded on WebEx and then will be transcribed using Otter.ai, a web-based transcription software.

Adverse Events. Adverse events will be documented during the intervention and follow-up phase. AE's will be formally assessed at follow-ups 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. UConn will then report it to the IRB (immediately if it's serious, or at the time of annual renewal). If participants gain 5% or more weight during the intervention, this will be treated as an adverse event. The participant will receive a phone call from a 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.

After we have completed all data analysis for the study, and it is put into a master dataset we will delete the Facebook group.

Measures

Data Collected	List of Measures	Screening/ Baseline	6-month pilot	F/up	Method
Inclusion/Exclusion criteria	Initial screening survey*	X			REDCap or Qualtrics
BMI	Height	X			REDCap
	Weight	X	X	X	REDCap
Demographics	Marital status, education, race/ethnicity, sexual orientation, work status, household income, household members*	X			REDCap
Binge Eating Disorder	SCID Eating Disorder Examination Questionnaire[47]		X**	X**	REDCap
Depression	Patient Health Questionnaire (PHQ-8[48])	X			REDCap
Weight Loss Problem Solving Skills	Social Problem-Solving Inventory-Revised (Modified for weight loss) [49]	X		X	REDCap
Group Climate Questionnaire	Group cohesion[51-56]			X	REDCap

Engagement	Facebook Engagement		X		Grytics into REDCap
App use	App use data*		X		WPI server and REDCap
Diet tracking	Data extraction*		X		MFP records
Usability Feedback	Acceptability, contamination, satisfaction, burden*, and user engagement[50]			X	REDCap and focus group

* = investigator derived

** = as needed for AEs

Psychometric properties for non-investigator derived measures:

SCID Interview for BED: The SCID's severity scales demonstrated substantial internal consistency (all Cronbach's alphas >.80), test-retest reliability, concurrent, and predictive validity.[47]

Patient Health Questionnaire (PHQ)-8: The PHQ-8 is an 8-question measure like PHQ-9 (with the omission of one question). The 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.

Social Problem-Solving Inventory-Revised: The internal consistency reliability (Cronbach's α 0.95) was high. The SPSI-R score was significantly associated ($p < .05$) with various subscales from calories, exercise, distress, and quality of life suggesting concurrent validity.[49]

The User Engagement Scale Short Form (UES-SF): The UES-SF has shown to be statistically reliable ($\omega = 0.88$).[50] Furthermore, each subscale highly correlates with the remaining items in the scale. This suggested that each subscale can accurately represent the value of the

components from which the subscales were derived. Accordingly, these items were defined to be the UES-SF and were taken forward for evaluation.[50]

Group Climate Questionnaire Short: The GCQ-S is a 12-item questionnaire with 3 subscales: engagement, avoidance, and conflict.[51] Construct validity of the GCQ has been comprehensively examined and has been shown to be strong.[52-55] Cronbach alpha levels for the subscales of the GCQ were high at .94 for engagement, .92 for avoidance, and .88 for conflict.[56]

Analytic Plan

Data will be analyzed using an intent to treat approach. For missing data, 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. If more than 5% data missing, we will use multiple imputation.[57] We will use IBM SPSS Statistics for Windows, Version 27.0. (Armonk, NY: IBM Corp.) and STATA 17 (College Station, TX: StataCorp LLC.).

Recruitment. We will report numbers and reasons for exclusion using a CONSORT diagram,[60, 61] and we will compare recruitment sources by gender and race/ethnicity yields.

App use. In the Habit app condition, descriptive statistics will be performed to summarize the number of days participants used each feature. These numbers will be inspected relative to the use targets defined for each feature. In the MyFitnessPal condition, descriptive statistics will be performed to summarize the mean number of days participants used MyFitnessPal over the 6-month intervention. A total “app compliance” score will be developed for each participant based on the percent of days they completed of their assigned use. Exploratory analyses using ANOVAs will compare conditions on app compliance scores at 6 months.

Retention. We will calculate retention as the proportion of participants who complete the 6-month follow-up assessment in each condition and report this information using a CONSORT diagram.

Engagement. Number of Facebook reactions (e.g., like, care, wow, etc.), replies, posts, and polls per participant during the 6-month program.

Acceptability. We will report participant satisfaction.

Burden. Using descriptive statistics, we will summarize burden scores in both treatment conditions. ANOVAs will be used to compare conditions on burden.

Group Cohesion. Using ANOVAs, we will compare conditions on group cohesion and climate total and subscale scores at 6 months.

Contamination. We will report the percent of participants that used any outside programs that provided weight loss coaching/problem solving.

Weight Change (exploratory). We will calculate weight changes from baseline to 6 months in each treatment condition. We will compare percent weight change from baseline to 6 months across the two treatment conditions using a mixed effects model approach with weight as the continuous outcome variable, and time as a covariate using percent weight change calculated from all available objectively measured weekly weights. To adjust for within-subject correlation in the mixed model, first we will estimate an unstructured within-subject covariance matrix; estimates may suggest that a simpler structure, e.g., compound symmetry (random intercept) is satisfactory.

Changes in weight loss problem solving. Using a mixed effects model with weight loss problem solving as the continuous outcome variable, we will compare conditions in change in weight loss problem solving from baseline to 6 months.

Group cohesion. Using ANOVA, we will compare conditions on group cohesion measures at 6 months.

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, app set-up, and scale set-up, join the Facebook group), 2) become pregnant during the study period, 3) post inappropriate content in the Facebook group (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 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 asked to complete the follow-up assessments.

Potential risks

Potential risks for being in this study includes injury while exercising, accidental exposure of personal information, and discomfort with study procedures (e.g., feeling uncomfortable

with some questions asked on a survey or answering in a focus group). 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 told to go see their PCP. Injuries are unlikely to occur since we screen out medical conditions that could make someone prone to injury and we only suggest moderate activity. Moderate-level physical activity is 3.0 - <6.0 METs, which includes activities such as walking briskly (2.5 to 4 mph), playing doubles tennis, or pushing a lawn mower. 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. Regarding the focus groups, they can request a one-on-one interview with study staff, or we can provide them with an alias in the focus group so others will not know who they are. 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 the exercise and lifestyle changes and improvements in mental, physical, social, and emotional health. Through interacting with other participants and the counselor in the Facebook group, 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 moderate activity 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). 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. Focus groups can be done one-on-one or use an alias to hide their identity.

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 in the form of online Amazon gift cards. Participants will receive $100 for completing the follow-up assessments which involve a weigh-in, survey, and focus group. The procedures for each assessment will need to be completed before providing compensation. Additionally, participants may keep the study scale provided to them.

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

Data Safety Monitoring

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

I. Frequency of monitoring

During the pilot phase data reports will be reviewed and sent to the two safety officers once follow-ups have been completed and will include the following reports:

Recruitment rates and adherence to inclusion/exclusion criteria, and ethnic diversity goals:

Recruitment progress, including baseline characteristics, will be reviewed. This review will ensure that project deadlines are being met, that participants meet eligibility criteria, and that the ethnic diversity goals are being met. Recruitment progress is monitored weekly.

Adherence to study protocols:

Quality control will be conducted in all phases of the project. The Facebook group will be monitored daily for intervention protocol adherence.

Adverse events:

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

Participant retention

Engagement will be tracked during the intervention, and completion of follow-ups will be documented. Participants will be reminded of upcoming study assessments. If a participant chooses to drop from the intervention, they will be given the option to skip the rest if the intervention, but still complete the follow-up. Retention is reviewed and discussed throughout the study and at follow-up.

Data review (completeness/outliers):

Data reports will be reviewed by the data manager, program director, statistician, and PI. Reports will include completeness of data; missing information within surveys; descriptive information for each endpoint without statistical testing; and quality control analyses for primary outcome. Data will be cleaned at the end of the study. A data review report will be provided to the IRB after the study is over and the team has time to create the report and sent off to the study sponsor (NIH).

II. AE reporting process

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. Safety monitoring procedures will be documented in a standard protocol and overseen by the PI and coordinator. Any adverse events will be immediately reviewed by the coordinator. The safety officers will be informed of all adverse events during data review. Serious adverse events will be communicated immediately to the PI and safety officers. The NIH and UConn IRB will be notified immediately in the event of serious adverse event. Any death of a study participant will be reported to the NIH and UConn IRB whether or not it appears to be related to the study.

III. Safety Monitoring Committee

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

Privacy and 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 study apps and Facebook group. We will encourage them throughout the study to use each app and 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 and focus group, 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 and use an alias during the focus group).

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 and see each other's names and profile picture, 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. Any participants will be marked ineligible during screening/baseline if they do not wish to use Facebook 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 (aside from focus groups). Surveys are provided to them through secure links via REDCap that is unique to each participant.

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 will use Otter.ai transcription software to produce transcripts. Otter.ai retains no ownership rights to the recordings or transcripts. Staff will verify and edit the transcripts and then save the de-identified transcripts to the research drive on the UConn servers and delete the recordings from the drive and the Otter.ai platform. Please refer to these two sections of the terms of service and privacy policy: Terms of Service; Section 9 and specifically Section 9.3: https://otter.ai/terms: In summary, research team retains right to audio recordings and controls how the content is processed, transported, and distributed on the otter.ai platform. Once we delete the recordings from our trash, they are permanently deleted from platform. And from Section 2 of Privacy Policy: https://blog.otter.ai/privacy-policy/ “We train our proprietary artificial intelligence technology on aggregated, de-identified audio recordings. Only with your explicit permission will we manually review certain audio recordings to further refine our model training data.”. 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.

UConn IRB and their representatives as well as the study sponsor (NIH) will have access to the research data if requested.

Worcester Polytechnic Institute (WPI) will be able to see PII via the app use data that is entered into the Habit app that they can view on the backend. Additionally, study staff from WPI will join the Facebook group to assist participants with any Habit app issues. They all have had CITI training at WPI, will be approved personnel, and will not have a link to their study ID. Also, it is possible that participants in this study know each other.

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.

The research assistants/coordinators will by sending a link via email to obtain consent.

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 webinar process prior to consent 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 PI who will determine whether to exclude the participants on this basis.