UConn
IRB-1 Study Protocol Form
October 2021

IMPORTANT - Please review the following items before you prepare the protocol application. It will facilitate review of the study:

- Review the Researcher's Guide section of the OVPR website (https://ovpr.uconn.edu/services/rics/irb/researcher-guide/) for information and guidance concerning computer/internet-based research, consent, deception, recruitment/advertising, etc.
- Review this form in its entirety *before* completing it.
- Read each item carefully and provide the information requested *where* it is requested.
- Please contact the Research Compliance Services at 6-8802/0986 or irb@uconn.edu with any questions.

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

9/14/2023

Study Protocol Title: Mentoring in mHealth and Social Networking Interventions for CVD Risk Reduction: Intervention Phase

Does this study involve one or more collaborating institutions, as listed on the IRB application in InfoEd?

☒ No

☐ Yes-> Please check the appropriate box regarding IRB review:

☐ Each site has or will obtain their own local IRB approval (please upload available IRB approval letters with this submission).

or

☐ One IRB (sIRB) is being requested to serve as the IRB of record for this study. Identify:

☐ UConn

☐ External, identify:

Clinical Trial/GCP Training

Is this a research study in which one or more human subjects are prospectively

assigned[1] to one or more biomedical or behavioral interventions[2] (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes[3]?

☐ No ☒ Yes → This is a clinical trial

Federal Funding requirement:

Is this clinical trial funded by a federal department or agency (NIH, DoD, etc.)?

☐ No/Not Applicable ☒ Yes → The Revised Common Rule requires that a federally-funded clinical trial consent form be publicly posted "after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject." Consent forms can be posted on Regulations.gov or ClinicalTrials.gov. For assistance with ClinicalTrials.gov, contact Ellen Ciesielski.

NIH Funding requirements:

Is this clinical trial fully or partially funded by the NIH?

☐ No/Not Applicable ☒ Yes →

Have the required key personnel completed Good Clinical Practice (GCP) Training?

☐ No ☒ Yes

Is this clinical trial registered on ClinicalTrials.gov?

☒ No ☐ Yes

NIH-funded clinical trials must be registered within 21 days of enrollment of the first participant. Please contact Ellen Ciesielski for assistance.

FDA requirement (all funding sources):

Does this clinical trial evaluate at least one drug, biological, or device product regulated by the United States Food and Drug Administration (U.S. FDA)?

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[1]The term "prospectively assigned" refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.

[2]An intervention is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive/behavioral therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.

[3] 3.Health-related biomedical or behavioral outcome is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical or behavioral status or quality of life. Examples include: positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and /or information retention, behavioral intervention for psychiatric symptoms); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and, positive or negative changes to quality of life.

☒ No/Not Applicable ☐ Yes → **Regardless of funder**, federal law requires registration and results posting of this clinical trial in ClinicalTrials.gov. Please see the ACT checklist to confirm, and contact Ellen Ciesielski for assistance.

Purpose/Introduction:

State the reason for the study, the research hypothesis, and the goals of the proposed study as related to the research question(s):

The behavioral strategy that most strongly predicts weight loss in behavioral weight loss programs is dietary tracking,[1] a task that involves having participants record everything they consume (food and beverage) every day using a mobile app. Once participants lose weight, they can discontinue tracking and restart only when they begin to regain weight. However, dietary tracking is a burdensome task and adherence declines precipitously during a weight loss program, even long before participants have met their weight loss goals.[2,3] Our data show that by the end of a weight loss program, only a small minority of participants are still tracking. Given how strong of a predictor of weight outcomes that diet tracking is, we need to identify ways to enhance tracking adherence. The goal of this study is to randomize participants into 3 groups that vary based on their diet tracking prescription to explore ways to potentially improve adherence to dietary tracking.

One way to increase adherence to diet tracking may be to schedule "breaks" in diet tracking. Breaks might not only ease the burden of diet tracking but also give participants a chance to practice healthy diet skills without tracking which might boost their confidence in their ability to eat healthy on their own. The drawback of tracking breaks though is that participants might lose their tracking momentum and have difficulty restarting after the break. No studies have examined different tracking prescriptions so we know very little about how people will respond to them. In the present study, we will conduct an 8-week weight loss intervention in which participants will take part of a Facebook Diabetes Prevention Program (DPP), weigh-ins, assessments and be randomized into 3 different tracking prescriptions, one being the traditional prescription of daily tracking and the other two involving different schedules of breaks.

The **Daily Tracking Group** will be given the traditional prescription of tracking every day during the 8-week intervention. The **1 On/1 Off Tracking Group** will be asked to track every day for a week, then to take a week off, and so on throughout the 8 weeks. This group will then track on weeks 1, 3, 5, and 7 for a total of 4 weeks of tracking. Although this group will only be tracking at the most 50% of the time, our previous study found that tracking 40% of the time was the threshold needed to lose ≥5% of weight which is the lower end of the program weight loss goal (5-10%). The **2 On/1 Off Tracking Group** will be asked to track every day for 2 weeks, then to take 1 week off, and so on throughout the 8 weeks. This group will then track on weeks 1, 2, 4, 5, 7, and 8, for a total of 6 weeks of tracking. Although this group will only be tracking at the most 67% of the time, our previous study found that tracking 67% of the time was the

threshold needed to lose ≥10% of weight which is the high end of the program weight loss goal (5-10%).
All three groups will be asked to continue their schedule of tracking in the month following the 8-week intervention (i.e., 12 weeks). We will compare groups on weight loss at 8 weeks, total days of tracking over 8 weeks, % who adhered to their prescription during the 8 week program, % who tracked <50% of the time, % who tracked >50% of the time, % who tracked >67% of the time, tracking burden, tracking enjoyment, intentions to continue tracking past 8 weeks, number of days tracked in the subsequent month, and weight loss at 12 weeks. Findings will inform a fully powered clinical trial of tracking prescriptions during a full-length weight loss program (6 months in duration).

Provide a clear and succinct summary description of the background information that led to the plan for this project:

Lifestyle interventions are effective at producing modest weight loss.[4] One of the strongest predictors of weight loss is food tracking[5], which involves logging all food and beverage consumed each day in an effort to stay within a daily calorie goal. Standard lifestyle interventions prescribe daily food tracking for the length of the program which can range from 3-24 months[6]. This can be a taxing prescription that is not feasible to do long term for many people[7]. In a study of an 8-week mobile app-delivered lifestyle intervention, food tracking declined from six days per week at week 1 to two days per week at week 8[8]. Another study of a 12-week lifestyle intervention found that 68% of participants were consistently tracking in the first week, but this number fell to 21% by 12 weeks[9]. Randomized trials of 6-month lifestyle interventions have reported mean tracking frequency of about 50% of intervention days[8,10], which is far below the daily prescription. In spite of modest adherence to food tracking in lifestyle interventions, it remains a strong predictor of weight loss[8].

Many studies show an association between food tracking and weight loss[11-13], but it remains unclear *how much* tracking is necessary to achieve different weight loss milestones. Some studies have examined the association between various thresholds of food tracking and weight loss. For example, one study showed that tracking at least 6 out of 7 days on at least 9 out of 12 of weeks of a lifestyle intervention was associated with greater weight loss and greater odds of losing clinically significant weight (i.e., ≥5%)[9]. Specifically, 48% of participants who met that tracking threshold lost ≥5% compared to 13% of participants who fell below that threshold. Another study classified participants in a 12-month lifestyle intervention as “rare trackers (n=25),” defined as having tracked <33% of days, “inconsistent trackers (n=5),” defined as having tracked between 33-66% of days, or “consistent trackers (n=15),” defined as having tracked >66% of days[14]. They found that consistent trackers lost significantly more weight than the other two groups and sustained their weight loss over time whereas the other two groups did not. Together, these studies suggest that the prescription to track everything all the time results in very few people actually doing so, but those who track one-half to two-thirds of the time appear to lose significantly more weight than those who track less.

One approach to improving food tracking adherence is to reduce the burden of the task by simplifying the prescription. Simplification may involve reducing the frequency (e.g., 5 days a

week versus every day) or reducing the amount of intake to track (e.g., some foods/meals vs all foods/meals). To reduce burden, some studies had participants track diet patterns or servings of food groups (instead of calories) and others had participants track by taking photos of their food[13]. A recent systematic review found that 3 out of 4 studies using such abbreviated food tracking approaches reported an association between food tracking and weight loss[13], which is evidence that the prescription of tracking everything all the time may not be necessary[15]. The only approach to tracking that was not associated with weight loss was where participants took photos of foods[16], which suggests this approach may be too far afield from the traditional tracking method to produce meaningful impacts on weight.

We recently conducted an analysis of 153 participants of a digitally delivered weight loss program and found that the optimum threshold of diet tracking that predicted ≥3%, ≥5%, and ≥10% weight loss at 6 months was tracking on 28.5%, 39.4%, and 67.1% of intervention days, respectively. That participants could track about two-thirds of the time and still lose 10% of their baseline weight is an encouraging sign that perfect food tracking adherence is not necessary to be successful. Because participants can reach the weight loss goal while tracking 40-67% of the time, perhaps tracking prescriptions that match those levels would result in less burden and the same or higher success rate. The purpose of this study is to test this very question.

Provide references as appropriate and, when applicable, previous work in animal and/or human studies:

References are provided at the end of the protocol.

Provide previous UConn protocol number, if applicable:

N/A

For each participant population proposed for this study, what is the total # of participants (or, for record reviews, total # of records) required to answer the study question:

The total number of subjects that will be enrolled into the study is 108. It is estimated that we will screen ~1,500 participants to achieve this recruitment goal. Since the initial contact is via an online link, there will be many incomplete responses driving up the number of screened-out participants.

Justification of Sample Size:

For qualitative and pilot studies, describe how the proposed sample size is appropriate for achieving the anticipated results. For quantitative studies, provide a power analysis that includes effect size, power, and level of significance with references for how the sample size was determined. Explain the rate of attrition and possible number who fail the screening, with references as appropriate.

Leon et al state "power analyses should not be presented in an application for a pilot study that does not propose inferential results."[17] As they and others recommend,[17,18] we based the sample size of 108 on necessities for examining feasibility thus identifying modifications required to the trial design or study procedures before conducting the full-scale factorial trial. Having 108 participants allows us to recruit online groups of 36, which our previous work shows is feasible and breeds regular engagement.

Enrollment of UConn Students and/or Employees:

Will UConn students be enrolled?

☐ No ☒ Yes -> Is it possible that any of the listed study key research personnel teach, or are supervisors of, any of the students?

☒ No ☐ Yes -> Provide justification for inclusion of this population, provide name of the member of key personnel, and explain how undue influence and bias will be prevented:

Will UConn employees be enrolled?

☐ No ☒ Yes -> Is it possible that any of the employees report to one or more study key personnel?

☒ No ☐ Yes -> Provide justification for inclusion of this population, and explain how undue influence and bias will be prevented:

UConn students and employees may be enrolled if they meet eligibility requirements and are interested in completing the study. Students or employees that report to, are taught by, or have supervisors on key personnel of this project will be excluded from participation.

Enrollment of Key Personnel, Spouses or Dependents/Relatives:

Will study key personnel, spouses of study key personnel, or dependents/relatives of any study key personnel be enrolled in the study?

☒ No ☐ Yes -> Specify, provide justification for inclusion of this population, and explain how undue influence and bias will be prevented:

Recruitment procedures:

For each participant population, provide full detail:

How will the participants be notified or approached about the research (include copies of all recruitment tools, in any media)?

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.[19] 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 the 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.[20]

Other recruitment methods we may use include strategies used in our previous remote trials.[21] 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 on Facebook groups throughout the US. We will also use Research Match which connects volunteers to research studies.[22,23] To meet our goal of reaching males, we may also recruit on Reddit, where 74% of users are male.[24] 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;[25] N=240[26]; N=328[27]). 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.

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 people of other 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 30% minority participants. 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 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.

How will participants notify the study team of their interest in being in the study?

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.

Anticipated Study Time Frame:

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

This study will last for approximately 9 months from October 2023-June 2024. See approximate timeline below.

The timeline is subject to change (depending on how study start up and recruitment goes).

	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun
Recruitment	X	X	X						
Intervention				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 approximately 4 months, which will include the screening/onboarding phase, an 8-week intervention, and the follow up assessments.

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) Baseline survey (15 min) Scale and app set-up (10 min)	95
<u>Weight Loss Program</u> Online weight loss group and mobile app use (8-weeks)/15 min/day (840 min)	840
<u>Study follow-up #1 (week 9)</u> Weigh-in (5 min) Online survey (15 min) <u>Study follow-up #2 (week 12)</u> Weigh-in (5 min)	25
Total	960 minutes (approx. 16 hours)

Design, Procedures, Materials and Methods:

Describe the study design, including all study procedures in the order they are being conducted, and scheduling/time required for each. Experimental procedures should be clearly described and labeled as such. If the study uses control or experimental groups, or different treatment arms, provide details for each. Include flexibility in the study design where possible (e.g., timing of study visits should be reflected in terms of approximate, rather than a specific # of days apart, etc.) If this study offers treatment for the participants' condition, complete the Treatment Study Supplemental Form (IRB-1C) and attach it to this application for review. Use of a table is often helpful for this section.

Note:

- Where platforms such as Zoom are being used, indicate if the use will be under UConn's agreement/license with the vendor.
- Be sure to provide copies of **interview and focus group** questions/topic areas with your submission.
- If the study includes **measures, survey instruments and/or questionnaires (including the collection of demographic data),** identify each, specify if created for the study, and provide copies with your submission.
- If applicable, describe and justify the use of **digital and/or video recordings** and indicate if this is a requirement of participation.
- If the study involves use of **deception or incomplete disclosure**, include explanation of why this intervention is necessary to meet the study aims, and complete the alteration of consent section later in this application.

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 MyFitnessPal and scale set up. Participants will then be randomized (stratified by gender) and complete an 8-week intervention, and then two assessments at 9-weeks (weigh-in, survey) and 12-weeks (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 participants 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 the recruitment section (starting on page 6) for full recruitment details.

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. 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. 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 R 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 the online baseline survey about demographics, nutrition literacy[28], depression, and history of

weight loss attempts and use of diet tracking and diet tracking apps. 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 participants. 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 app and confirm they are working. If the participant prefers, the set-ups can be done over the phone as well.

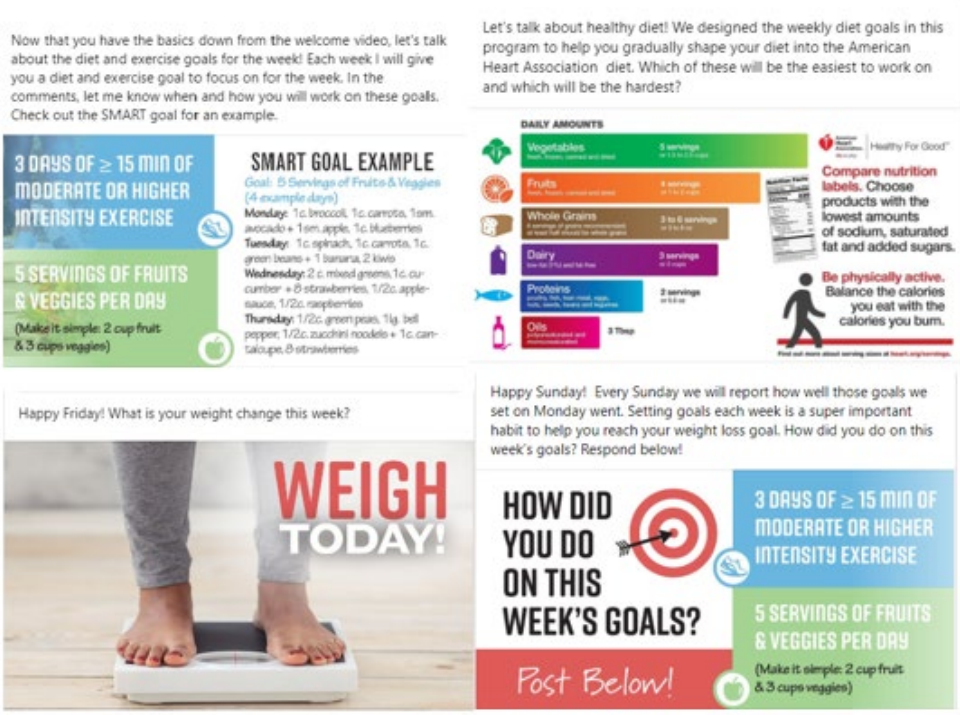
Participants will need to complete both surveys (screening and baseline), webinar, consent, set-up the scale and provide the study team with a baseline weight to confirm BMI (done with scale we ship to them), and set-up all study apps before being randomized into the trial. Participants will be randomized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

Intervention. All participants will join an 8-week counselor-led (counselors go through the DPP lifestyle coach training) Diabetes Prevention Program (DPP) lifestyle intervention in a private Facebook group. Depending on which group participants are randomized to will determine which Facebook group they join. The DPP content will stay the same across all groups. Participants will also be asked to track their diet and exercise on MyFitnessPal as part of the program. Participants will be randomized into one of three groups that differ regarding dietary tracking. Group One will be called the **Daily Tracking Group** and will be asked to track their diet every day in the program. Group Two will be called the **1 On/1 Off Tracking Group** and will be asked to track every other week which would result in 4 weeks of tracking and 4 weeks off from

tracking. Finally, Group Three is called **2 On/1 Off Tracking Group** and will be asked to track for 2 weeks, then they will get a 1-week break and repeat that pattern until the end of the program.

Facebook Groups. The DPP lifestyle intervention will be delivered within all three counselor-led Facebook groups with twice daily pre-programmed posts as in our previous studies (see 4 sample posts below).[27,29,30,31] 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 coach/study team will also post about MyFitnessPal to give them tips/tricks with their tracking and remind the relevant groups which weeks they are tracking and are not tracking. 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.

MyFitnessPal. All participants regardless of which group they are randomized into will be asked to use MyFitnessPal, the differences in the groups are the rate of which they track. 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. On days they are tracking, 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. Participants will use the free version of MyFitnessPal for this study.

Weigh-ins. Participants will receive a Wi-Fi 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 an app designed for the scale. 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 scale to the participants' account. Participants will be asked to set up an account for the study and share login with the study staff so that the staff can record the weight taken. Study staff will help the participants set up their 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 password. 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/Assessments: The follow-ups/assessments will occur at the 9 and 12-week marks after the intervention has begun. At the 9-week mark (the week after the program ends), 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. Then, at both the 9 and 12-week assessments, the participants will also weigh in. At the 12-week assessment, we will also collect their MFP diary entries, but that does not require the participant to do anything. 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 the 9-week assessment 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 and/or email 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	8-week Intervention	F/up #1	F/up #2	Method
Inclusion/Exclusion criteria	Initial screening survey*	X				REDCap or Qualtrics or BuildClinical
BMI	Height	X				REDCap
	Weight	X	X	X	X	REDCap
Demographics	Marital status, education, race/ethnicity, sexual orientation, work status, household income, household members*	X				REDCap
Nutrition Literacy	The Nutrition Literacy Assessment Instrument (NLit)[28]	X		X		REDCap
History of Weight Loss	Weight loss attempts*	X				REDCap

	Use of diet tracking* Use of diet tracking apps*					
Binge Eating Disorder	SCID Eating Disorder Examination Questionnaire[32]		X**	X**		REDCap
Depression	Patient Health Questionnaire (PHQ-8[33])	X				REDCap
Engagement	Facebook Engagement*		X			Grytics into REDCap
Diet tracking	Data extraction*		X		X	MFP records
Diet Tracking Acceptability (0-10 scales)	Difficulty* Time Consuming* Helpfulness*			X		REDCap
Intervention Feedback	Burden* Contamination*			X		REDCap
Adverse Event Assessment	Adverse Events*			X		

* = investigator derived
** = as needed for AEs

The Nutrition Literacy Assessment Instrument: The NLit demonstrated both factor validity and reliability (0.97, CI =0.96–0.98) as well as test-retest reliability (0.88, CI=0.85–0.90).[28]

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.[32]

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.[33] Together, this data shows the PHQ-8 is as valuable as the PHQ-9.

Data Analysis

For all studies, specify the analytic techniques the researcher will use to answer the study questions. Indicate the statistical procedures (e.g., specific descriptive or inferential tests) that will be used and why the procedures are appropriate. For qualitative data, specify the proposed analytic approaches.

Intervention prescription. We will report the % of participants meeting the prescription. % of participants who are high trackers (tracked >70% of the time), medium trackers (tracked 40-69% of the time), and low trackers (tracked <40% of the time).
Recruitment. We will report numbers and reasons for exclusion using a CONSORT diagram and we will compare recruitment sources by gender and race/ethnicity yields.
Retention. We will calculate retention as the proportion of participants who complete the follow-up assessments 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 program.
Diet tracking prescription acceptability. We will report on the difficulty level, time consuming, and helpfulness of tracking prescription, as well as intentions to keep tracking in the next month.
Nutritional Literacy. We will report on the % who are considered likelihood of poor nutrition literacy, possibility of poor nutrition literacy, and likelihood of good nutrition literacy.
History of Weight loss attempts, diet tracking and diet tracking apps. Using descriptive statistics, we will summarize those who have a history of weight loss attempts, and use of diet tracking and diet tracking apps.
Amount of tracking. We will report the amount of tracking participants did throughout the intervention as well as one month following the intervention.
Contamination. We will report the percentage of participants that used any outside programs that provided weight loss coaching or another app to help with weight loss/exercise.
Burden. Using descriptive statistics, we will summarize burden scores in both treatment conditions. ANOVAs will be used to compare conditions on burden.
Weight loss. We will calculate weight change from baseline to 8 weeks as well as baseline to 12-weeks. As this pilot trial is not powered to detect differences, average changes will not be compared by treatment condition.

Inclusion/Exclusion Criteria

List ALL inclusion and exclusion criteria. Any proposed exclusion criterion based on gender (women of childbearing potential), age, or race must include rationale for the exclusion.

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

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

- 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
- 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 twice a week or more
- 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
- Participated in previous weight loss studies under the PI
- Unable to attend the orientation webinar
- 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.)
- Is a student and/or staff of the PI.

Removal from Study

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

☐ N/A

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 threatening or disturbing 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 Harms/Risks and Inconveniences:

Describe the potential risks to participants (and secondary participants, if applicable) and *steps taken to minimize risks* for each participant population. For each risk, you must assess the likelihood of occurrence, and, if it were to occur, the associated severity. Types of risks to consider include, but are not limited to: physical, psychological, social, legal, employment, and financial.

☐ N/A (no foreseeable risks anticipated) or,

Describe any anticipated inconveniences the participants may experience (such as: their time, abstention from food, etc.)**:** ☐ N/A

Potential risks for being in this study includes injury while exercising and/or cardiovascular event, accidental exposure of personal information, and discomfort with study procedures (e.g., feeling uncomfortable with some questions asked on a survey or something someone said in Facebook group). 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. 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.

Benefits:

Describe anticipated benefits to the individual participants. If test results will be provided, describe, and explain procedures to help participants understand the results. Identify who provides results to participants. If individual participants

may not benefit directly, state so here. Do not include compensation or earned course credits in this section.

Participants may or may not benefit from participating in the study. Benefits that could occur are losing weight through 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.

Describe anticipated benefits to society (i.e., added knowledge to the field of study) or a specific class of individuals (i.e., athletes or autistic children).

Societal benefits include providing evidence to support more sustainable yet still effective ways to help people achieve healthy lifestyle goals and improve the outcomes of their health.

Risk/Benefit Analysis:

Describe the ratio of risks to benefits. Risks to research participants should be justified by the anticipated benefits to the participants or society. Provide your assessment of anticipated risks to participants and steps taken to minimize these risks, balanced against anticipated benefits to the individual or to society.

The possible risks of the study 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). 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:

Will there be any costs to the participants?

☒ No ☐ Yes -> Describe:

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/Course Credit to Participants:

Will there be any payment or course credit to the participants?

☐ No

☐ Yes -> ☐ Payment ☐ Course Credit

- What is the amount of payment/course credit? Please describe below.
- Describe the scheduling of payment/course credit, i.e., how the amount will be prorated across the duration of the study:

Participants will be paid in the form of online Amazon gift cards. Participants will receive compensation at two points in the study. The participants will receive $50 for completing the first follow-up assessment (the week after the intervention ends) which includes a weigh-in and a survey. Further, participants will receive $25 at the second follow-up assessment (one month after the intervention ends) which includes a weigh-in. Payment will be in the form of an online gift card paid after the follow-up procedures are completed at each time point. The procedures for each assessment will need to be completed before providing compensation. Additionally, participants may keep the study scale provided to them.

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

Data Safety Monitoring

(Complete this section for research that is greater than minimal risk, i.e., anticipating full board review)

☐ N/A (research is minimal risk to the participants)

Describe your data safety monitoring plan:

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

1. Frequency of monitoring

The data report for the 8-week intervention will be sent to the two safety officers once follow-ups have been completed. Recruitment is monitored daily during the recruitment phase by the research coordinators and research assistants. All surveys are monitored once submitted to REDCap within 48 business hours by the research coordinators and research assistants. The

Facebook group is monitored daily by the coaches. Weigh-in submissions are monitored weekly by the research coordinators and research assistants. App usage is monitored weekly by the research assistants, research coordinators, and the data managers. All data is continuously reviewed by the data managers.

2. Safety Monitoring Committee

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

3. What data will be monitored:

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

Recruitment progress, including baseline characteristics, will be reviewed. This review will ensure that project deadlines are being met, that participants meet eligibility criteria, and that the ethnic diversity goals outlined in the grant proposal are being met. Recruitment progress is monitored weekly, and a final report will be provided in the safety report.

Adherence to study protocols:

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

Adverse events:

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

Participant retention

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

Data review (completeness/outliers):

Reports will include completeness of data (visits completed, % of expected forms submitted, % of submitted forms passing edit); missed visits and missing information within visits; descriptive

information for each endpoint (change in weight and physical activity) without statistical testing; and quality control analyses for primary outcome (change in weight). Data will be cleaned at the end of each phase (screening, intervention, and follow-up). A final data review report will be provided in the safety report.

4. Data evaluated for problems

Data reports will be reviewed by the data manager, statistician, and PI.

5. Actions taken during certain occurrences

Baseline participants who report conditions that could create a safety concern while receiving the intervention will be excluded. Adverse events that occur during the intervention will be assessed, recorded, and followed up until resolved. Safety monitoring procedures will be documented in a standard protocol and overseen by the PI and program director. Any adverse events will be immediately reviewed by the program director. The safety officers will be informed of all adverse events during data review. Serious adverse events will be communicated immediately to the PI and safety officers. The NIH and UConn IRB will be notified immediately in the event of serious adverse event. Any death of a study participant will be reported to the NIH and UConn IRB whether or not it appears to be related to the study.

6. IRB Communications

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

7. Informing sponsor procedures

The sponsor will be notified within 48 hours of serious events that the IRB recommends we report.

Are there any plans to do an interim analysis? ☒ No ☐ Yes

If yes, describe the interim analysis plan:

Have stopping rules been established for the study? ☒ No ☐ Yes

If yes, describe the stopping rules:

Are there defined criteria for when study interventions should be discontinued?

☒ No ☐ Yes

If yes, describe the criteria:

Are there exams or procedures that the subject will be asked to have done or follow to safely withdraw from the study? ☒ No ☐ Yes

If yes, describe the procedures for safe withdrawal of subjects (NOTE: Withdrawal procedures should also be described in the consent):

Privacy/Confidentiality:

Explain how the privacy interests of participants will be maintained during the study (note that privacy pertains to the individual not to the data):

For the initial screening survey, participants can answer the questions at their own pace 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 and where they use MyFitnessPal and Facebook group. We will encourage them throughout the study to use the 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, 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 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. Surveys are provided to them through secure links via REDCap that is unique to each participant.

Describe how confidentiality of the data (including audio/video recordings) will be maintained (where stored, how stored, security of storage, coding of data/how coded, how long the data will be kept in identifiable or de-identified format, obtaining a certificate of confidentiality, etc.):

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). 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.

List any exceptions to confidentiality (e.g., mandated reporting) and identify any external agencies (study sponsor, FDA, collaborating institution IRB etc.) that will have access to the data. ☐ N/A

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

Also, it is possible that participants in this study may know each other.

If participants **fail screening,** describe the plans for storage or destruction of **their** identifiable data: ☐ N/A

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.

Complete and submit the Data Security Assessment Form (required for all studies):

The form is available here (https://ovpr.uconn.edu/services/rics/irb/irb-forms-templates/). This form will be used to assess procedures for protecting confidentiality of data collected during the study and stored after closure. It will also be used to assess plans for storage and security of electronic data in accordance with University Best Practices. Review the tip sheet here: http://content.research.uconn.edu/pdf/storrs/rcs/irb/TipsDataSecurityAssessmentForm.docx.

Informed Consent Process

The PI is responsible for ensuring that participants are fully informed about the study prior to their agreement to participate.

Consent/permission Setting:

☐ N/A - Waiver of consent is being requested below.

Describe the consent/permission process ***that is respectful of the participant's privacy***, including:

When will consent be obtained:

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 (via signature) 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, i.e., they appreciate the information being presented (may be warranted in studies with complicated study procedures, those that require extensive time commitments or those that expose participants to greater than minimal risk): ☐ N/A

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.

Consenting participants with limited decision capacity, language barriers etc.:

Describe how the capacity to consent will be assessed for participants with limited decision-making capacity, language barriers, or hearing difficulty. If a participant is incapable of providing consent, you will need to have IRB approval in order to include this individual and obtain permission from the participant's legally authorized representative. ☐ N/A

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.

Parent/Guardian Permission and Assent:

If enrolling children, state how many parents/guardians will provide permission, when the child's assent will be obtained and if assent will be written or oral. Provide a copy of the script to be used if oral assent will be obtained. For longitudinal studies, assent may happen at several points during the study, and the child's consent to continue in the study will need to be obtained when they reach 18 years old. ☒ N/A

Documentation of Consent:

☐ N/A - Waiver of the documentation of consent is being requested below.

Specify the forms that will be used for each participant population, i.e., adult consent form, surrogate consent form, parental permission sheet. child assent form (written form or oral script) or an information sheet. Copies of all forms should be attached to this application in the same format that they will be given to participants (templates and instructions are available on the IRB website):

An information sheet will be used for the study participants in addition to a consent form. An information sheet is given before the eligibility survey just to make sure they are interested and understand what data we collect from them at that point and then the official consent is given after they complete the webinar.

Waiver or Alteration of Consent:

The IRB may waive or alter the elements of consent in some minimal risk studies. If you plan to request either a waiver of consent (i.e., participants will not be asked to give consent), an alteration of consent (e.g., deception) or a waiver of signed consent (i.e., participants will give consent after reading an information sheet without signing a form), please answer the following questions using specific information from the study:

*Note: An IRB may approve a research proposal in which an investigator will obtain information or biospecimens **for the purpose of screening, recruiting, or determining the eligibility** of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:*

(1) The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or

(2) The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

Why is the study considered to be minimal risk?
N/A

Why will the waiver not affect the individual's rights and welfare?
N/A

Explain why the research could not be practicably carried out without the waiver. For studies that involve deception, explain how the research could not be done if participants know the full purpose of the study:
N/A

Explain why the research could not be practicably carried out without using identifiable private information and/or identifiable biospecimens (if identifiable information or biospecimens are not being obtained, state N/A):
N/A

If appropriate (e.g., research that uses deception/incomplete disclosure), how will additional pertinent information be provided to the participants (state N/A if this doesn't apply to the waiver request)?
N/A

Explain if the waiver/alteration as noted above is applicable to the entire study or to a portion of the study:
N/A

Waiver of documented (signed) consent (i.e. , no signature, participants give consent only after reading an information sheet or through oral discussion).
*Choose the (one) appropriate criterion below, and justify:

(i) The only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; (*not applicable to FDA-regulated studies)*
Explain:
N/A

(ii) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context (e.g., short telephone or web-based survey, etc.)

Explain:

N/A

(iii) If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained. *(Not applicable to FDA-regulated studies, or DOJ-funded studies)*

Explain:

N/A

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