Study title: The Healthy Moms Study: Comparison of a Post-Partum Weight Loss Intervention Delivered Via Facebook or In-Person Groups

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Study Protocol

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Study Protocol Title: The Healthy Moms Study: Comparison of a Post-Partum Weight Loss Intervention Delivered via Facebook or In-Person Groups

Clinical Trial/GCP Training

Is this a research study in which one or more human subjects are prospectively assigned[1] to one or more biomedical or behavioral interventions[2] (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes[3] (i.e a clinical trial)? Indicate "yes," "no," or "N/A" in the space immediately below.

Yes.

Is the study fully or partially funded by the NIH? Indicate "yes," "no," or "N/A" in the space immediately below.

Yes. NIH grant number R34HL136979.

Have the required key personnel completed Good Clinical Practice (GCP) Training? Indicate "yes," "no," or "N/A" in the space immediately below. (Note that IRB approval will not be given for NIH funded clinical trials until all required key personnel complete the GCP training.)

Yes.

Research Plan

Purpose/Introduction: [State the reason for the study, the research hypothesis, and the goals of the proposed study as related to the research question(s). Provide a clear and succinct summary description of the background information that led to the plan for this project. Provide references as appropriate and,

[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.

when applicable, previous work in animal and/or human studies. Provide previous UConn protocol number, if applicable.]

The goal of this research project is to conduct a pilot randomized trial with 72 overweight or obese post-partum women comparing delivery of a post-partum weight loss intervention via Facebook or in-person group sessions.

Post-partum weight retention contributes to obesity for many women,[1-3] increasing risk for cardiovascular disease and other chronic diseases[4] and complicating future pregnancies.[5,6] While on average women retain 0.5-3 kg, as many as 50% of women retain ≥5 kg.[2,7,8] Lifestyle interventions have shown to be modestly efficacious for post-partum weight loss in randomized controlled trials,[9] yet interventions with numerous visits are logistically challenging for many post-partum women.[10-16] Innovative, efficacious, and cost-effective[17,18] treatment models for post-partum weight loss that fit into the busy lives of new moms are needed.[19]

Facebook may be an efficient platform for delivering evidence-based weight loss programming to post-partum women. Facebook is currently the most popular online social network,[20] used by 81% of online moms.[21] 70% of Facebook users engage daily, including 43% multiple times per day,[22] for upwards of 50 minutes a day.[23] Many women seek support about health and parenting from their Facebook network.[21,24] Interactions via Facebook are frequent, brief, and asynchronous, with women seeking support when they need it. Delivering interventions via Facebook allows us to connect with post-partum women where they are, more fully integrating into their lives and daily routines. Weight loss interventions that use Facebook appear promising.[25-27]

We have developed a post-partum weight loss intervention based on the Diabetes Prevention Program,[28] tailored to needs of post-partum women and for delivery via Facebook. Participants receive counseling from a coach through posts and discussions via a private Facebook group. We conducted a one-arm pilot study of this intervention with 19 overweight or obese women (95% retention). Average weight loss was 4.8% (SD: 4.2%), and 58% achieved clinically significant weight loss (i.e., ≥5%[29,30]). 88% said they would be likely/very likely to participate again if they had another baby, and 82% would recommend the program to a post-partum friend. While delivering the intervention via Facebook offers many advantages, we have no reason to believe it will be more efficacious than a traditionally-delivered intervention (i.e., via in-person group sessions), especially when intervention content is identical. Instead, we hypothesize that in a large trial delivery via Facebook will be at least non-inferior for weight loss compared to in-person delivery, but superior in cost-effectiveness.

Additional preliminary data is needed to support the conduct of a large randomized non-inferiority trial to compare our Facebook-delivered post-partum weight loss intervention to in-person delivery of the intervention. In our pilot study, some intervention posts garnered low or no participant engagement. We have identified posts with low and high participant engagement, and will solicit feedback from women on how to make low engagement posts more engaging. As noted in the grant proposal (Section 3.B/Impact), the research described in this protocol is a step in a line of investigation to develop and test the efficacy and effectiveness of a Facebook-delivered post-partum weight loss intervention. Subsequent steps of this program of research include implementation in real-world settings. It is possible that the best model for widespread dissemination would be to develop a commercial product.

This project has three Specific Aims:

Aim 1: Feasibility. We will examine the feasibility of recruitment (especially the proportion of women unwilling to be randomized to either condition), sustained participation, contamination, retention, and

feasibility of assessment procedures, particularly measurement of cost-related data, in both treatment conditions. We will describe weight loss as an exploratory outcome.

Aim 2: Intervention refinement. In post-intervention focus groups, we will solicit women's feedback on posts with low engagement, and will iteratively refine these posts to make them more engaging.

Aim 3: Measuring time on Facebook. We will compare self-reported time spent on Facebook to participate in the intervention with application-tracked time on Facebook, changes in use, and time spent visibly engaging, to develop procedures for measuring time that balance accuracy and participant burden.

Please see the Specific Aims (page 1) and sections 3.A through 3.D.1.5 of the enclosed grant application (pages 2-7) for additional background information supporting the proposed research. The current protocol will cover research activities described as Phase 2 in the grant application; a separate protocol covers research activities described as Phase 1 (IRB # H17-203).

For EACH Participant Population State the Number of Participants to be Enrolled and Screened, if applicable: [State the total number of participants to be enrolled and, if enrolling more than one participant population, describe the total enrollment for each. Tip: consider attrition and the number of participants who may fail screening. Use of a range may provide flexibility.] Note that the range must be justified in the **Justification of Sample Size section below**.

N=72-125

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

The main purpose of the pilot trial is to examine the feasibility of recruitment (especially the proportion of women unwilling to be randomized to either condition), sustained participation, contamination, retention, and feasibility of assessment procedures, particularly measurement of cost-related data, in both treatment conditions, thus identifying modifications required before examining non-inferiority in a large randomized controlled trial. Leon, Davis, & Kraemer (2011) state "power analyses should not be presented in an application for a pilot study that does not propose inferential results."[31] As they and others recommend,[31,32] we based the sample size on necessities for examining feasibility, thus identifying modifications required to the design of the trial or study procedures before conducting the subsequent full-scale non-inferiority trial. Conducting two waves allows us to iteratively refine how we deliver intervention content via Facebook, and each wave includes n=36 women allows us to assess the feasibility of recruitment and engagement under the conditions of the subsequent trial. While we will aim to maximize retention in both conditions, with retention of ≥80% to be acceptable, a priori, we decided that a retention rate in either condition lower than 60% would indicate that the non-inferiority trial is not feasible as designed. With n=36 per treatment condition, the 95% confidence interval (CI) for the estimated retention rate will be within ±13% if observed retention is 80%. Given n=36 per condition, the lower limit of the 95% CI for the observed retention rate in either treatment condition should not be lower than 60%.

We will enroll up to 125 participants with the intention of randomizing 72 participants. As the current study is a feasibility study, we are unsure the proportion of enrolled (consented) participants who will be randomized, as some participants will fail to complete baseline measures or may be found to be ineligible after baseline assessments.

For EACH Participant Population State Describe the Study Population(s): [Describe the participant population(s) including gender, ethnicity, income, level of education and age range.]

All participants will be adult women (aged 18 years or older). We anticipate minority enrollment of at least 30% as expected by the NIH/NHLBI. We are not targeting enrollment by income or level of education; we aim to recruit a diverse sample with respect to these characteristics.

Enrollment of UConn Students and/or Employees: [Will UConn students be enrolled? If so, describe if these students include those who any key research personnel teaches, or for whom any key research personnel has responsibility. Will UConn employees be enrolled? If so, describe if these employees report to any key personnel. For each group, explain why this population is *necessary* to the study. Tip: convenience is not sufficient justification.]

UConn students and/or employees who any key personnel teach or who report to any key personnel will not be included; we will assess these relationships during eligibility screening.

Enrollment of Key Personnel, Spouses or Dependents/Relatives: Will study key personnel, spouses of key personnel, or dependents/relatives of any key personnel be enrolled in the study? If so, describe and provide justification.

No. We have included this as an exclusion criterion.

For EACH Participant Population Describe Recruitment Methods: [Specify each method and describe specific procedures for how participants will be identified and recruited. Attach copies of all advertisement/recruitment materials for IRB review. Describe how UConn Students/Staff and Key Personnel/Spouses/Dependents/Relatives will be identified and recruited, if applicable.]

We will recruit post-partum women from the community. We will distribute flyers in local obstetric or pediatric clinics or practices (e.g., Women's Ambulatory Health Services of Hartford Hospital), WIC offices, community organizations, and community venues and events. We will post study advertisements on craiglist.org and online social networks including Facebook, Instagram, and Twitter. We will contact the administrators of local Facebook groups to post our recruitment messages/images in their groups, as needed. We will connect with local businesses/organizations to have our ad/flyer emailed to their employees and/or students. We will submit announcements to be included in UConn distribution lists/newsletters such as the Daily Digest and the UConn Health Lifeline.

We will also recruit women who are currently pregnant who are expected to deliver before mid-June 2019 from the community as described above. Pregnant women will be asked to email us, call us, or complete a brief online form that includes their name, email address, phone number, and expected due date. Approximately 2 months after their expected due date, we will contact them about their interest in the study and if interested, screen them for eligibility.

Additionally, potential volunteers will be contacted by ResearchMatch with IRB-approved recruitment content for this study, not including direct study contact information such as study phone number. When posting on Research Match we will specify women with BMI≥25 kg/m^2 and aged 18-50 years, and set the geographic limits (50 miles) to prevent distribution of the recruitment message to individuals unlikely to be eligible for the study. Volunteers will have the option of replying 'yes' or 'no' through a set of quick links available in the recruitment message. If a volunteer chooses to respond in the affirmative, they will authorize ResearchMatch to release their contact information to the PI (or ResearchMatch designee) who will be responsible for managing that information according to institutional guidelines.

Recruitment flyers ("flyer" style with tear-away tabs and "pamphlet" style) and online recruitment messages/accompanying images are enclosed.

For EACH Participant Population Describe Screening Procedures, if applicable: [Describe when participants will be screened and how this will occur. Include copies of all screening forms and related documents. Describe procedures to notify participants of the screening result. Tip: if screening will be conducted online or by phone prior to consent, be sure to request a waiver of signed consent, if appropriate. Provide a copy of the screening instrument.]

Research staff will screen potential participants for eligibility in person or via phone. Research staff will answer questions potential participants have about the research study at any point during the recruitment and screening process. For online recruitment specifically, staff will answer questions in the mode they are posed (e.g., email, reply to social media post) and include in the response an offer to talk with the individual via phone to answer any questions. In most cases, staff will notify participants immediately of the screening result. However, in some cases, staff will refer with the PI to determine the screening result (e.g., unclear whether medication is exclusionary) and call the participant as soon as possible but within 3 days to inform them of the screening result.

The eligibility screener is enclosed. We will assess whether potential participants are UConn students and/or employees who any key personnel teach or who report to any key personnel; such relationships will be exclusionary. We will also assess whether potential participants are key personnel, spouses of key personnel, or dependents/relatives of any key personnel; such relationships will be exclusionary. We will identify such exclusionary relationships using a two-step process: first, by asking potential participants to disclosure any known relationships during eligibility screening, and second, by review of potential participant name by study staff before randomization.

Screening will be conducted prior to consent; we request a waiver of signed consent.

Design, Procedures, Materials and Methods: [Describe the study design, including the sequence and timing of all study procedures. Experimental procedures should be clearly described and labeled as such. If the study uses control or experimental groups, or different treatment arms, clearly describe what participation will be like for each of the groups or study arms. Tip: describe procedures in the order conducted. The IRB strongly suggests that investigators incorporate *flexibility* into the study design to accommodate anticipated events (i.e. explain how missed study appointments can be made up by participants). If the research involves study of *existing samples/records*, describe how authorization to access samples/records will be obtained. If the study involves use of *deception* explain the reason why this is necessary. If applicable, describe the use of audiotape and/or videotape and provide justification for use. If this study offers treatment for the participants' condition, complete the Treatment Study Supplemental Form (IRB-1C) and attach it to this application for review. If the study includes *measures, survey instruments and questionnaires*, identify each and, if available, provide references for the measures. Describe what they intend to measure (relate to purpose/hypothesis) and their psychometric properties (e.g., reliability and validity). Identify any that were specifically created for the study.]

Participation will include a baseline assessment, an orientation webinar, participation in a 6-month weight loss intervention, and follow-up assessments at 6 and 12 months. Study visits and in-person treatment sessions will take place in a private space (such as a conference room, exam room, or classroom) at UConn Storrs, UConn Hartford, the Hartford Public Library, Hartford Hospital, Women's Ambulatory Health Services, or WIC offices. Overall, it is estimated that completing study assessments will take approximately 5-6 hours and participating in treatment sessions (in-person condition) or engaging with

the counselor and other participants online (Facebook condition) will take approximately 90 minutes per week over the 6-month intervention period.

Baseline assessment. Staff will call and/or email participants within 3 days of their scheduled baseline assessment to remind them of the appointment. The baseline assessment will include informed consent measurement of height and weight, completion of a contact information sheet, and completion of additional measures which will be used to determine eligibility (screeners for depression and binge eating disorder). Study personnel will also help participants download My Fitness Pal app (all) and an app to track time on Facebook (Android users) and provide instruction of how to use these apps. For iPhone users, personnel will also show them how to locate Facebook app usage data using the battery settings. We expect the baseline study visit to take 30-45 minutes. Following the baseline assessment, research staff will fax the medical clearance form to participants' primary care provider or OBGYN. After the baseline visit, staff will email participants a link to complete a survey via REDCap. A copy of the baseline survey is enclosed. We will email participants a $20 gift card after they have completed the baseline visit and online survey.

Orientation Webinar. Participants will complete a 60-minute orientation webinar. The purpose of the webinar is to educate participants about what research is, review study procedures, review importance of participation of enrolled participants, and to allow participants another opportunity to evaluate if joining this study is the right choice for them. This webinar is being conducted to improve study retention. The webinar moderator will record in REDCap tracking which participants completed the webinar.

Pre-Randomization Survey. Following the orientation webinar, we will email participants a short online survey that includes Facebook time measures and completion of a randomization agreement. We will email participants a copy of the randomization agreement form for their records. A copy of the pre-randomization survey is enclosed.

Participants will need to complete the telephone screening, baseline assessments (visit and survey), and orientation webinar, and pre-randomization survey before being randomized.

Randomization. We will randomize participants 1:1 to the FB and IP conditions in randomly permuted blocks of size 4 and 6. Randomization will be stratified by weeks post-partum at enrollment (8 weeks to <6 months, 6-12 months) and smartphone type (iPhone vs Android) .

Weight loss intervention. The 6-month intervention will include dietary and exercise counseling and tips to help participants meet their healthy lifestyle goals. Participants will receive personalized calorie and physical activity goals to help them achieve a healthy weight loss of 1-2 pounds per week. Breastfeeding women will receive daily calorie goals that will facilitate weight loss while accounting for energy needs to support lactation; weight loss expectations do not differ by breastfeeding status. Participants will be encouraged to increase physical activity to 150 minutes per week of moderate intensity activity. While we will provide information about specific exercises designed to help with recovery from childbirth (e.g., pelvic floor exercises), participants will not be required to engage in any particular exercises or activity program. Counselors will encourage and support participants to make a plan for incorporating regular physical activity into their lives in a way (i.e., duration per session, frequency per week) that works for that individual woman. We will encourage participants to track their diet and exercise daily. We will encourage participants to use My Fitness Pal to track their diet and activity. In the in-person condition, the intervention will be delivered via weekly 90-minute group meetings for the first four months and then every other week in months 5 and 6. In the Facebook condition, the intervention will be delivered via a secret (private) Facebook group. See section 3.D.2.2.9 (3.D.2.2.9.1 through 3.2.2.9.6; pages 9-10) of the enclosed grant application for more details on the interventions.

Due to weather or to prevent spread of illness (e.g., coronavirus), we may hold intervention meetings for the in-person condition via video or telephone conference call.

Weekly time survey. Weekly, participants in both treatment conditions will complete a brief online survey to report current weight and time spent on Facebook. We expect the survey to take less than 5 minutes. The survey will be administered via REDCap. A copy of the weekly survey is enclosed.

6-month follow-up assessment. At 6 months, women will participate in an in-person focus group session. We will email participants a link to complete an online survey before this visit. The survey will be administered via REDCap. Research staff will measure participants' weight individually as women are arriving for the focus group. We will ask participants in both treatment conditions to elaborate on what motivated or hindered participation. Focus groups with women in the Facebook condition will explore their reactions to and ratings of the format of low or high engagement posts (same procedures as the pre-trial focus group in Phase 1). For participants unable to attend the focus group session, we will schedule individual follow-up assessments and will conduct an individual interview (in-person or via phone) following the content of the focus group guide. We will audiotape the focus group and individual interviews. When scheduling the 6-month assessment, we will remind participants that we will audiotape the focus groups. For participants who are not comfortable with this discussion being audiotaped, we will schedule an individual visit and take notes during the interview. For follow-up assessments (both 6-month and 12-month), participants who are not willing to attend an in-person visit will be asked to self-report their current weight, and those who do not complete the survey online will be offered the option of completing the survey via phone. We expect that this study visit will take 1-1.5 hours and the survey will take 30-45 minutes. We will email participants a $40 gift card after they complete the study visit and survey.

Due to weather or to prevent spread of illness (e.g., coronavirus), we may hold the focus group discussions via video or telephone conference call. In this case, participants would complete ratings of intervention posts via online survey. In the case of remote focus groups, we would ask participants to self-report their weight and not require in-person visits.

12-month follow-up assessment. 12-month individual follow-up visits will include measurement of weight. Research staff will provide participants with instructions on how to remove the My Fitness Pal and time-tracking apps from their phones, and will assist participants with removal of these apps if desired. We will email participants a link to complete the survey at home following the 12-month follow-up study visit. The survey will be administered via REDCap. We expect that the survey will take about 30 minutes, and the visit will take about 15-45 minutes. We will email participants a $40 gift card after they complete the study visit and survey.

Due to weather or to prevent spread of illness (e.g., coronavirus), we may participants to self-report their weight and not require in-person visits.

For all study assessments, research staff will call subjects who do not attend their scheduled in-person study visit to reschedule. Calls will follow the same calling procedures as the eligibility screen (see Eligibility Screen). We will reschedule the study visit a maximum of 5 times, with a maximum of 5 calls per scheduled visit before considering the woman lost to follow-up. Women who do not complete the online surveys will be sent two reminder emails containing a personalized link, at least 24 hours apart. After 7 days, research staff will may participants who have not completed the measures online to provide the participant the option of completing any remaining measures over the phone. Calls will follow the same calling procedures as the eligibility screen (see Eligibility Screen).

Baseline, weekly, and follow-up surveys are enclosed. Data collection will include data to be collected in the subsequent non-inferiority trial (see Subsequent Clinical Trial Description, pages 14-16, of the grant application). In the baseline survey, participants will report relevant obstetric history,[33] pre-pregnancy weight and gestational weight gain during the index pregnancy,[34] contraception use, smoking/e-cigarette use, employment status, household composition, and other demographics. At each time point (baseline, 6-months, 12-months), participants will complete measures of quality of life (PROPr),[35,36] infant feeding,[37,38] sleep (PSQI [partial]),[39,40] depressive symptoms (EPDS),[41] and social support for weight loss.[42] At each follow-up, participants will also be queried about incident pregnancies as part of the participant survey. At 6 months, women in both conditions will rate their satisfaction with the intervention, how likely they would be to recommend it to a post-partum friend, and how likely they would be to participate again, and group cohesion.[43] At 6 months, we will ask women whether they participated in other weight loss programs (online or in-person), sought weight loss support on Facebook or other online social networks,[44] and if so, to what extent and reasons they sought this support.

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.]

We will use Research Electronic Data Capture (REDCap)[45] for data collection and monitoring completion of study assessments. Datasets will be exported from REDCap and merged within SAS with cost-related data. PI Dr. Waring will supervise data management and quality control. We will use NVivo 11 (QSR International, Melbourne, Australia) to manage and analyze qualitative data and SAS 9.4 (SAS Inc, Cary, NC) to analyze quantitative data.

Aim 1: Feasibility. We will examine the feasibility of recruitment (especially the proportion of women unwilling to be randomized to either condition), sustained participation, contamination, retention, and feasibility of assessment procedures, particularly measurement of cost-related data, in both treatment conditions. We will describe weight loss as an exploratory outcome.

- Recruitment. Recruitment rates will be calculated from the number of patients approached and reasons for ineligibility and non-participation. We will report numbers and reasons for recruitment using a CONSORT diagram.[46,47]
- Sustained participation. We will calculate sustained participation as time to last intervention session attended in the IP condition and as time to last post, comment, or reaction (based on date of last post or comment reacted to) in the Facebook condition. In the Facebook condition, we will also calculate a secondary measure of sustained participation that includes last report of lurking.[25]
- Contamination. We will describe the proportion of participant in both treatment conditions who report participating in other weight loss programs (online or in-person), seeking weight loss support on Facebook or other online social networks[44] at 6 months. We will also describe the extent of contamination and reasons women sought these extra sources of support using survey data and qualitative data from post-intervention focus groups.
- Retention. We will calculate retention as the proportion of participants who complete the 6- and 12-month follow-up study visits in each condition and report this information using a CONSORT diagram[46,47]
- Feasibility of assessment procedures. We will examine the extent and mechanisms of missing data on each measure to be included in the subsequent non-inferiority trial.
- Weight loss. We will calculate percent weight change at 6 and 12 months by subtracting baseline weight from follow-up weights. We will define clinically significant weight loss as ≥5%.[29,30]

Aim 2: Intervention refinement. In post-intervention focus groups, we will solicit women's feedback on posts with low engagement, and will iteratively refine these posts to make them more engaging. We will

identify low- and high-engagement post using engagement data downloaded from Facebook. We will describe the total number of participant interactions (i.e., comments, reply-posts, and reactions) with counselor posts, overall and compare the number of interactions by post format (e.g., asking women to post a photo, informational without explicitly soliciting a response). We will also examine the number of comments/reply-posts and reactions separately, as post topics and formats may be differentially related to commenting versus reacting to posts.[48] Following transcription of audio recordings of focus groups, Dr. Waring will lead a directed content analysis[49] of responses to open-ended questions of how to make low-engagement posts more engaging. We will also examine characteristics of posts that are rated as highly likely to engage women versus low-rated posts and will describe characteristics of posts that are judged as engaging (e.g., ask a question, include a picture) and a list of general characteristics of posts that are judged as not engaging (e.g., longer than 2 sentences, negative sentiment). Dr. Waring will develop an initial codebook based on the key questions in the focus group guide. We will revise the codebook to incorporate additional themes emerging during the initial review. The investigators will discuss initial results and finalize themes before final independent coding and consensus. We will calculate inter-rater reliability[50] and will reach consensus on any discrepant coding through discussion. We will summarize women's ratings of posts as mean (SD), or median (inter-quartile range) if ratings are not normally distributed.

Aim 3: Measuring time on Facebook. We will compare self-reported time spent on Facebook to participate in the intervention with application-tracked time on Facebook, changes in use, and time spent visibly engaging, to develop procedures for measuring time that balance accuracy and participant burden. We will compare self-reported time spent on Facebook to participate in the intervention with (1) application-tracked time spent on Facebook, (2) change in application-tracked time over the intervention, and (3) estimated time spent visibly engaging in the intervention using paired t-tests and Wilcoxon rank-sum tests, as appropriate. We will also examine accuracy in reporting total time on Facebook at baseline and adjust self-reported time spent on Facebook to participate in the intervention accordingly. From these comparisons, we will develop procedures for measuring time spent on Facebook to participate in the intervention that maximize accuracy while not placing undue burden on participants nor changing their behavior as a result of surveilling their social media activities.

Inclusion/Exclusion Criteria: [List ALL inclusion and exclusion criteria. Any proposed exclusion criterion based on gender (women of childbearing potential), age, or race must include justification for the exclusion. Describe the conditions under which participants may be removed from the study, i.e., noncompliance with study rules, study termination, etc.]

Only women will be included as the aim of this study is to refine a post-partum weight loss intervention.

Inclusion criteria. Women aged ≥18 years, 8 weeks to 12 months post-partum at enrollment, overweight or obese (BMI≥25 kg/m^2) per measured height and weight at the baseline visit, owns a scale (we will provide women with a scale if needed), comfortable reading and speaking English, owns an iPhone or Android smartphone, active Facebook user as defined as daily Facebook use and posts/comments at least weekly over the past 4 weeks, clearance from primary care provider or obstetrician/gynecologist, willing and able to participate in either treatment condition (Facebook or in-person), available to attend in-person meetings over the 6-month study period in Hartford, CT, 45 minutes or less to travel to intervention meetings, and willing and able to provide informed consent.

Exclusion criteria. During screening procedures women who are key personnel on this study, a spouse, dependent, or relative of any key personnel, a UConn employee who reports to key personnel on this study, or a UConn student whom key personnel on this study teaches will be excluded from participation. Additionally, women who are currently pregnant or plans to conceive during the study period, current participation in a clinical weight loss program, Type 1 or 2 diabetes, medical conditions or medications

affecting weight, incapable of walking ¼ mile without stopping, pain that prevents engagement in exercise, previous bariatric surgery, planned surgery during study period, plans to move out of the area during the study period, high depressive symptoms or suicidal ideation, positive screen for binge eating disorder (BED), failure to complete the baseline survey or orientation webinar.

Participants will be withdrawn from the study if: they become pregnant, disrupt in-person groups, or repeatedly post inappropriate content on Facebook.

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

The possible risks of this study include an injury while being physically active, possible discomfort from completing questionnaires, and breach of confidentiality. Study activities do not differ from typical everyday activities of post-partum women (e.g., interacting with others on Facebook, using a mobile app, talking to other women) and/or activities done or recommended clinically and in line with national recommendations for weight loss during the post-partum period (e.g., eating a balanced nutritious diet, regular exercise, measurement of weight) and thus does not pose more than minimal risk/slight increase over minimal risk.

Participants will be screened for ability to engage in physical activity. Medical conditions preventing the increase of physical activity will be exclusionary. We will obtain medical clearance from each participant's primary care provider (PCP) or obstetrician/gynecologist (OB/GYN) including clearance to participate in physical activity. Participants who experience discomfort will be asked to meet with their PCP /OBGYN prior to returning to physical activity.

At the beginning of each study assessment, participants will be reminded that they do not have to answer any question they do not wish to, either in the focus group or surveys, and that they are free to leave at any time. The focus group leader will ask participants not to share information they learned about other participants during the group with others outside of the focus group. We will audio record the focus group discussion. We will ask participants to say their first name before she offers an opinion or answers a question. When we transcribe the audio recordings, we will remove participants' name and enter study ID instead. All participant surveys will be completed via a secure web form via REDCap. Additional efforts to protect participant confidentiality are described below.

For participants randomly assigned to the Facebook condition, information posted on Facebook is subject to Facebook's terms of use and privacy policy, including terms of use for their website and mobile application. As all eligible participants already use Facebook, we will instruct participants to re-review these terms and the privacy policy. The Facebook group will be private ("secret") and posts are only available to group members. We will ask participants not to post their locations or contact information when talking to other study participants. We will also ask participants not to disclose that they are in a research study to protect confidentiality of other participants and not to share posts of the Facebook group with people not in the group. Online social interactions will be monitored by study staff to help ensure the protection of privacy. Intervention counselors will log into Facebook daily to deliver the intervention, engage with participants, and monitor online social interactions.

We suggest My Fitness Pal as a tool to help participants track their dietary intake and physical activity. We will ask participants who have an Android phone to download a free, commercially available app and

report to us throughout the study how much time they are spending on Facebook. Information participants enter into an app or website or allow an app or website to access from their phone (such as My Fitness Pal) is subject to that company's terms of use and privacy policy. We will instruct participants to review these terms and the privacy policy carefully before choosing to download and use the app or use the website. During the study, if we become aware of any changes made to applicable privacy policies, we will notify participants by email promptly that this has occurred and will encourage them to review their privacy settings.

While not expected to be related to study participation, over the course of the study the research staff may become aware of depressive symptoms among our participants. The study assessment includes the Edinburgh Postnatal Depression Scale (EPDS), a screen for depressive symptoms for use during the post-partum period, and a modification of the SCID-I Binge Eating Disorder module. Elevated depressive symptoms, suicidal ideation, and positive screen for binge eating disorder are exclusionary. Research staff will alert participants that their scores make them ineligible to participate, and will let them know that when depression is very high, it's best to focus on that first rather than focusing on multiple things such as depression plus weight loss. In the conversation for BED, we will let them know that the weight loss intervention is not an appropriate intervention because we don't provide psychological help in the intervention, and receiving professional help, specifically cognitive behavioral therapy, will be more beneficial to them. We will offer to send a list of local resources to these participants. If suicidal ideation is present, the program director will call to assess safety and suggest professional help if needed as described below. Women who score 12 or greater (suggestive of high risk of clinical depression) and score negative on the EPDS suicide question (#10) will be encouraged to contact their provider to discuss their symptoms. After consulting with the PI, research staff will also contact the participant's PCP/OBGYN and let her/him know that the participant's score was suggestive of depression. Women who score positive on the EPDS suicide question (#10) will be considered at acute risk of injury or harm. In the unlikely event, the study PI Dr. Waring, clinical psychologist Co-I Dr. Pagoto, or project director Ms. Oleski will be contacted immediately and the participant will be assessed for the need for immediate referral for psychiatric evaluation. Urgent evaluation will be arranged for the participant as indicated, and the participants' provider will be made aware of the situation. Staff will confirm participants' contact information prior to each study follow-up assessment including contact information for their PCP/OBGYN. In the case that a participant's EPDS score necessitates communication with her PCP/OBGYN and the participant reports not currently being under the care of either a PCP or an OBGYN, research staff will ask the participant whether she is being seen by another health care provider, and if so, ask the participant for contact information with the purpose of communicating with the provider about her depressive symptoms. In the case that the participant is not currently being seen by any health care provider, research staff will offer to send the participant information about mental health resources in her local area and will follow-up with the participant via phone and/or email until she has connected with a new healthcare provider, then contact the new provider per our protocol. Research staff will stop contacting participants after they have attempted to contact the participant on a maximum of 10 times over a maximum of 4 weeks. Participants will be made aware of this protocol in the original consent for the study. All referrals will be documented and reported to the study PI.

Inconveniences participants may experience include time spent to participate in the research. This includes time to travel to/from study assessments, and, for women randomized to the in-person condition, time to travel to/from the group meetings. We have planned study procedures to minimize the time needed by only collecting data needed to achieve study aims.

Participants may receive a benefit of weight loss, however since this is a research study this cannot be promised. If a participant expresses upset over lack of weight loss during the intervention period, research staff will encourage her to engage fully in the intervention and seek help from the counselor and other women in their group to make lifestyle changes supportive of weight loss. If a participant expresses upset with her weight loss following the intervention period, we will remind her that weight loss was not guaranteed, and encourage her to keep up with the healthy changes she made during the intervention or seek assistance with further weight loss from her PCP or OBGYN or by joining a formal weight loss program.

Benefits: [Describe anticipated benefits to the individual participants. If test results will be provided, describe and explain procedures to help participants understand the results. If individual participants may not benefit directly, state so here. Describe anticipated benefits to society (i.e., added knowledge to the field of study) or a specific class of individuals (i.e., athletes or autistic children). Do not include compensation or earned course credits in this section.]

Participants may or may not benefit from participating in the trial. Benefits that could occur are losing weight through the exercise and lifestyle intervention. Results from this research will help refine the delivery of this intervention with the intent of increasing the efficacy of the intervention.

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

This research does not involve more than minimal risk/slight increase over minimal risk. As described above, we will take steps to minimize these risks. Participants may derive direct benefit from participation. Additionally, results are intended to benefit future populations of post-partum women.

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

Facebook, My Fitness Pal, and time-tracking apps we will recommend do not cost any money to use. We will encourage participants to check their data usage plan to ensure they are using the appropriate settings on their phone to minimize the use of their data so they don't incur any charges due to any increased use of apps during participation in the study.

Participants will receive a $20 gift card after completing the baseline assessment (visit and survey) and a $40 gift card after completing each follow-up study assessment (6 months and 12 months) to compensate them for their time, for a total of $100. Participants will be reimbursed up to $5 for parking or bus fare for each study visit (both conditions) and group intervention session (participants randomized to the in-person condition), as needed.

Data Safety Monitoring: [This is a prospective plan set up by the study investigators to assure that adverse events occurring during studies are identified, evaluated, and communicated to the IRB in a timely manner. Although the investigators initially propose a Data Safety Monitoring Plan (DSMP), the IRB must approve the plan and may require revision of the plan. A DSMP is required for all human studies at the University of Connecticut except for studies determined to be exempt from continuing IRB

review. For studies that present more than minimal risk to participants, the IRB will review and determine on a case-by-case basis whether a data safety monitoring board is most appropriate. Please refer to the IRB's policy regarding data safety monitoring *before* completing this section - http://research.uconn.edu/policies-procedures.

Issues that should be addressed in the DSMP include the following:

1. frequency of the monitoring
2. who will conduct the monitoring (Under UConn policy a student cannot be the sole person responsible for monitoring the data and safety of the protocol procedures)
3. what data will be monitored (include compliance with approved IRB protocol)
4. how the data will be evaluated for problems
5. what actions will be taken upon the occurrence of specific events or end points
6. who will communicate to the IRB and how communication will occur
7. describe procedures to inform the sponsor

Sample response to issues listed above for minimal risk/slight increase over minimal risk – "Survey results will be monitored by the PI in conjunction with the student investigator once every two weeks (items 1, 2 and 3). Survey responses will be reviewed to monitor for clarity (i.e., the same question is skipped by 5 or more participants). In that case, the question will be revised and an amendment will be submitted to the IRB (items 4, 5 and 6)."

Every two weeks (item 1), the PI and research coordinator (item 2) will review survey responses and collection and storage of additional data (item 3) to insure compliance with study protocols (item 4). Any deviations to protocol or adverse event reported by participants will be reported to the IRB through the appropriate process via InfoEd (item 5) by the PI (item 6), and we will submit an amendment if appropriate (item 5). The report of adverse events is built into our tracking database. Staff will assess the presence of adverse events during all participant contacts. We will report to NIH any serious unanticipated harms or unexpected threat to privacy as appropriate (item 7). We will convene a Data Safety and Monitoring Board (DSMB) to monitor the safety of participants throughout the proposed research, in particular for the occurrence of adverse events (both serious and otherwise). See attached grant proposal section 6 (pages 30-31).

Privacy/Confidentiality Part 1:

[Explain how the privacy interests of participants will be maintained during the study (note that **privacy pertains to the individual not to the data**). Describe how data will be coded. Do not use the any potentially identifiable information such as initials of participants as part of the code. If identifiable, sensitive information (illegal drug use, criminal activity, etc.) will be collected, state whether a Certificate of Confidentiality will be obtained. Be sure to state whether any limits to confidentiality exist and identify any external agencies (study sponsor, FDA, etc.) that will have access to the data. If participants will be screened, describe the plans for storage or destruction of identifiable data for those that failed the screening.]

Each participant will be assigned a unique study ID number that does not include any potentially identifiable information such as initials as part of the code. We will ask participants not to share information they learned about other participants during the group with others outside of the group. Investigators and research staff undergo training to help participants feel at ease with the study and to understand how their information will be protected. The research team will not access information about a participant after data have been collected except on an as-needed basis (such as to correct a telephone number).

During the study, should the research team become aware of any changes made to the privacy policies of Facebook, My Fitness Pal, or any time-tracking app recommended, research staff will notify participants that the policy has been updated and will encourage participants to review their privacy settings. The private (secret) Facebook group will be deleted by research staff 6 months after the last post or reply posted by a research participant. Photographs uploaded to Facebook by participants during the study will be accessible to participants as with any photo they upload to Facebook; research staff will not download participant photographs from Facebook when capturing engagement data.

Data from ineligible participants: Contact information will be stored in a file with an indication that they are not eligible and reason(s) for ineligibility. After enrollment is complete, data collected from the screening, including reason ineligible, will be stored in a de-identified dataset.

The identified data will be kept in a locked cabinet and/or electronically using password-protected and encrypted files. Any study documents containing identifying information or other sensitive data will be transported in a lockbox. Data from paper forms (e.g., eligibility screeners, contact information sheet, Facebook post rating forms) will be entered by research staff into REDCap. Study documents will be retained for at least 3 years after the completion of the research as required by Federal regulations. Downloaded datasets will be kept on password-protected research drive accessible only by appropriate research staff. Study documentation will be kept on password-protected research drives and/or locked filing cabinets in the PI's office. The link between identifiable information will be maintained in a REDCap database. Access to the REDCap database will be limited only to appropriate research staff. The link between identifiable information and de-identified study data will be deleted after all study procedures are completed and permanent de-identified study datasets have been created. The PI is responsible for the management of data.

Research staff will transcribe focus group discussions. During transcription of focus group audio recordings, participants' names will be replaced with an identification number to permit linking of statements with de-identified survey data. Uniquely identifying statements (e.g., names of people or companies) will be masked during transcription. After the recordings have been checked for accuracy they will be deleted. Interview transcripts will be stored on a password-protected research drive accessible only be appropriate research staff. When the research results are published or discussed in conferences, manuscripts or grants, no information will be included that reveals patient identity.

The following security protocols will also be applied to all data: physical protections -- all recordings and data will be stored on secure servers behind firewalls. All hard copy files will be locked in secure cabinets; logical protections – all recordings and data will be password protected and/or encrypted; and access protections – access will be granted to data on a need to know basis only. All records consisting of personal identifiers will be destroyed upon completion of the study by shredding of the hard paper copy, redacting the PHI/PII from the hard paper copy, and/or destruction of the electronic files.

Privacy/Confidentiality Part 2: Complete the Data Security Assessment Form

: [**This form IS REQUIRED for ALL studies**. The form is available here - http://research.uconn.edu/irb/irb-forms-infoed/. This form will be used to assess procedures for protecting confidentiality of data collected during the study and stored after closure. It will also be used to assess plans for storage and security of electronic data in accordance with University Best

Practices. Review the document proving tips to complete the form located at http://content.research.uconn.edu/pdf/storrs/rcs/irb/TipsDataSecurityAssessmentForm.docx.

The Data Security Assessment Form is enclosed.

Informed Consent

As PI, you are responsible for taking reasonable steps to assure that the participants in this study are fully informed about and understand the study. Even if you are not targeting participants from "Special Populations" as listed on page 4, such populations may be included in recruitment efforts. Please keep this in mind as you design the Consent Process and provide the information requested in this section.

Consent Setting: [Describe the consent process including *who* will obtain consent, *where* and *when* will it be obtained, and *how* much time participants will have to make a decision. Describe how the privacy of the participants will be maintained throughout the consent process. State whether an assessment of consent materials will be conducted to assure that participants understand the information (may be warranted in studies with complicated study procedures, those that require extensive time commitments or those that expose participants to greater than minimal risk).]

During eligibility screening, study staff will describe the study and answer any questions about participation. This process is intended to ensure that they understand the procedures, risks, and benefits involved in study participation. The consent process will take place at the baseline assessment. Ample time will be allowed for discussion or questions. Participants will be given enough time as needed to review the consent form and ask any questions prior to signing. Prior to signing the consent form, we will provide a verbal review of the consent form and allow time for questions to make that the participant understands all sections on the form and all aspects of study participation. This verbal review and questions will occur during screening, and we will provide the participant a copy of the consent form in advance of the baseline assessment either in hard-copy or via email. Before signing, research staff will verbally review the consent again and answer any questions before asking participants to sign. On the last page of the consent form the participant and the research staff member obtaining the consent will sign and date the form. We will ask participants to sign two copies of the consent form; following staff signature, we will provide participants with one of these copies.

Capacity to Consent: [Describe how the capacity to consent will be assessed for participants with limited decision-making capacity, language barriers or hearing difficulty. If a participant is incapable of providing consent, you will need to obtain consent from the participant's legal guardian (please see the IRB website for additional information).]

All participants must be capable of providing informed consent. Eligible individuals must be able to complete the eligibility screening process in English and must endorse that they feel comfortable reading and writing in English in order to participate. The screening and consent process will include discussion of what participating in the study involves, including risks and benefits. If research staff conducting eligibility screening or obtaining informed consent has concerns about an individual's ability to understand the study or her decision-making capacity, the case will be discussed with the PI who will determine whether the exclude the individual from participation on this basis.

Parent/Guardian Permission and Assent: [If enrolling children, state how many parents/guardians will provide permission, whether the child's assent will be obtained and if assent will be written or oral. Provide a copy of the script to be used if oral assent will be obtained.]

N/A.

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

Written informed consent will be obtained. The consent form is enclosed.

Waiver or Alteration of Consent: [The IRB may waive or alter the elements of consent in some minimal risks studies. If you plan to request either a **waiver of consent** (i.e., participants will not be asked to give consent), an **alteration of consent** (e.g., deception) or a **waiver of signed consent** (i.e., participants will give consent after reading an information sheet), please answer the following questions using specific information from the study:]

Waiver (i.e. participants will not be asked to give consent) or alteration of consent (e.g. use of deception in research):

- Why is the study considered to be minimal risk?
- How will the waiver affect the participants' rights and welfare? The IRB must find that participants' rights are not adversely affected. For example, participants may choose not to answer any questions they do not want to answer and they may stop their participation in the research at any time.
- Why would the research be impracticable without the waiver? For studies that involve deception, explain how the research could not be done if participants know the full purpose of the study.
- How will important information be returned to the participants, if appropriate? For studies that involve deception, indicate that participants will be debriefed and that the researchers will be available in case participants have questions.

Waiver of *signed* consent (i.e. participants give consent only after reading an information sheet):

- Why is the study considered to be minimal risk?
- Does a breach of confidentiality constitute the principal risk to participants? Relate this to the risks associated with a breach of confidentiality and indicate how risks will be minimized because of the waiver of signed consent.
- Would the signed consent form be the only record linking the participant to the research? Relate this to the procedures to protect privacy/confidentiality.
- Does the research include any activities that would require signed consent in a non-research setting? For example, in non-research settings, normally there is no requirement for written consent for completion of questionnaires.

We request a waiver of written consent to conduct eligibility screening. We will obtain verbal consent to conduct eligibility screening. Following eligibility screening, eligible individuals who indicate that they wish to participate in the research study will be asked for their full names, phone number, and email address. Staff will inform participants that we call and/or email them the day before their baseline assessment to remind them of appointment and confirm that they intend to attend, and that we plan on leaving a message if we do not reach them by phone. Participants may choose not to provide a phone number or email address if they do not wish to, or may request that we not leave a message on the phone's voicemail or answering machine.

Why is the study considered to be minimal risk? The probability and magnitude of harm or discomfort anticipated from the screening process is not greater than those ordinarily encountered in daily life or during the performance of routine psychological examinations or tests.

How will the waiver affect the participants' rights and welfare? Individuals may choose to not answer any eligibility screening questions they do not want to answer and may stop their participation in the eligibility screening at any time. However, all questions on the eligibility screener are required to determine eligibility for participation, so individuals who choose not to answer all questions will be excluded from further participation.

Why would the research be impracticable without the waiver? Given the study procedures, it would not be practical to obtain written informed consent before screening interested individuals for eligibility.

How will important information be returned to the participants, if appropriate? Following eligibility screening, we will ask ineligible individuals whether we may keep their answers to the eligibility screening questions. If they decline, we will destroy their information. See enclosed eligibility screener.

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