Postpartum weight loss for women at elevated cardiovascular risk: a randomized controlled trial

Principal Investigator: Jennifer Lewey, MD, MPH
Assistant Professor of Medicine
Division of Cardiovascular Medicine
Perelman Center for Advanced Medicine
3400 Civic Center Boulevard, Pavilion 2 East
Philadelphia, PA 19104
Phone: 267-588-2327

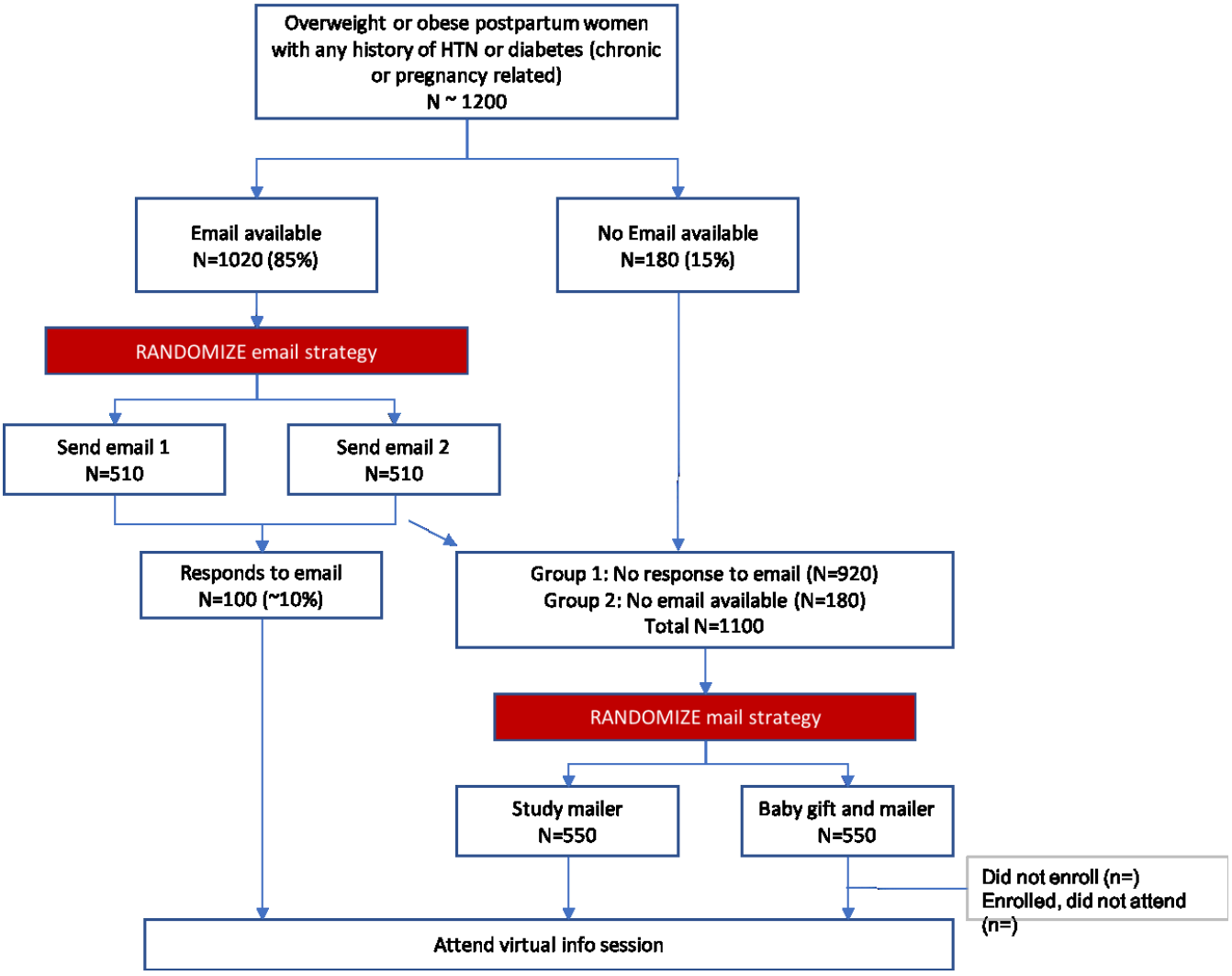
Co-principal investigator: Kelly Allison, PhD
Professor of Psychology
Department of Psychiatry

Protocol Outline

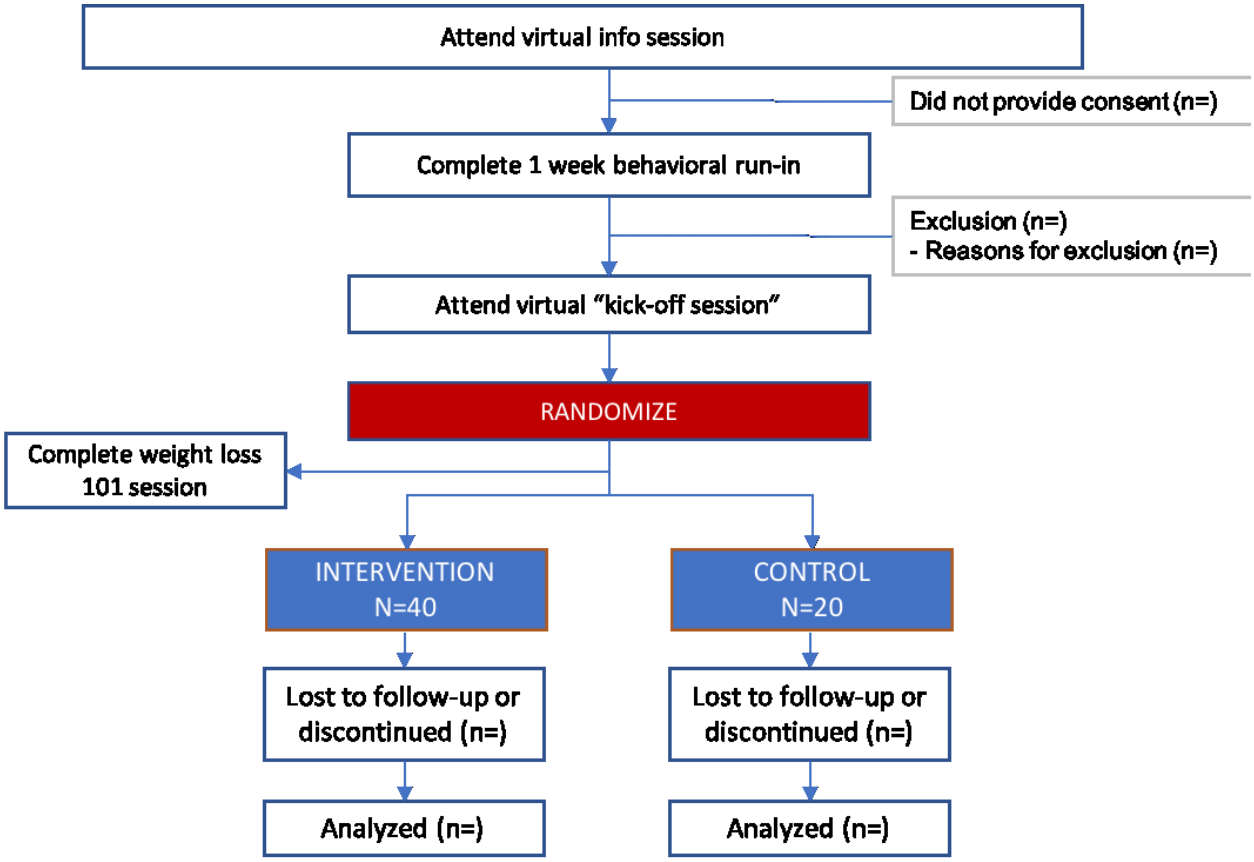
1. Abstract
2. Overall objectives
3. Aims
    - 3.1 Primary outcome
    - 3.2 Secondary outcomes
4. Background
5. Study design
    - 5.1 Design
    - 5.2 Study duration
    - 5.3 Target population
    - 5.4 Accrual
    - 5.5 Key inclusion criteria
    - 5.6 Key exclusion criteria
6. Subject recruitment
7. Subject compensation
8. Study procedures
    - 8.1 Consent
    - 8.2 Procedures
    - 8.3 COVID-19 precautions
9. Analysis plan
10. Investigators
11. Human research protection
    - 11.1 Data confidentiality
    - 11.2 Subject confidentiality
    - 11.3 Subject privacy
    - 11.4 Data disclosure
    - 11.5 Data safety and monitoring
    - 11.6 Risk/benefit
        - 11.6.1 Potential study risks
        - 11.6.2 Potential study benefits
        - 11.6.3 Risk/benefit assessment

STUDY SCHEMA

A. Enrollment strategies



B. Intervention allocation and follow-up



1. Abstract

Two-thirds of women have overweight or obesity, and women of reproductive age have experienced the greatest increase in obesity rates of any group.(1) Obesity during reproductive years is a risk factor for pregnancy complications and higher risk of mortality later in life.(2) Women with cardiovascular (CV) risk factors, such as hypertension (HTN) or diabetes (DM) are at higher risk of obesity-related CV complications, as are women with pregnancy complications such as gestational hypertension, preeclampsia, and diabetes. The Diabetes Prevention Program (DPP) is an intensive in-person program resulting in sustained weight loss.(3,4) Behavioral weight loss (BWL) programs modeled after DPP and adapted to online platforms have shown success in different settings. An online behavioral weight loss program modelled after the DPP may be attractive to postpartum women, who may have difficulty attending in-person sessions due to competing demands of caring for a newborn.(5) The objective of this study is to use a randomized clinical trial to test the feasibility and effectiveness of a 16-week online behavioral weight loss program compared to usual care to promote weight loss in the postpartum period among women with CV risk factors. We will also be testing different behavioral strategies to recruit postpartum women to the study. We will be partnering with collaborators at the University of Connecticut (UConn) who have extensively evaluated this platform in different populations.

2. Overall objectives

The objective of this study is to evaluate the feasibility of an online behavioral weight loss program on weight loss among postpartum women at increased cardiovascular risk. A secondary objective is to evaluate the effectiveness of different behavioral strategies to recruit a diverse population of women to enroll in the study.

3. Aims

3.1 Aim 1: To understand feasibility and compare weight loss between postpartum women participating in an online behavioral weight loss intervention compared to usual care.

3.2 *Aim 2*: To compare recruitment and enrollment strategies in enrolling postpartum women in a weight loss intervention.

4. Background

Pregnancy represents a life transition when many women become at risk for unhealthy lifestyle habits, such as excess weight gain and limited physical activity. At one year postpartum, nearly one-half of lower-income women will weigh 10 pounds more than their pre-pregnancy weight, and one-third will develop new overweight or obesity onset. Overweight and obesity are risk factors for cardiovascular risk (CV) factors, such as hypertension and diabetes, as well as maternal complications in future pregnancies.

The Diabetes Prevention Program (DPP) is one of the most successful behavioral programs for weight loss and diabetes prevention, however the program is designed to be in-person which is challenging for many women with young children at home. Efforts to develop an on-line version of the DPP program have been successful in motivating weight loss among individuals from

diverse backgrounds and early research suggests that it may be modestly effective in postpartum women. Therefore, we propose a pilot feasibility study to examine opportunities to improve engagement in an online DPP program among postpartum women and measure preliminary efficacy by comparing it to usual care.

5. Study design

5.1 Design

We will conduct a pilot two-arm randomized, controlled trial comparing the effect of an online BWL program (intervention) to usual care on weight loss after 16 weeks. The enrollment process and intervention will all be conducted remotely. All interested participants will be asked to complete a 7-day run-in period during which time they will complete surveys and submit a daily food log. Participants will be randomized 2:1 into the intervention and control arms, respectively. At the end of the 16-week intervention, participants will be asked to complete end-of-study surveys and complete an end-of-study virtual weigh-in.

Study population

We will recruit women who have recently delivered at the Hospital of the University of Pennsylvania or Pennsylvania Hospital. We will recruit women who are 6 weeks – 12 months postpartum at the time of study recruitment and have $\geq$ 1 CV risk factor.

Trial arms

Arm 1. Usual care: Participants will receive educational resources on weight loss and a digital scale.

Arm 2. Online behavioral weight loss: Participants will receive educational resources on weight loss and a digital scale. Participants will participate in a "Weight Loss 101" virtual session, where they are introduced to successful components of weight loss. They will be enrolled in a 16-week online program that is based on the Diabetes Prevention Program (DPP) and involves weekly brief videos, a self-monitoring platform, and automated feedback.(3,6–8)

Intervention

Participants in all arms will attend a virtual Information session, undergo a 1-week behavioral run-in period, and attend a virtual Kick-off session. (see Study Schema). After completing these steps, all participants will be asked to complete a virtual weigh-in at the start and end of the 16-week intervention. In addition, the intervention arm will receive:

a. Weight loss and physical activity goals as part of the Weight Loss 101 session. All participants will be asked to lose 10% of their body weight, corresponding to 1-2 lb/week over the 16-week study. Participants will be enrolled in the online behavioral weight loss program. The program involves the following components and described in more detail in Appendix 1:
b. Weekly multimedia videos (lesson plan): These illustrated videos are < 5 minutes in length and include topics such as stimulus control, goal setting, and problem solving.

Each video is accompanied by online lesson plan that includes additional information and is posted every Monday morning.

c. Self-monitoring platform (daily log): Participants are asked to track their daily weight, total calories, and exercise minutes and enter it on the website. These can be entered daily or at the end of the week. As long as values are entered before 11:59pm on Sunday night, the participant will receive automated feedback.
d. Automated feedback: Based upon the metrics entered into the daily log, participants will receive automated feedback by email on Monday morning with specific goal to work on each week. This may focus on reinforcing daily weights, encouraging adherence calorie or exercise goals, or resetting goals. The overall messaging of the automated feedback is supportive.
e. Access to health coach: Participants will be able to contact study staff if they are encountering barriers to following the lesson plan or meeting their weight loss goals.

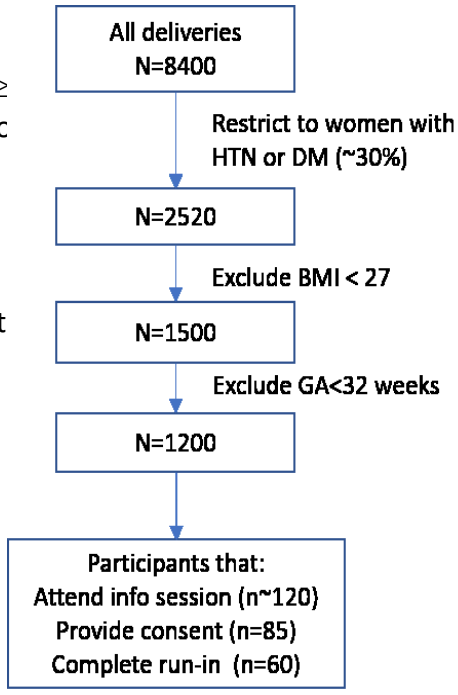
5.2 Study duration

This is a 16-week intervention that starts after the 1-week behavioral run-in and attending the Weight Loss 101 session. Overall duration of study from enrollment to final evaluation is 20 weeks.

5.3 Target population

Postpartum women with overweight or obesity, age ≥ 18 years with ≥ 1 CV risk factor, including chronic hypertension or diabetes mellitus, c pregnancy complication placing them at increased CV risk, such as hypertensive disorder of pregnancy or gestational diabetes.

Fig 1: Estimated sample size



5.4 Accrual

The study population will be drawn from adult postpartum women at Penn (the Hospital of the University of Pennsylvania (HUP) or Pennsylvania Hospital (PAH)). We will aim to randomize 60 participants, 2:1 in the intervention and usual care groups (40 in the intervention and 20 in usual care). As some participants will be excluded during the run-in period (e.g. because they did not complete the daily food log or BMI < 27), we will plan to consent 85 patients to reach our goal randomization. Approximately 8,400 deliveries occur annually at Penn. Assuming about 30% will have any hypertensive disorder or diabetes, 60% will have a BMI ≥ 27 kg/m^2, and up to 20% may be excluded for other reasons, we estimate that approximately 1,200 women will be potentially eligible (see Figure 1)

5.5 Key inclusion criteria

1) Age ≥18 years;
2) Delivered a baby at HUP or PAH within 8 weeks-12 months prior to study enrollment;
3) BMI ≥ 27 kg/m^2

4) Diagnosis of one of the following medical conditions: chronic hypertension, gestational hypertension, preeclampsia, eclampsia, gestational diabetes, or diabetes mellitus (type 1 or 2) based on diagnosis codes in the EMR
5) Has online access through smartphone or computer and has email address
6) Ability to read and provide informed consent to participate in the study

5.6 Key exclusion criteria

1) Delivered prior to 32 weeks gestation in the EMR
2) Documentation of fetal demise or neonatal demise in the EMR
3) Currently pregnant or planning to get pregnant within the next 5 months
4) Does not speak English
5) Answers yes to any of the following questions:
    - Are you currently participating in any other weight loss or physical activity studies?
    - Do you have any medical conditions or other reasons why you could not participate in a 16-week weight loss or physical activity program?
6) Participants will be excluded after completing the run-in period if they do not complete the daily food log or their baseline BMI is < 27 kg/m^2

6. Subject recruitment

We will use EPIC to identify a cross-sectional cohort of potentially eligible patients. Given the lag time between identifying potentially eligible patients and enrollment, we will identify women with a delivery occurring between the time of the data pull and 365 days prior. We will identify women based on the inclusion and exclusion criteria above. In order to optimally recruit women with a BMI ≥ 27 kg/m^2 at time of enrollment, we will use the following BMI criteria as documented in EMR:

a. Pregravid BMI ≥ 30, regardless of delivery BMI
b. Pregravid BMI 28-29.9 and delivery BMI ≥ 33
c. If pregravid BMI missing, will include delivery BMI ≥ 33

Potentially eligible patients will have their current address, phone number, email address, demographics, and clinical history abstracted. We will compare two approaches to patient recruitment (see study schema above, enrollment strategies)

a. Email: For patients meeting inclusion criteria with a documented email address, we will randomize them to one of two recruitment emails that test behavioral approaches to engaging patients. Group 1 (reserved a spot) will receive an email notifying them that we reserved a spot for them in the upcoming online information session for a weight loss program designed for postpartum women. Group 2 (commit today) will receive an email asking participants if they are ready to commit to their health. Participants will be able to click on an embedded link in the email which will take them to a secure Redcap survey that will allow them to sign up for the virtual information session. Once participants sign up, they will receive a text reminder prior to the information session with the Zoom link. See

Appendix 2 for text of recruitment emails. For participants who do not respond, a reminder email will be sent 48 hours after the initial email.

b. Mailer: We will combine participants who received an email but did not respond and patients who do not have an email address documented in the EMR. We will then randomize them to one of two mailer strategies: study mailer alone versus mailer plus gift. The mailer alone group will receive a flyer and mailer that focuses on achieving a healthy lifestyle postpartum and explaining the weight loss study (see Appendices 3 and 4). The mailer plus gift group will receive a mailed package containing the flyer and mailer plus a baby bib inscribed with study logo. Recruitment materials will be sent in waves until the expected number of participants are enrolled.

Patients will be able to sign up for the virtual information session hosted on Zoom through the study website (Redcap). Information on how to sign-up will be included on the mailer. In addition, patients will be able to call or text the study phone number to talk to a clinical research coordinator (CRC) in the Maternal and Child Health Research Center (MCHRC) to learn more about the study and/or sign up for an information session. We will try to accommodate patients who cannot make any of the scheduled sessions by scheduling additional sessions. In order to sign up, participants will need to provide their name, contact information, and date of birth.

As of 9/25/2021, we have reach target randomization using email recruitment alone. In order to compare the mailer versus mailer plus baby gift as outlined in Aim 2, we will continue recruitment using the mail strategy (see Study Schema, enrollment strategies above). When participants click on the Redcap link to sign up for a virtual information session, they will be informed that study enrollment is full. They will have the option to watch a 10-15 minute recorded video of study staff reviewing evidence based approaches to weight loss, which will be posted on the Recap website.

7. Subject compensation

All eligible participants will receive a scale if they complete the 1-week behavioral run-in period. Participants will receive $30 after completing the 16-week intervention, virtual weigh-in and exit survey at the end of the study. Compensation will be delivered via Greenphire ClinCard.

8. Study procedures

8.1 Consent

Interested participants will sign up for and attend an online information session that will be conducted by research staff over Zoom. Prior to the information session, participants will be emailed a copy of the informed consent form. In order to achieve a goal of 10 participants per session, we will invite 15-20 individuals for each session. The research staff will present a PowerPoint via screen share that reviews study rationale, expectations, adherence to the run-in period and interventions, and assessments. Participants will be muted for the presentation. Participants can choose to have their video turned on or off for the presentation, however they will be asked to have their first name displayed on their Zoom window.

At the end of the presentation, the participants will be un-muted. Participants who are interested in enrolling and providing informed consent will be asked to stay on the Zoom call and make sure their video is turned on. Participants who are not interested in enrolling will be invited to leave the call. At this point, research staff will review the informed consent form and allow participants to ask questions. Once all questions are answered, participants who are interesting in providing informed consent will be asked to type their name in the chat box and indicate that they consent to participate. This will count as verbal consent provided in a group format. Documentation of verbal informed consent will be kept in the research record. Participants will be provided with details regarding how to contact the research team via phone at any time if they subsequently wish to withdraw from the study. Participants will be asked to electronically sign the consent form via Redcap when they receive the surveys as part of the behavioral run-in period and prior to randomization.

8.2 Procedures

a) Virtual information session: All potentially eligible and interested participants will first complete this session. At the end of the session, participants will provide verbal informed consent and will be invited to complete the behavioral run-in period.

b) Behavioral run-in: participants will be emailed a link to a secure Redcap survey and asked to complete the following steps:

- Electronic consent
- Survey to determine eligibility
- Profile with contact information, including correct address to send scale and contact preferences (email or text)
- Online W9 form to facilitate delivery of incentives
- Baseline demographic and study specific surveys (see Appendix 5)

Participants will be asked to complete 5 days of food logging. Participants can log food in MyFitnessPal (MFP), a free app for food tracking, and share with research staff or they can keep a food diary on paper and send in screenshots via text or email. Participants who provide informed consent and complete the run-in period will be sent a digital scale along with handouts in preparation for the virtual kick-off session.

c) Virtual kick-off session: Once participants have received the scale, they will be eligible to sign up for a virtual kick-off session, during which participants will be randomized. Participants can sign up through the study website (via Redcap) or by contacting a CRC. This session will be conducted by research staff over Zoom. Randomization will occur at the beginning of the session and participants will be placed in one of two breakout rooms for the intervention or control arm.

- Control arm: study staff member will inform participants that they are in the control arm.

- Intervention arm: study staff will lead the Weight Loss 101 session. This session will review weight, calorie, and physical activity goals and evidence-based weight loss strategies, including food logging and daily weights. All participants will be asked to lose 10% of their body weight, corresponding to 1-2 lb/week over the 16-week study. Participants will receive a brief introduction to the online BWL study website. The session will also include information about weight loss and exercise while breastfeeding.

d) Virtual weigh-in: All participants will be asked to complete a virtual weigh-in on the Monday following the kick-off session. Their weight on the Monday morning will serve as their baseline weight for the program. Participants in both arms will be asked to take a photo of the scale with the morning weight and send it to study staff by text or email. The number stays on the scale for 3 seconds after stepping off.

e) Health coach: A study staff member will be trained as a weight loss coach by the PIs. If participants in the intervention arm are having trouble using the platform, reaching their weight loss goals, or have stopped logging into the platform, research staff will reach out to help triage and troubleshoot any barriers.

g) At the end of the 16-week intervention, all participants will be asked to complete their final virtual weigh in and send a photo of the scale to study staff by text or email. At the end of the study, participants will be asked to complete an exit survey. In addition, participants will be offered an opportunity to participate in an online group feedback session on Zoom. Participants will receive $30 incentive for completing the final weigh-in and exit survey. Study staff will abstract clinically relevant data from the electronic medical record to collect data on demographics, clinical comorbidities, and health care utilization. The collection of these data will obviate the need to further burden participants by asking them additional questions during the survey periods.

9. Analysis plan

Primary outcomes include:

- Enrollment rate, comparing email recruitment strategies (reserved a spot versus commit to health) and comparing mail strategies (mailer versus mailer plus gift)
- Change in weight from baseline to 16-week follow-up
- Proportion of participants losing $\geq$ 5% of weight

Secondary outcomes:

- Study completion rate between 2 arms
- In the intervention arm, engagement with online BWL platform, including number of total logins, number of weeks with $\geq$ 1 login, number of weeks that calories, physical activity minutes, and body weight were reported for at least 5 of the 7 days

Exploratory outcomes

- Differences in any of the primary or secondary outcomes according to race/household income

To compare sample characteristics between arms we will use t-tests or Wilcoxon rank-sum tests for continuous variables and Pearson chi square tests or Fisher's exact tests for categorical variables. Generalized linear mixed effects models will be used to assess for differences in weight, given repeated observations. We will use fixed effects to adjust for study arm, baseline weight, and calendar month, which may reflect seasonal variations that make weight loss harder or easier. We will conduct a number of sensitivity analyses to evaluate the robustness of our findings. All hypothesis tests will be two-sided using a two-sided alpha of 0.05 as our threshold for statistical significance. We will use Stata and/or SAS to analyze the data. We will use multiple imputation for missing data.

10. Investigators

Jennifer Lewey, MD, MPH is the co-Principal Investigator (PI) and is an Assistant Professor of Medicine at the Perelman School of Medicine. She is Director of the Women's Cardiovascular Health Program. She has experience running lifestyle interventions among postpartum women.

Kelly Allison, PhD is the co-Principal Investigator (PI) and is a Professor of Psychology in Psychiatry at the Perelman School of Medicine. She is Director of the Center for Weight and Eating Disorders. She has extensive experience designing and running behavioral weight loss clinical trials.

Tricia Leahey, PhD is a co-investigator. She is Associate Professor in the Department of Allied Health Sciences and Co-Director of the Weight Management Research Group at the University of Connecticut (UConn). She developed the online BWL platform along with collaborators at the University of North Carolina.

The Clinical Research Coordinator has experience with administering studies involving interventions with pregnant and postpartum populations and also has experience training Research Assistants to follow study protocols.

11. Human research protection

11.1 Data confidentiality

Participants who are randomized into the online BWL program will be enrolled in the platform using the contact information (name, email address, and phone number) provided at the beginning of the study. The platform was designed by Dr. Tricia Leahey (co-I) and collaborators and is being provided to the Penn study team to use as part of the study at no cost. Research staff working with Dr. Leahey at UConn will be responsible for enrolling participants into the platform. Penn study staff will be provided a login and password to securely access any data entered into the platform by Penn participants. Penn study staff will not be able to enroll participants directly into the platform because this requires an administrator account, which would permit access to all studies that are ongoing within the platform at UConn. The participant information needed for enrollment (name, email, and phone number) will be

securely shared with the UConn research staff via a Penn Box link. Paper-based records will be kept in a secure location and only be accessible to personnel involved in the study. Computer-based files will only be made available to personnel involved in the study through the use of access privileges and passwords. Wherever feasible, identifiers will be removed from study-related information. Precautions are in place to ensure the data are secure by using passwords and encryption, because the research involves web-based surveys.

11.2 Subject confidentiality

Research material will be obtained from participant surveys and clinical data abstracted from the EMR. All participants will provide informed consent for access to these materials. The data to be collected include demographic data (e.g., age, sex, self-identified race) and outcome data. Research material that is obtained will be used for research purposes only. The same procedure used for the analysis of automated data sources to ensure protection of patient information will be used for the survey data, in that patient identifiers will be used only for linkage purposes or to contact patients. The study identification number, and not other identifying information, will be used on all data collection instruments. All study staff will be reminded to appreciate the confidential nature of the data collected and contained in these databases.

11.3 Subject privacy

Enrollment will include a description of the voluntary nature of participation, the study procedures, risks and potential benefits in detail. The enrollment procedure will provide the opportunity for potential participants to ask questions and review the consent form information with family and friends prior to making a decision to participate. Participants will be told that they do not have to answer any questions if they do not wish and can drop out of the study at any time, without affecting their medical care or the cost of their care. They will be told that they may or may not benefit directly from the study and that all information will be kept strictly confidential, except as required by law. Subjects will be given a copy of the consent document. All efforts will be made by study staff to ensure subject privacy.

11.4 Data disclosure

The following entities, besides the members of the research team, may receive protected health information (PHI) for this research study in order to enroll patients in the online platform (intervention group only). These data will be limited to: participant's name, email address, and cell phone number, in addition to any data entered into the online platform (limited to daily weight, caloric intake, and exercise duration).

- The research team of Dr. Tricia Leahey (co-I) at the University of Connecticut

11.5 Data safety and monitoring

At the time of enrollment in the study, all patients are given anticipatory guidance on when to seek medical attention. In addition, participants will be asked to report to the study team any episodes of shortness of breath, light-headedness, or other changes during periods of exercise. They will be instructed to call the study team. The study coordinator will call the participant to

collect information regarding the issue and then the PI will review and determine whether it is ok to proceed, further investigation is needed, or the participant should stop the study.

11.6 Risk/benefit

11.6.1 Potential study risks

To minimize the chance for serious and unexpected adverse events, study participants will be screened through exclusion criteria for any health conditions that may be exacerbated by participating in a physical activity study. The intervention tries to motivate a modest weight loss and increase in exercise that should pose little health risk to participants. Participants are given guidance on when to seek medical attention and a reporting protocol is in place to capture any changes in symptoms with physical activity. Another potential risk of this study is a breach of participant confidentiality. We will minimize this risk by linking individual identifying information with participant ID numbers only in one single secure file that will only be accessed by the study team in the case of an adverse medical event, participant dropout, or if otherwise deemed necessary by the Principal Investigator. All other identifying information will be discarded after initial contact with the Study Coordinator. Due to the financial incentives in this study, we will be collecting social security numbers so that we can complete W-9 forms for participants. Social security numbers only will be used to generate W-9 forms and will be deleted once they are no longer needed. We will also collect home addresses to mail scales and incentive payments. Accidental disclosure of social security numbers could lead to identity theft. We will use commercial-grade encryption to protect social security information in transit. Names and addresses will be stored in encrypted databases. These data will be viewable only by the respective participants and the study coordinator. All other members of the research team will be able to view only participant ID numbers. There will be no functionality in the web application to export a dataset with identifiable information. Even the study arms will be identified by code letters until both the statistician and PI agree that analysis is complete.

11.6.2 Potential study benefits

Through participation in this study, each participant will have the potential to lose weight and increase their physical activity, which could improve their health and reduce their risk for future cardiovascular disease or other conditions such as diabetes and hypertension. If this approach is effective, it could have tremendous benefits for society if adopted on a wide scale to help women lose weight after delivering a baby. It is expected that other people will gain knowledge from this study and that participation could help understand how to effectively deliver a virtual program for weight loss in a variety of populations. Participants may also receive no benefit from their participation in the study.

11.6.3 Risk/benefit assessment

Anticipated risks of this study should be minimal and the risk/benefit ratio is very favorable. To minimize the chance for serious and unexpected adverse events, study participants will be screened through exclusion criteria for any health conditions that may be exacerbated by participating in a weight loss study.

12. References

1. Ladabaum U, Mannalithara A, Myer PA, Singh G. Obesity, abdominal obesity, physical activity, and caloric intake in US adults: 1988 to 2010. Am J Med. 2014 Aug;127(8):717-727.e12.

2. Chen C, Ye Y, Zhang Y, Pan X-F, Pan A. Weight change across adulthood in relation to all cause and cause specific mortality: prospective cohort study. BMJ. 2019 Oct 16;367:l5584.

3. Knowler WC, Barrett-Connor E, Fowler SE, Hamman RF, Lachin JM, Walker EA, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. N Engl J Med. 2002 Feb 7;346(6):393–403.

4. Ali MK, Echouffo-Tcheugui J, Williamson DF. How effective were lifestyle interventions in real-world settings that were modeled on the Diabetes Prevention Program? Health Aff Proj Hope. 2012 Jan;31(1):67–75.

5. Phelan S, Hagobian T, Brannen A, Hatley KE, Schaffner A, Muñoz-Christian K, et al. Effect of an Internet-Based Program on Weight Loss for Low-Income Postpartum Women: A Randomized Clinical Trial. JAMA. 2017 Jun 20;317(23):2381–91.

6. Leahey TM, Subak LL, Fava J, Schembri M, Thomas G, Xu X, et al. Benefits of adding Small Financial Incentives or Optional Group Meetings to a Web-based Statewide Obesity Initiative. Obes Silver Spring Md. 2015 Jan;23(1):70–6.

7. Leahey TM, Thomas G, Fava JL, Subak LL, Schembri M, Krupel K, et al. Adding evidence-based behavioral weight loss strategies to a statewide wellness campaign: a randomized clinical trial. Am J Public Health. 2014 Jul;104(7):1300–6.

8. Thomas JG, Leahey TM, Wing RR. An Automated Internet Behavioral Weight-Loss Program by Physician Referral: A Randomized Controlled Trial. Diabetes Care. 2015 Jan;38(1):9–15.