Feasibility of a meal delivery intervention for postpartum weight management

Study Protocol & Statistical Analysis Plan

NCT05579990

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STATEMENT OF COMPLIANCE

The trial will be conducted in accordance with International Conference on Harmonisation Good Clinical Practice (ICH GCP) and applicable United States (US) Code of Federal Regulations (CFR). The Principal Investigator will assure that no deviation from, or changes to, the protocol will take place without prior documented approval from the Institutional Review Board (IRB), except where necessary to eliminate an immediate hazard(s) to the trial subjects. All personnel involved in the conduct of this study have completed Human Subjects Protection and ICH GCP Training.

The protocol, informed consent form(s), recruitment materials, and all subject materials will be submitted to the local Institutional Review Board (IRB) for review and approval. Approval of both the protocol and the consent form must be obtained before any subject is enrolled. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form will be IRB approved; a determination will be made regarding whether a new consent needs to be obtained from subjects who provided consent, using a previously approved consent form.

1 PROTOCOL SUMMARY

1.1 SYNOPSIS

Title:	Feasibility of a meal delivery intervention for postpartum weight management
Study Description:	This is a single-group pilot study to assess the feasibility and acceptability of a meal delivery intervention among low-income postpartum women with obesity.
Objectives:	The objectives of the study are to assess the feasibility and acceptability of a meal delivery intervention among low-income postpartum mothers with obesity.
Endpoints:	The primary endpoint is participant adherence to the 8-week study intervention.
Study Population:	Participants will be 11 mothers who are 5-45 weeks postpartum, have obesity, and qualify for Medicaid or the Special Supplemental Nutrition Program for Women, Infants, and Children (i.e., have a household income at or below 185 percent of the federal poverty line).
Phase:	N/A
Description of Study Intervention:	An 8-week meal delivery intervention consisting of 10 home-delivered meals per week provided by a local meal delivery company supplemented by remote weekly behavioral support with study staff to help low-income postpartum women with obesity lose weight.
Study Duration:	8-weeks
Subject Duration:	8-weeks

1.2 SCHEDULE OF ACTIVITIES (SOA)

	Enrollment/ Baseline	Weekly during Meal Delivery Intervention	8-weeks (Follow-Up)
Demographics	X		
Pregnancy & Medical History	X		
Intervention Adherence Survey		X	
Diet Satisfaction (Diet Satisfaction Questionnaire; DSAT-28)[1]	X		X
Anthropometrics (weight, height)	X		X
Food Security (18-item US Household Food Security Survey Module)	X		X
Perceived Stress (10-item Perceived Stress Scale; PSS-10)[2,3]	X		X
Healthy Eating Self-Efficacy (from Lipsky LM et al. 2016)[4]	X		X
Weight Control Self-Efficacy (from Lipsky LM et al. 2016)[4]	X		X

2 INTRODUCTION

2.1 STUDY RATIONALE

Many women fail to return to their pre-pregnancy weight postpartum (i.e., postpartum weight retention, PPWR).[5-10] PPWR and interpregnancy weight gain are important predictors of long-term obesity risk.[11-13] Despite gaining similar amounts of weight during pregnancy, Black women are more likely to retain and accrue considerable amounts of weight postpartum compared to White women.[13-16] PPWR and interpregnancy weight gain negatively impact maternal cardiometabolic health and increase risk for adverse outcomes in subsequent pregnancies which are more common among Black women and those of lower socioeconomic status.[17-24] Black and lower income women are also disproportionately burdened by obesity,[25] which further increases the risk for PPWR, interpregnancy weight gain, and adverse health outcomes.[26-28] Behavioral interventions to prevent PPWR have had limited success, particularly among women with obesity.[29-32] Most PPWR interventions involve high participant burden and fail to sufficiently address both the psychological (e.g., low self-efficacy) and material (e.g., food insecurity) barriers and needs of low-income, minority women.[31-36] One promising and novel alternative approach capable of overcoming many of these barriers is the provision of healthy, home-delivered meals. In non-pregnant populations, meal delivery has been used to help manage various conditions including obesity with cost-effective and encouraging results.[37-43] Importantly, meal delivery for postpartum weight management may be sustainable given the cost-savings demonstrated in other populations and the recent expansion by public and private insurers to cover home-delivered meals.[41,42,44-46] Despite demonstrated success for managing other medical conditions, meal delivery for managing postpartum weight has not been studied.[37-43,47] Thus, the purpose of the proposed pilot study is to assess the feasibility and acceptability of a meal delivery intervention for postpartum weight loss among predominantly Black and low-income postpartum women with obesity using a single-group design. Findings from this pilot study will inform future refinements to the intervention which we plan to test and further refine in a future pilot study.

2.2 BACKGROUND

An estimated 60-75% of women fail to return to their pre-pregnancy weight (i.e., postpartum weight retention, PPWR) and up to 60% of women actually gain weight postpartum. [5-10] PPWR and interpregnancy weight gain are important predictors of long-term obesity risk.[11-13] Women of lower socioeconomic status and from racial/ethnic minority groups are disproportionately affected[13] and represent “priority populations” (i.e., those deserving priority in public health and clinical efforts).[48] Despite gaining similar amounts of weight during pregnancy,[13] Black women are estimated to retain an average of 6.4 pounds more and are twice as likely to retain more than 20 pounds at 1-year postpartum compared to their White counterparts.[14,15] Additionally, there is evidence of racial/ethnic differences in weight trajectories postpartum. On average, Black and White women lose similar amounts of weight across the first 6 weeks to 3 months postpartum, after which Black women exhibit gains in weight and body mass index (BMI) from 3 to 12 months postpartum while White women continue to lose weight across the first year postpartum.[49,50] Women with lower levels of education and those of lower income have also been shown to be an increased risk of PPWR.[5,7] This is extremely concerning, as excess weight retention or weight gain following pregnancy may be particularly harmful, given evidence of preferential central fat deposition postpartum.[51-53] Visceral adipose tissue, which is associated with several cardiometabolic risk factors,[54,55] is estimated to increase by 30-45% in the first year postpartum.[51-53]

PPWR and interpregnancy weight gain can exacerbate these unfavorable changes in body composition and cardiometabolic health, which can have important short- and long-term health implications.[51,52,56,57] PPWR and interpregnancy weight gain not only alter a woman's future chronic disease trajectory, increasing the risk for new or worsening obesity,[11,12,58] but also increase risk for adverse outcomes in subsequent pregnancies including hypertensive disorders of pregnancy,[17] preterm delivery,[18,19] and caesarean birth[20,59] which are more common among women from priority populations.[21-24] Black and lower income women are also disproportionately burdened by obesity,[25] which further increases the risk for PPWR, interpregnancy weight gain, and adverse maternal-child health outcomes.[26-28] Thus, there is great interest in effective interventions to improve postpartum weight management due to the important health implications for women and children, particularly among priority populations.

Unfortunately, even the most intensive behavioral interventions, which typically focus on caloric restriction, improving diet, and/or increasing physical activity, have had limited success for PPWR, particularly among women with obesity.[29-32,60] Based on meta-analyses, <2.5-kg weight reductions are observed with postpartum lifestyle intervention compared to standard care.[29,30,32] Lifestyle interventions for PPWR also show high levels of attrition and poor intervention adherence.[29-32,60] The postpartum period is important not only for maternal weight management and long-term obesity risk, but also for preparing women for healthy subsequent pregnancies as part of preconception planning. Entering subsequent pregnancies with excess adiposity increases the risk for PPWR,[10,27] creating a cycle in which women accrue additional weight with each pregnancy, leading to new or worsening obesity.[27] Exposure to maternal overweight/obesity in utero, in turn, increases the child's subsequent risk for developing obesity,[61,62] type 2 diabetes,[63-65] and cardiovascular disease.[66] Thus, postpartum weight management interventions are needed to promote healthy weight and prevent new or worsening obesity among mothers, as well as to prevent complications in subsequent pregnancies and reduce offspring long-term risk for obesity and chronic diseases.[26,61,66]

Most postpartum weight management interventions are intensive, comprehensive, and involve high participant burden by requiring significant effort and psychological and physical resources (e.g., self-regulation, time, financial means, access to healthy foods).[32,33] Such interventions may not adequately address social determinants of health (SDH; e.g., income, education, race/ethnicity, access to care, residential environment) that contribute to disparities in PPWR and obesity in priority populations.[67] Most PPWR interventions also fail to address psychological (e.g., stress, low self-efficacy) and material (e.g., food insecurity, transportation) barriers of low-income and minority women.[31-36] Achieving meaningful behavior change may be especially challenging postpartum, as women face additional stressors and barriers including lack of time for cooking/shopping, limited access to healthy food, and lack of basic cooking skills.[31,34-36,68-70] Women with a higher BMI may have more perceived barriers and lower self-efficacy to healthy behavior change postpartum.[70] A simplified approach targeting a few key behaviors may be particularly well-suited for under-resourced populations.[71] Also, postpartum weight management strategies are needed that more effectively address insufficient and/or diminished effort and resources, which is particularly relevant for priority populations.

Meal delivery overcomes many barriers common to postpartum weight management interventions that disproportionately burden priority populations. The provision of prepared meals to women's homes offers access to healthy food, thereby providing a physical and financial resource to support healthy eating regardless of income, geographic location, or access to transportation. Meal delivery reduces time and effort involved for meal planning, shopping, and preparation and requires less cognitive and behavioral self-regulation. In addition, pre-portioned meals modify the home food environment, which can support healthy habit formation and improve weight outcomes.[72,73]

Previous studies in non-postpartum populations demonstrate that meal delivery is an effective tool for managing weight, type 2 diabetes, and cardiovascular disease.[37-43] However, use of meal delivery to manage PPWR and promote the attainment of a health weight postpartum has not been studied. Meal delivery also has additional health benefits that may be particularly impactful postpartum. In non-postpartum priority populations, the provision of home-delivered meals has been shown to improve food insecurity and self-efficacy, reduce stress, and participants report high levels of treatment satisfaction.[40,74-78] These factors may have important implications for promoting healthy weight loss postpartum. For instance, food insecurity has been associated with PPWR, and this association may be stronger among women with obesity.[79] There is also evidence that lower self-efficacy for healthy behaviors and weight control may be an important predictor of PPWR,[4] and women with obesity are more likely to report lower self-belief in their ability to manage their weight postpartum.[70] Similarly, perceived stress has been shown to predict weight retention following childbirth.[80] Thus, by potentially improving these constructs, meal delivery may confer additional benefits for postpartum weight management.

The purpose of the proposed pilot study is to assess the feasibility and acceptability of a meal delivery intervention among predominantly Black and low-income postpartum women with obesity using a single-group design. If meal delivery is effective for managing weight postpartum, it may be sustainable given the cost-savings demonstrated in other populations (e.g., individuals with type 2 diabetes, cardiovascular disease).[37-41] In 2020, Medicare Advantage expanded to allow coverage of home-delivered meals.[44] More insurers are piloting meal delivery programs to address SDH for chronic disease management,[45,46,81-84] with hundreds of contracts between medically-tailored meal providers and health insurance plans nationwide.[85] A growing number of meal delivery programs are participating in healthcare innovation projects and receiving reimbursement for Medicaid, Medicare, and dually-eligible populations in at least 17 states.[46,81] Thus, there is the long-term possibility for meal delivery for maternal weight management postpartum to be offered as a covered health care service, thereby providing an accessible community resource and shift in health care policies.

2.3 RISK/BENEFIT ASSESSMENT

2.3.1 KNOWN POTENTIAL RISKS

This study involves providing a healthy meal delivery intervention to promote weight loss among low-income mothers who are 5-45 weeks postpartum. Those with conditions that may put them at increased risk or unique nutritional needs that would make the meal delivery intervention inadvisable will be excluded. Although unlikely, participants may experience normal and temporary physiologic reactions or weight fluctuations associated with healthy dietary changes, such as flatulence (frequency: rare; severity: mild). There is a risk of experiencing an allergic reaction to meals, which is judged to be low as participants self-select meals from provided menus with ingredients. Additionally, participants will be asked to report any food allergies or intolerances at baseline and the PI (who is a registered dietitian) will work with the study's meal delivery partner to accommodate participant food allergies and intolerances, as needed. Participants will also be provided with meal plans designed by the PI (who is a Registered and Licensed Dietitian) in accordance with current micronutrient and macronutrient recommendations for postpartum women. Participants will be instructed to self-weigh at least once per week during the study intervention using a study-provided scale and will be asked to report their weekly weight measurements using a Qualtrics survey sent via email each week of the study intervention.

Concerning weight fluctuations (e.g., weight gain) will be reported to and reviewed by the PI. Concerning weight fluctuations will be investigated and adjustments will be made to meal plans or study procedures, if necessary. Participants will also be closely monitored for any negative effects relating to the meal delivery intervention. Should it be determined that continued participation is contraindicated for a participant, they will be withdrawn from the study. Given that this is a non-invasive meal delivery intervention for postpartum weight management, we do not anticipate that withdrawals will be common. There is a risk of foodborne illness with meal delivery which is judged to be low as we are partnering with an experienced meal delivery company that operates in compliance with local, state, and federal food safety regulations. All meals will be delivered in insulated packaging with frozen gel packs to keep food cold in transit and meal delivery times will be scheduled with participants. In compliance with the Alabama Department of Public Health, home-delivered meals can be safely stored in the refrigerator for 7 days. Thus, fully prepared, refrigerated meals will be delivered once per week to participants' homes. All meals will also come with re-heating instructions. In the unlikely event a participant experiences distress from completing any of the self-report surveys, she will be allowed to skip items or discontinue the assessment. There is a low risk of emotional or psychological discomfort from participants answering personal questions about their health, eating, and activity behaviors.

2.3.2 KNOWN POTENTIAL BENEFITS

Participants will receive 10 healthy meals per week during the 8-week study at no cost to them. Participants in the study may feel less stress by saving time on planning, shopping, and preparing meals, improving food insecurity, and may feel good about themselves by eating a healthier diet postpartum. Having a healthier diet and less stress postpartum could have mental and physical health benefits postpartum.

Meal delivery may reduce postpartum weight retention and improve cardiometabolic health management, diet quality, food security, stress, and reduce barriers to healthy eating postpartum. This is important give that approximately 60-75% of women fail to return to their pre-pregnancy weight (i.e., postpartum weight retention) and many women gain weight postpartum. Postpartum weight retention and interpregnancy weight gain are important predictors of long-term obesity risk. Postpartum weight retention and interpregnancy weight gain negatively impact maternal cardiometabolic health and increase risk for adverse outcomes in subsequent pregnancies which are more common among Black women and those of lower socioeconomic status. Black and lower income women are also disproportionately burdened by obesity, which further increases the risk for postpartum weight retention, interpregnancy weight gain, and adverse health outcomes. To-date, traditional diet and weight management programs for postpartum women have been largely unsuccessful. Thus, promotion of healthy diet and postpartum weight loss may improve these outcomes. Participation in this study may enhance our understanding of meal delivery as a strategy for improving maternal health among underserved populations. Given the health risks associated with postpartum weight retention and interpregnancy weight gain, and the challenges of successful weight management postpartum, such information is clinically relevant and has potential for public health impact. Ultimately, results could inform public policy to leverage programs and/or modify insurance coverage to promote sustainability, which would have a meaningful public health impact on both short and long-term maternal health.

3 STUDY DESIGN

3.1 OVERALL DESIGN

This is a single-group intervention trial in which mothers who are 5-45 weeks postpartum and enroll in the trial will receive 10 meals per week for a total of 8-weeks.

Potentially eligible participants will be primarily recruited through the UAB Center for Women's Reproductive Health (CWRH). CWRH nursing staff will prescreen medical records of participants who delivered at UAB. Potentially eligible women will be approached in the postpartum recovery unit following delivery or at their 6-week postpartum appointment by a CWRH research nurse and told about the study. Interested women who meet initial eligibility criteria will be contacted by study staff at 5-45 weeks postpartum to complete a secondary pre-screening via telephone to confirm eligibility. Supplemental recruitment will occur via flyers/ads distributed at UAB obstetrics/gynecological offices, UAB pediatrics clinics, UAB lactation centers, UAB Nurse Family Partnership, local day care centers and churches, local breastfeeding and/or parent support groups, and Birmingham neighborhood associations. Interested women will respond via phone call or email to the public advertisements and be screened by phone.

Interested and eligible women will be scheduled to attend an Enrollment/Baseline Assessment visit during which informed consent will be completed. Those who consent to enroll in the study will then complete baseline study measurements including surveys and anthropometrics.

Within 1-2 weeks of completing the baseline assessment, participants will receive their first study meal delivery order. All participants will receive the study meal delivery intervention for a total of 8-weeks. During the study intervention, participants will be emailed a weekly Qualtrics survey to complete to report intervention adherence.

During the final week of the study meal delivery intervention, participants will complete Follow-up (week 8) assessment visit measurements, including surveys and anthropometrics.

3.2 END OF STUDY DEFINITION

While Primary Completion will be defined as the date of the week 8 follow-up assessment data collection of the last participant, the End of Study will be the date of completion of the participant medical record data abstraction, as these data will provide necessary data to characterize postpartum weight retention and necessary covariates for the conduct of our statistical analyses (e.g., accounting for gestational weight gain).

4 STUDY POPULATION

4.1 INCLUSION CRITERIA

To be eligible women must meet the following inclusion criteria:

- Medicaid eligible and/or have a household income at or below 185 percent of the federal poverty line
- 18 years of age or older

- Initiated prenatal care at a University of Alabama at Birmingham prenatal clinic
- Experienced a healthy singleton pregnancy
- 5-45 weeks postpartum at enrollment
- Body mass index of 30 kg/m^2 or greater at enrollment
- Residing within the meal company's delivery radius
- Willing to consent

4.2 EXCLUSION CRITERIA

- Self-reported major health condition (such as renal disease, cancer, or Type 1 or Type 2 diabetes)
- Current treatment for severe psychiatric disorder (such as schizophrenia)
- Past or current diagnosis of anorexia or bulimia
- Current use of medication expected to significantly impact body weight
- Current substance abuse
- Participation in another dietary and/or weight management intervention postpartum
- Unable to understand and communicate in English
- Unwilling or unable to consume study meals

4.3 SCREEN FAILURES

Interested women who do not meet study inclusion criteria will be informed of this decision by study staff and reassured that this will not change the quality of the services and care that they receive through the University of Alabama at Birmingham.

4.4 STRATEGIES FOR RECRUITMENT AND RETENTION

Recruitment will primarily occur through UAB Center for Women's Reproductive Health (CWRH) inpatient research staff. For this, CWRH inpatient clinical research staff will perform chart reviews of women on the postpartum recovery unit (following delivery) or who are attending their 6-week postpartum checkup (6th floor of the Women and Infants Center). Participants who meet initial eligibility criteria based on the chart review will be approached by a CWRH inpatient research staff member to briefly tell the potential participant about the study, give them a study flyer, and assess initial interest. Because enrollment will not occur until participants are 5-45 weeks post-delivery, participants who are interested when approached by CWRH inpatient research staff will be asked to give their permission to be contacted when they are 5-45 weeks postpartum to remind them about the study/confirm they are still interested in participating. Participant contact information will be collected for participants who opt-in to being contacted when they are within the 5–45-week postpartum enrollment window by study staff. When potential participants recruited through the CWRH inpatient research staff are 5-45 weeks post-delivery, they will complete a secondary pre-screening by telephone to confirm eligibility. Supplemental recruitment will occur via flyers/ads distributed at UAB obstetrics/gynecological offices, UAB pediatrics clinics, UAB lactation centers, UAB Nurse Family Partnership, local day care centers and churches, local breastfeeding and/or parent support groups, and Birmingham neighborhood associations. Interested women will respond via phone call or email to the public advertisements and be screened by phone.

While participants will receive 10 free meals/week for the duration of the 8-weeks study, we will employ strategies (implemented with participants in both intervention arms) that we have found effective for retention, including: (1) providing gift cards of $40 for completion of baseline and follow-up data collection visits, with incentives paid after each assessment; (2) ensuring frequent contacts with participants through weekly check-ins to not only obtain meal orders but also maintain engagement and foster open communication; and (3) providing reminder phone calls before scheduled study visits.

5 STUDY INTERVENTION

5.1 STUDY INTERVENTION(S) ADMINISTRATION

5.1.1 STUDY INTERVENTION DESCRIPTION

After completing baseline data collection, all participants will receive 10 fully prepared lunch/dinner-style meals per week for a total of 8 weeks. Prior studies indicate that providing 10 meals or meal replacements per week is effective for weight management.[43,86] We are partnering with a local company, Nourish Foods, to prepare and deliver study meals. Participants will select the 10 meals that they want each week from a weekly rotating menu that includes nutrition and ingredient information to accommodate participants with food aversions or allergies. Participants place meal orders weekly with study staff who will submit orders to the meal delivery partner. During these weekly contacts, trained staff also provide brief behavioral support, including evidence-based strategies of problem-solving, action-planning, and principles of motivational interviewing to help participants identify and navigate adherence barriers.[87-91] Staff will document the duration and topics discussed. Each week of the intervention, participants will be automatically sent an electronic survey to report the number of study-provided meals consumed by participants (versus others in the household versus thrown out), as we understand meals may be shared in food insecure households. The study coordinator will be available when collecting weekly meal orders to help participants navigate these challenges in multi-member households. If a participant does not place their weekly order, study staff will select meals based on participant preferences and allergies collected at baseline. Meals will be delivered once per week to participants' homes, which is in compliance with the Alabama Department of Public Health guidelines.

To supplement provided meals, participants will be given a study scale and instructed to weigh themselves at least once per week and report their weekly weight measurement on an automated weekly electronic survey. The study coordinator will monitor participant weights and report any concerning weight fluctuations to the PI who is a Registered Dietitian and can make adjustments to participant meal plans as needed to support healthy weight loss postpartum. This weight measurement will also allow study staff to track participant weight gain across the intervention as the goal is to support participants in losing 0.5 to 1 kg (or 1 to 2.2 pounds) of weight per week. To support adherence to the 0.5 to 1 kg (i.e., 1 to 2.2 pound) per week weight loss, participants will be given a Weight Tracking Sheet handout to help them track their weekly weight loss. Staff will also keep a Weight Tracking Sheet for each participant. To support the healthy integration of study meals within participants' diets to promote 0.5 to 1 kg/week (i.e., 1 to 2.2 pounds/week) weight loss, participants will be given a variety of written meal plans corresponding to their individual calorie goal, as well as relevant tools (i.e., measuring cups, portion size guides) to support use of meal plans, portion control, and appropriate integration of prepared meals into participant's diets. Calories goals will be calculated using the USDA Dietary Reference Intake Calculator for Medical Professionals[92] with gender, age, height, weight, activity

level, and lactation status as inputs, and reduced by 750 calories/day to promote weight loss of 0.5 to 1 kg per week.[93,94] Meal plans will comply with current micronutrient and macronutrient recommendations for postpartum women.[95] Participants will also be given a Fast-Food Handout to help them select healthier meals when eating out.

5.1.2 DOSING AND ADMINISTRATION

Participants in the study receive 10 lunch/dinner-style meals per week delivered to their homes free of charge for a total of 8-weeks. Participants will select the 10 meals that they want each week from a weekly rotating menu that includes nutrition and ingredient information to accommodate participants with food aversions or allergies. Participants place meal orders weekly with study staff who will submit orders to the meal delivery partner. If a participant does not place their weekly order, study staff will select meals based on participant preferences and allergies collected at baseline to ensure they receive meals each week. Each week of the intervention, participants will be automatically sent an electronic survey to report the number of study-provided meals consumed by participants (versus others in the household versus thrown out).

5.2 STUDY INTERVENTION COMPLIANCE

Participants place meal orders weekly with study staff who will submit orders to the meal delivery partner. If a participant does not place their weekly order, study staff will select meals based on participant preferences and allergies collected at baseline to ensure they receive meals each week. Each week of the intervention, participants will be automatically sent an electronic survey to report the number of study-provided meals consumed by participants (versus others in the household versus thrown out). Study staff completing weekly check-in calls with participants will document the duration and topics discussed.

6 STUDY INTERVENTION DISCONTINUATION AND SUBJECT DISCONTINUATION/WITHDRAWAL

6.1 DISCONTINUATION OF STUDY INTERVENTION

Participants will continue to receive the study intervention for the 8-weeks study. The study intervention may be discontinued for a participant if a clinical adverse event (AE) or other medical condition or situation occurs such that continued participation in the study intervention would not be in the best interest of the subject.

6.2 SUBJECT DISCONTINUATION/WITHDRAWAL FROM THE STUDY

Subjects are free to withdraw from participation in the study at any time upon request.

An investigator may discontinue or withdraw a subject from the study for the following reasons:

- Significant study intervention non-compliance

- If any clinical adverse event (AE), laboratory abnormality, or other medical condition or situation occurs such that continued participation in the study would not be in the best interest of the subject

Subjects who sign the informed consent form, receive the study intervention, and subsequently withdraw, or are withdrawn or discontinued from the study, will not be replaced.

6.3 LOST TO FOLLOW-UP

A subject will be considered lost to follow-up if he or she fails to complete 3 scheduled check-in visits in a row or fails to complete the follow-up visit and is unable to be contacted by the study site staff.

The following actions must be taken if a subject fails to be available for a required study visit:

- The site will attempt to contact the subject and reschedule the missed visit and counsel the subject on the importance of maintaining the assigned visit schedule and ascertain if the subject wishes to and/or should continue in the study.
- Before a subject is deemed lost to follow-up, the investigator or designee will make every effort to regain contact with the subject (where possible, 3 telephone calls and, if necessary, a certified letter to the subject's last known mailing address or local equivalent methods). These contact attempts should be documented in the subject's medical record or study file.
- Should the subject continue to be unreachable, he or she will be considered to have withdrawn from the study with a primary reason of lost to follow-up.

7 STUDY ASSESSMENTS AND PROCEDURES

7.1 STUDY ASSESSMENTS

All study participants will complete 2 in-person study assessments: 1) Enrollment/Baseline Visit and 2) Week 8 Follow-up Visit. During the 8-week meal delivery intervention, participants will also be sent a weekly electronic survey to report adherence with consuming the study meals (the number of study-provided meals consumed by participants [versus others in the household versus thrown out]) and to self-report their last weight measurement.

Enrollment/Baseline Visit: This visit will take place when participants are 5 to 45 weeks post-delivery. Participants will come to the study laboratory and the visit will take approximately 2-2.5 hours. Staff will review the consent form in detail with the potential participant and answer all of their questions. After providing informed consent to participate in the study, the Baseline Visit will continue with the completion of the following:

Weight and height measurements: Participant weight and height will be measured.

Questionnaires: At the Baseline Visit (i.e., Study Visit 1), participants will complete the following questionnaires:

- FORM 01: Food Allergies & Aversions
- FORM 02: Demographics
- Income Supplemental Questions Form

- FORM 03: Pregnancy & Infant History
- FORM 04: Pittsburgh Sleep Quality Index (PSQI)
- FORM 05: Perceived Stress Scale (PSS-10)
- FORM 06: Diet Satisfaction (DSAT-28)
- FORM 07: Self-Efficacy
- FORM 08: Barriers to Healthy Eating
- FORM 09: Infant Feeding
- FORM 10: Edinburgh Postnatal Depression Scale (EPDS)
- FORM 11: Multidimensional Scale of Perceived Social Support (MSPSS)
- FORM 12: Nutrition Security Survey
- Household Food Security Survey
- International Physical Activity Questionnaire

24-hour diet recalls: Participant 24-hour dietary recalls will be collected using the Automated Self-administered 24-hour Dietary Assessment Tool (ASA24). For this, participants will be asked to report everything they had to eat and drink during the previous day (from midnight-to-midnight) including any dietary supplements. The diet recall will take approximately 30-45 minutes. Participants will be given measuring cups and spoons to assist them with estimating portion sizes when completing the diet recall. Participants will also be given the ASA24 Information handout to assist them with completing 2 additional dietary recalls after Study Visit 1. For this, in the 1-2 weeks following Study Visit 1 (e.g., before beginning the meal delivery intervention) participants will be contacted to complete two additional 24-hour dietary recalls. These recalls may be completed by participants using a unique login for the ASA24 system or, if participants struggle to complete recalls or do not have internet or computer/tablet/cellphone access to complete the recalls themselves, a study staff member may complete the 24-hour recall with the participant over the phone using ASA24. The ASA24 Dietary Assessment Tool is a free, web-based tool developed by the National Cancer Institute of the National Institutes of Health for the collection of 24-hour dietary recalls for research. The ASA24 system does NOT collect any identifying data for study participants. Rather, researchers specify a unique numeric identifier for each respondent. Researchers must use a separate system or database outside of the ASA24 system to store participant numeric identifiers.

Intervention Data Collection: All N=11 women who enroll in the study will receive the study meal delivery intervention. At the baseline visit, women who consent to participate in the study will meet with a trained study staff member who will explain the procedures for placing weekly meal orders and show them how to complete weekly online Qualtrics Surveys which will be sent to participants via email. Participants will be given a study scale and instructed to weigh themselves at least once per week and report their weekly weight measurement on the weekly Qualtrics survey. As part of the weekly emailed Qualtrics survey, participants will also be asked to report intervention adherence (e.g., number of study meals they ate versus others versus that they threw away), adverse events (e.g., flatulence, new or worsening gastroesophageal reflux), and satisfaction with the study meals. Staff will complete weekly calls with participants to obtain their meal orders and to complete a brief check-in to see on how they are doing and utilize motivational interviewing techniques to help women who are struggling to comply with the intervention to problem-solve and develop weekly goals. Staff will document the duration and topics discussed during weekly telephone contacts.

Week 8 Follow-up Visit: This visit will take place during the final week for the study meal delivery intervention. Participants will come to the study laboratory and the visit will take approximately 2-2.5 hours. Participants will be asked to complete the following:

Weight measurements: Participant weight will be measured with participants in light clothing and no shoes.

Questionnaires: At the Follow-up Visit, participants will complete the following questionnaires:

- FORM 04: Pittsburgh Sleep Quality Index (PSQI)
- FORM 05: Perceived Stress Scale (PSS-10)
- FORM 06: Diet Satisfaction (DSAT-28)
- FORM 07: Self-Efficacy
- FORM 08: Barriers to Healthy Eating
- FORM 09: Infant Feeding
- FORM 10: Edinburgh Postnatal Depression Scale (EPDS)
- FORM 11: Multidimensional Scale of Perceived Social Support (MSPSS)
- FORM 12: Nutrition Security Survey
- FORM 13: Health & Demographics Update
- FORM 14: Program Satisfaction
- Household Food Security Survey
- International Physical Activity Questionnaire

Semi-structured, one-on-one interview: Participants will complete a semi-structured, one-on-one interview with a member of the research team. These one-on-one interviews (lasting up to 60 minutes) will be conducted using an interview guide. Interviews will be audio-recorded, transcribed verbatim, and the file will be erased after the transcripts have been verified for completeness. The transcription will not have any identifiable data included as participants will use anonymous names or nicknames during the interview sessions. The recording will be stopped at the end of the interview.

24-hour diet recalls (Follow-Up): Participants will be contacted on 3 separate days and asked to complete three 24-hour dietary recalls over the last 2 weeks of the study intervention (e.g., when participants are still receiving the meal delivery intervention) using the same procedures as described for the Baseline Visit. Briefly, the 24-hour recalls will either be completed directly by participants using the ASA24 system or will be completed over the phone with study staff (and study staff will enter participant recall information into ASA24). Participants will be asked to report everything they had to eat and drink during the previous day (from midnight-to-midnight) including any dietary supplements. Each diet recall will take approximately 30-45 minutes. Participants will be sent a copy of the How to Add a Nourish Meal Instructions handout that will instruct them on how to add one of the study-provided meals to a dietary recall in ASA24.

Participant Medical Records: A designated study staff member with appropriate approvals will obtain access to participant medical records for the retrieval of: date at gestational age (weeks at first dating ultrasound, date (which will be used to calculate gestational age (weeks)) and weight measured at the first prenatal visit; maternal weight and date (which will be used to calculate gestational age (weeks)) at their last prenatal care visit; maternal weight (if available) and gestational age at delivery; maternal diagnosis with gestational diabetes or hypertensive disorders of pregnancy and mode of delivery.

7.2 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

7.2.1 DEFINITION OF ADVERSE EVENTS (AE)

Adverse event means any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention-related (21 CFR 312.32 (a)).

7.2.2 DEFINITION OF SERIOUS ADVERSE EVENTS (SAE)

An adverse event (AE) is considered "serious" if, in the view of either the investigator or sponsor, it results in any of the following outcomes:

- Death
- A life-threatening adverse event (of note, the term "life-threatening" refers to an event in which the subject was at risk of death at the time of the event, rather than to an event which hypothetically might have caused death if it were more severe)
- inpatient hospitalization or prolongation of existing hospitalization
- a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- or a congenital anomaly/birth defect.

Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

7.2.3 CLASSIFICATION OF AN ADVERSE EVENT

7.2.3.1 SEVERITY OF EVENT

For adverse events (AEs), the following guidelines will be used to describe severity:

- **Mild** – Events require minimal or no treatment and do not interfere with the subject's daily activities.
- **Moderate** – Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.
- **Severe** – Events interrupt a subject's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating. Of note, the term "severe" does not necessarily equate to "serious."

7.2.3.2 RELATIONSHIP TO STUDY INTERVENTION

All adverse events (AEs) must have their relationship to study intervention assessed by the clinician who examines and evaluates the subject based on temporal relationship and his/her clinical judgment. The degree of certainty about causality will be graded using the categories below. In a clinical trial, the study product must always be suspect.

- **Related** – The AE is known to occur with the study intervention, there is a reasonable possibility that the study intervention caused the AE, or there is a temporal relationship between the study intervention and event. Reasonable possibility means that there is evidence to suggest a causal relationship between the study intervention and the AE.
- **Not Related** – There is not a reasonable possibility that the administration of the study intervention caused the event, there is no temporal relationship between the study intervention and event onset, or an alternate etiology has been established.

7.2.3.3 EXPECTEDNESS

The Principal Investigator will be responsible for determining whether an adverse event (AE) is expected or unexpected. An AE will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the study intervention.

7.2.4 TIME PERIOD AND FREQUENCY FOR EVENT ASSESSMENT AND FOLLOW-UP

The occurrence of an adverse event (AE) or serious adverse event (SAE) may come to the attention of study personnel during study visits or via weekly electronic surveys sent to participants during the study intervention which asks participants to report potential AEs.

All AEs including local and systemic reactions not meeting the criteria for SAEs will be captured on the appropriate case report form (CRF). Information to be collected includes event description, time of onset, clinician's assessment of severity, relationship to study product (assessed only by those with the training and authority to make a diagnosis), and time of resolution/stabilization of the event. All AEs occurring while on study must be documented appropriately regardless of relationship. All AEs will be followed to adequate resolution.

Any medical condition that is present at the time that the subject is screened will be considered as baseline and not reported as an AE. However, if the study subject's condition deteriorates at any time during the study, it will be recorded as an AE.

Changes in the severity of an AE will be documented to allow an assessment of the duration of the event at each level of severity to be performed. AEs characterized as intermittent require documentation of onset and duration of each episode.

The Study Coordinator will record all reportable events with start dates occurring any time after informed consent is obtained until 7 (for non-serious AEs) or 30 days (for SAEs) after the last day of study participation. At each study visit, the Study Coordinator will inquire about the occurrence of AE/SAEs since the last visit. Events will be followed for outcome information until resolution or stabilization.

7.2.5 ADVERSE AND SERIOUS ADVERSE EVENT REPORTING

All serious adverse events must be reported to the IRB according to regulatory requirements. The Principal Investigator will immediately report to the sponsor any serious adverse event, whether or not considered study intervention related, including those listed in the protocol or package insert and must include an assessment of whether there is a reasonable possibility that the study intervention caused the event. Study endpoints that are serious adverse events (e.g., all-cause mortality) must be reported in accordance with the protocol unless there is evidence suggesting a causal relationship between the

study intervention and the event (e.g., death from anaphylaxis). In that case, the investigator must immediately report the event to the sponsor.

All serious adverse events (SAEs) will be followed until satisfactory resolution or until the Principal Investigator deems the event to be chronic or the subject is stable. Other supporting documentation of the event may be requested and should be provided as soon as possible.

7.3 UNANTICIPATED PROBLEMS

7.3.1 DEFINITION OF UNANTICIPATED PROBLEMS (UP)

The Office for Human Research Protections (OHRP) considers unanticipated problems involving risks to subjects or others to include, in general, any incident, experience, or outcome that meets **all** of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the Institutional Review Board (IRB)-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
- Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

7.3.2 UNANTICIPATED PROBLEM REPORTING

The investigator will report unanticipated problems (UPs) to the reviewing Institutional Review Board (IRB). The UP report will include the following information:

- Protocol identifying information: protocol title and number, PI's name, and the IRB project number;
- A detailed description of the event, incident, experience, or outcome;
- An explanation of the basis for determining that the event, incident, experience, or outcome represents an UP;
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the UP.

To satisfy the requirement for prompt reporting, UPs will be reported using the following timeline:

- UPs that are serious adverse events (SAEs) will be reported to the IRB within 10 working days of the investigator becoming aware of the event.
- Any other UP will be reported to the IRB within 10 working days of the investigator becoming aware of the problem.

8 STATISTICAL CONSIDERATIONS

8.1 STATISTICAL HYPOTHESES

- Primary Efficacy Endpoint(s): The primary aim of this study is to assess the feasibility of the study meal delivery intervention. Hypothesis 1: We will successfully achieve >80% intervention adherence, defined as consuming at least 80% of received study meals, during the 8-week intervention.

- Secondary Efficacy Endpoint(s): The secondary aim is to characterize the acceptability of the study meal delivery intervention. Hypothesis 2a: We will collect data to characterize study participation rate and achieve <20% attrition. Hypothesis 2b: Participant reported diet satisfaction will show improvements from baseline to follow-up.

8.2 SAMPLE SIZE DETERMINATION

The goal of this pilot study was to collect preliminary data regarding the feasibility and acceptability of a meal delivery intervention among postpartum women. As this is a feasibility pilot with the primary goal of capturing process data, a formal power calculation was not conducted. Indeed, effect estimates based on small pilot studies are too imprecise and should not be used to inform future trials.[96] Instead, we followed recommendations from the National Center for Complementary and Integrative Health (NCCIH) that sample sizes for feasibility studies should be based on "practical considerations including participant flow, budgetary constraints, and the number of participants needed to reasonably evaluate feasibility goals." With these considerations in mind, the present study aimed to recruit a minimum of 10 participants and up to 20 participants based on the available budget. This was a single-group trial with the primary goal being to obtain process data and preliminary data to inform intervention refinements before pursuing funding for subsequent pilot testing.

8.3 STATISTICAL ANALYSES

8.3.1 GENERAL APPROACH

At each time of measurement, descriptive statistics will be used to summarize demographic characteristics and process measures, including rates of study participant, retention, and intervention adherence. Average values of outcome measures (e.g., diet satisfaction) will be calculated for baseline and follow-up. No formal statistical analyses will be conducted as this was a single group feasibility study that was not designed to be powered to detect statistical significance.

8.3.2 ANALYSIS OF THE PRIMARY EFFICACY ENDPOINT(S)

For the primary endpoint of participant intervention adherence, the proportion of weekly study meals that participants reported a)they consumed, b) other household members consumed, and c) that were thrown away/uneaten will be calculated based on completed weekly electronic surveys.

8.3.3 ANALYSIS OF THE SECONDARY ENDPOINT(S)

For secondary endpoints, study participation rate (percentage of eligible subjects who agreed to participate out of those who were screened) and retention rate (percentage of enrolled participants

who complete follow-up) will be calculated and reported. Visual representation of the flow of participants through the study will be reported through a CONSORT diagram. Change in participant satisfaction with the diet will be reported as the mean total diet satisfaction score, as well as the mean scores on subscales for Cost Factor and Planning & Preparation Factor, at baseline and follow-up will be reported.[1]

8.3.4 SAFETY ANALYSES

Rates and severity of adverse events will be summarized using descriptive statistics.

8.3.5 BASELINE DESCRIPTIVE STATISTICS

At baseline, descriptive statistics will be used to summarize demographic characteristics and outcome measures by study arm and for the entire sample.

9 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

9.1 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

9.1.1 INFORMED CONSENT PROCESS

9.1.1.1 CONSENT/ASSENT AND OTHER INFORMATIONAL DOCUMENTS PROVIDED TO SUBJECTS

Consent forms describing in detail the study intervention, study procedures, and risks are given to the subject and written documentation of informed consent is required prior to conducting study screening procedures. A separate screening consent form will not be used.

9.1.1.2 CONSENT PROCEDURES AND DOCUMENTATION

Informed consent is a process that is initiated prior to the individual's agreeing to participate in the study and continues throughout the individual's study participation. Consent forms will be Institutional Review Board (IRB)-approved and the subject will be asked to read and review the document. The investigator will explain the research study to the subject and answer any questions that may arise. A verbal explanation will be provided in terms suited to the subject's comprehension of the purposes, procedures, and potential risks of the study and of their rights as research subjects. Subjects will have the opportunity to carefully review the written consent form and ask questions prior to signing. The subjects should have the opportunity to discuss the study with their family or surrogates or think about it prior to agreeing to participate. The subject will sign the informed consent document prior to any procedures being done specifically for the study. Subjects must be informed that participation is voluntary and that they may withdraw from the study at any time, without prejudice. A copy of the informed consent document will be given to the subjects for their records. The informed consent process will be conducted and documented in the source document (including the date), and the form signed, before the subject undergoes any study-specific procedures. The rights and welfare of the subjects will be protected by emphasizing to them that the quality of their medical care will not be adversely affected if they decline to participate in this study.

9.1.2 STUDY DISCONTINUATION AND CLOSURE

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to regulatory authorities. If the study is prematurely terminated or suspended, the Principal Investigator (PI) will promptly inform study subjects and the Institutional Review Board (IRB), will provide the reason(s) for the termination or suspension. Study subjects will be contacted, as applicable, and be informed of changes to study visit schedule.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to subjects
- Demonstration of efficacy that would warrant stopping
- Insufficient compliance to protocol requirements
- Data that are not sufficiently complete and/or evaluable
- Determination that the primary endpoint has been met
- Determination of futility

Study may resume once concerns about safety, protocol compliance, and data quality are addressed, and satisfy the IRB.

9.1.3 CONFIDENTIALITY AND PRIVACY

Subject confidentiality and privacy is strictly held in trust by the participating investigators and their staff. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the Principal Investigator.

All research activities will be conducted in as private a setting as possible.

Representatives of the Institutional Review Board (IRB) may inspect all documents and records required to be maintained by the investigator, including but not limited to, medical records (office, clinic, or hospital) and pharmacy records for the subjects in this study. The clinical study site will permit access to such records.

The study subject's contact information will be securely stored at each clinical site for internal use during the study. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by the reviewing IRB and/or Institutional policies.

Study subject research data, which is for purposes of statistical analysis and scientific reporting, will be stored at the UAB Department of Medicine, Division of General Internal Medicine and Population Science research office. This will not include the subject's contact or identifying information. Rather, individual subjects and their research data will be identified by a unique study identification number. The study data entry and study management systems used by research staff will be secured and password protected.

9.1.4 QUALITY ASSURANCE AND QUALITY CONTROL

The site will perform internal quality management of study conduct, data collection, documentation and completion. Quality control (QC) procedures will be completed by the Data Manager during data entry into the appropriate CRF. Any missing data or data anomalies will be communicated to the Study Coordinator for clarification/resolution.

Following written Standard Operating Procedures (SOPs), the monitors will verify that the clinical trial is conducted and data are generated are collected, documented (recorded), and reported in compliance with the protocol, International Conference on Harmonisation Good Clinical Practice (ICH GCP), and applicable regulatory requirements.

The site will provide direct access to all trial related sites, source data/documents, and reports for the purpose of monitoring and inspection by local and regulatory authorities.

9.1.5 DATA HANDLING AND RECORD KEEPING

9.1.5.1 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

Data collection is the responsibility of the clinical trial staff at the site under the supervision of the Principal Investigator. The Principal Investigator is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

All source documents should be completed in a neat, legible manner to ensure accurate interpretation of data.

Hard copies of source document worksheets will be used for recording data for each subject enrolled in the study.

9.1.5.2 STUDY RECORDS RETENTION

Study documents should be retained for a minimum of 3 years after the completion of the study. These documents should be retained for a longer period, however, if required by local regulations.

9.1.6 PROTOCOL DEVIATIONS

A protocol deviation is any noncompliance with the clinical trial protocol requirements. The noncompliance may be either on the part of the subject, the investigator, or the study site staff. As a result of deviations, corrective actions are to be developed by the site and implemented promptly.

These practices are consistent with ICH GCP:

- 4.5 Compliance with Protocol, sections 4.5.1, 4.5.2, and 4.5.3
- 5.1 Quality Assurance and Quality Control, section 5.1.1
- 5.20 Noncompliance, sections 5.20.1, and 5.20.2.

It is the responsibility of the Principal Investigator to use continuous vigilance to identify and report deviations within 10 working days of identification of the protocol deviation. Protocol deviations must

be sent to the reviewing Institutional Review Board (IRB) per their policies. The Principal Investigator is responsible for knowing and adhering to the reviewing IRB requirements.

9.1.7 CONFLICT OF INTEREST POLICY

The independence of this study from any actual or perceived influence, such as by the pharmaceutical industry, is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the design and conduct of this trial.

9.2 ABBREVIATIONS

AE	Adverse Event
ANCOVA	Analysis of Covariance
CFR	Code of Federal Regulations
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form
DHHS	Department of Health and Human Services
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
ICH	International Conference on Harmonisation
ICMJE	International Committee of Medical Journal Editors
IRB	Institutional Review Board
LSMEANS	Least-squares Means
NCT	National Clinical Trial
NIH	National Institutes of Health
OHRP	Office for Human Research Protections
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SOA	Schedule of Activities
SOP	Standard Operating Procedure
UP	Unanticipated Problem
US	United States

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CONSENT FORM TO BE PART OF A RESEARCH STUDY

Title of Research: Feasibility of a meal delivery intervention for postpartum weight management

UAB IRB Protocol #: IRB-300010155

Principal Investigator: Camille Worthington, PhD, RDN, LDN

Sponsor: UAB Obesity Health Disparities Research Center

General Information	You are being asked to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described further in the consent form.
Purpose	The purpose of the study is to test if a meal delivery program helps postpartum women like you have healthier diets and lose weight after having a baby.
Duration & Visits	You will be in this study for up to 11 weeks.
Overview of Procedures	This study will include 2 assessment study visits: one at the start of the study when you are 5-45 weeks post-delivery and another about 8 weeks later. Within two weeks of each visit, a study member will call you three times to ask you about everything you had to eat/drink the day before to learn about your diet. At both visits, you will also be asked to fill out questionnaires about your health, stress, activity level, and sleep. Within 1-2 weeks of completing the first study assessment visit, you will begin getting 10 study-provided meals per week delivered to your home for you to eat for a total of 8 weeks. While you are receiving the study meals, you will be asked to complete a weekly online survey and a brief phone call with a study member about how you are doing with the meal program. At the second study visit, you will also complete a one-on-one interview with a study member to give us feedback on how you liked the meal program.
Risks	The most common risks may include normal reactions associated with healthy dietary changes, such as gastrointestinal discomfort, though this would be temporary.
Benefits	You may or may not benefit from being in this study.
Alternatives	If you do not want to take part in the study, the alternative is to not participate.

Purpose of the Research Study

We are asking you to take part in a research study. The purpose of this research study is to test whether providing women, like you, who recently had a baby with 10 meals per week can help them have a healthier diet and lose weight. We are partnering with a local meal delivery company, Nourish Kitchen, to provide the study meals. You will get to select which meals you want from Nourish Kitchen's weekly rotating menu of meal options. This is a pilot study, which is an initial small scale study to understand if the meal delivery program as we have designed it is well-liked and works for postpartum women. Therefore, we will also ask you to give us your feedback on how you like the meal delivery program and what changes you would like to see us make if we do more meal delivery programs like this in the future. You may want to talk about the study with your family, friends, or medical provider. If you do not understand parts of this form, please ask questions. This

study will enroll 20 women who are 5 to 45 weeks post-delivery and received their prenatal care at a University of Alabama at Birmingham (UAB) clinic.

Study Participation & Procedures

If you agree to join the study, you will be asked to complete 2 study visits: 1) at the beginning of the study when you are 5-45 weeks post-delivery and 2) the second about 8 weeks later. Starting 1-2 weeks after you complete the first study visit, you will begin receiving 10 study-provided meals per week delivered to your home. These meals will be provided to you free of charge and you will get to choose your study meals from Nourish Kitchen's rotating weekly menu. You will receive study meals for a total of 8 weeks. While you are receiving study meals, we will send you a brief electronic survey to complete once per week and call you each week to check-in on how you are doing and to get your meal delivery order for the next week. We describe all of these components of the study in detail, below.

Study Visit 1: When you are 5-45 weeks postpartum, you will come to the UAB Medical Towers Building for the first study assessment visit. This visit will take about 2 to 2 ½ hours. We will go over the consent form. If you agree to be in the study, we will measure your weight and height to be sure you are eligible. You will complete a series of surveys asking you about your health, work and education, usual sleep habits and stress, food insecurity, diet, and physical activity. You will also be asked to complete 3 diet recalls to tell us about what you had to eat the day before: 1 recall will be done at Study Visit 1 and the other 2 diet recalls can be done on the computer at home or by telephone with a research staff member in the 1-2 weeks after Study Visit 1. We estimate the total time you will spend completing the 2 diet recalls at home will be about 1 to 1 ½ hours.

Study Meal Delivery Program: All 20 women who enroll in the study will receive the study meal delivery program. So, if you agree to be in the study, you will begin receiving the study meal delivery program after you complete Study Visit 1 (including the telephone diet recalls). You will begin receiving 10 study meals per week delivered to your home beginning when you are 5-47 weeks post-delivery and continuing for a total of 8 weeks. Each week, a study staff member will call you to check-in to see how you are doing with eating your meals, help you problem-solve any challenges you are having, and take your meal order for the next week. All study meals will be provided and delivered by Nourish Kitchen, a local meal delivery company. Therefore, your contact information (name, phone number, email address, address where you want your meals delivered) will be shared with Nourish Kitchen and their staff so that they can schedule and deliver your study meals to your home each week. Nourish Kitchen publishes their menus, which change weekly, with ingredients on their website which you can use to help you decide which meals you want each week. Study staff will then place your meal order for you with Nourish Kitchen. Study meals will be delivered to you once per week by Nourish Kitchen. All study meals come with nutritional information and the ingredient list, as well as re-heating instructions. Meal expiration dates are clearly indicated on the label of each meal. You will also be given a variety of example meal plans to help show you what types of foods you should be eating outside of the study-provided meals and a weight tracking sheet to help you gradually lose weight postpartum.

Each week of the study meal delivery program, you will be sent an electronic survey to complete to confirm you received your 10 meals for the week, to report how many of last week's meals you ate and how much you enjoyed them, and to report any issues you think the meals are causing you (for instance, if you feel gassy after eating a study meal). At Study Visit 1, you will be given a weighing scale and asked to weigh yourself once per week during the study and to report your weekly weight as part of the weekly electronic survey. This is to help make sure that you are losing a healthy amount of weight postpartum while receiving the study meal delivery program.

Study Visit 2: During the last week of the study meal delivery program, you will be scheduled to come to the UAB Medical Towers Building to complete the second (and final) study visit. This study visit will take about 2 to 2 ½ hours. We will measure your weight and you will be asked to complete a series of surveys (similar to Study Visit 1) and to participate in a one-on-one interview with a member of the research team. In the 1-2 weeks before your scheduled Study Visit 2, you will be asked to complete 3 diet recalls to tell us about what you had to eat the day before. We estimate the time you will spend completing the 3 telephone diet recalls will be about 1 ½ to 2 ¼ hours.

The study surveys and other measures you will be asked to complete at study visits and during the study meal delivery program are described in detail below.

- *Weight measurement* (Visits 1 & 2; 2 minutes): We will measure your weight.
- *Height measurement* (Visit 1 only, 4 minutes): We will measure your height.
- *Food Allergies & Aversions Survey (Study Visit 1 only; 3 minutes)*: Asks questions about any food allergies or food intolerances (e.g., lactose intolerance) that you have, as well as any strong food aversions or foods you strongly dislike. This will help us know what foods you need to avoid when ordering your study meals.
- *Demographics Survey (Study Visit 1 only; 10 minutes)*: Asks questions about your employment, education, relationship status, income level, race, and nutrition programs you may participate in.
- *Pregnancy & Infant History Survey (Study Visit 1 only; 5 minutes)*: Asks questions about your pregnancy history.
- *Pittsburgh Sleep Quality Index [PSQI] Survey (Study Visit 1 and Study Visit 2; 3-5 minutes)*: Asks questions about your usual sleep habits during the past month.
- *Perceived Stress Scale [PSS-10] Survey (Study Visit 1 and Study Visit 2; 1-2 minutes)*: Asks about different thoughts and feelings you may have experienced during the last month.
- *Diet Satisfaction [DSat-28] Survey (Study Visit 1 and Study Visit 2; 2-3 minutes)*: Asks questions about your satisfaction with different aspects of your diet such as how healthy it is, cost, and convenience.
- *Self-Efficacy Survey (Study Visit 1 and Study Visit 2; 5 minutes)*: Asks about your feelings and thoughts about different statements related to eating healthy and losing weight after having a baby.
- *Barriers to Healthy Eating Survey (Study Visit 1 and Study Visit 2; 1-2 minutes)*: Asks you about certain barriers you may face related to eating healthy.
- *Infant Feeding Survey (Study Visit 1 and Study Visit 2; 4 minutes)*: Asks about the types of foods you are feeding your infant (e.g., breast milk, formula, solid foods).
- *Edinburg Postnatal Depression Scale (Study Visit 1 and Study Visit 2; 2 minutes*): Asks questions about how you have been feeling over the past 7 days.
- *Multidimensional Scale of Perceived Social Support (Study Visit 1 and Study Visit 2; 3 minutes*): Asks about the support you get from others around you.
- *Nutrition Security Survey (Study Visit 1 and Study Visit 2; 3 minutes)*: Asks about your household's ability to decide what you eat over the past 30 days.
- *Household Food Security Survey (Study Visit 1 and Study Visit 2; 1-5 minutes)*: Asks about the food eaten in your household in the last 30 days and whether you were able to afford the food you need.
- *International Physical Activity Survey (Study Visit 1 and Study Visit 2; 25-30 minutes)*: Asks you about how much time you have usually spent doing different types of physical activities.
- *24-hour Diet Recalls (Study Visit 1 and by computer or telephone; 30-45 minutes per recall)*: The 24-hour diet recall interview gets a detailed summary of all foods, drinks, and dietary supplements you had during a complete 24-hour period (from midnight-to-midnight) for the day before the interview. Information is collected on the *time* of each eating occasion, the *type of meal* (breakfast, lunch, supper, snack), and the *location* of the meal (home, school, other), as well as *what* and *how much* was consumed. You will be asked to complete 6 total diet recalls for the study: one at Study Visit 1 + two by

computer or telephone in the 1-2 weeks after Study Visit 1 + three by computer or telephone in the 1-2 weeks before Study Visit 2.

- *Telephone Recall Availability Form (Study Visit 1 and Study Visit 2; 3-5 minutes)*: Asks you to indicate days of the weeks/times you are most likely to be available to receive a call to complete a 24-hour telephone diet recall.
- *Weekly Electronic Survey (weekly during meal delivery program; 5 minutes)*: Each week of the meal delivery program, you will be emailed or texted a link to a study survey to indicate that you received your 10 study meals; to report the number study meals that you ate last week; to report any symptoms you have had after eating meals (like if you got an upset stomach after eating a study meal); to rank how satisfied you were with last week's meals; to report your weekly weight; and if your phone number or address where you want your study meals delivered has changed.
- *Health and Demographics Update Survey (Study Visit 2 only; 5 minutes)*: Asks about changes to your employment and nutrition programs you may participate in.
- *Program Satisfaction Survey (Study Visit 2 only; 5-7 minutes)*: Asks about how satisfied you were with the study meal delivery program staff and the study meals themselves.
- *One-on-one Interview (Study Visit 2 only; 30-60 minutes)*: During your interview you will be asked a series of questions related to health concerns you have since having a baby, your expectations about the study meal delivery program, experience in the study meal delivery program, including program structure, delivery, and other resources, program engagement, ideas for future improvements, and additional information you want to provide that you think would be helpful for us to know. Your interview will take about 30-60 minutes to complete and will be audio-recorded using a digital recorder. Then, a written record of the audio recording will be typed. The written reports from the recording will give researchers helpful information to understand your and other participants' experiences in the study meal delivery program and how to improve future meal delivery programs like this one.

Medical Record Data: As part of this study, we will retrieve medical records from your most recent pregnancy. The information study investigators will receive from your medical records include the date and your gestational age at your first dating ultrasound during your most recent pregnancy; the date and your gestational age and weight from your first and last prenatal care visit for your most recent pregnancy; your gestational age when you gave birth; your weight at delivery; and information about your pregnancy/birth outcomes (including whether you were diagnosed with any medical condition during your pregnancy such as gestational diabetes or preeclampsia and whether you baby was delivered by Cesarean section or vaginally).

If you are currently or have used any illicit (street) drug(s) during your most recent pregnancy, we ask that you not participate in this study.

Additional Information:
Your de-identified private information (private information with all identifiers removed) may be used for future research studies or distributed to another researcher for future research studies without additional informed consent. **This is only when there are no identifiers associated with the data.**

Risks and Discomforts

The risks to you for participating in this study are judged to be low.

- While unlikely, you may experience normal, temporary reactions associated with making new healthy diet changes, such as gastrointestinal discomfort or flatulence.
- There is a risk of experiencing an allergic reaction to meals, but this is judged to be very low since you will be selecting your meals each week from menus with ingredients provided by Nourish Kitchen.

- There is a risk of foodborne illness with meal delivery, which is judged to be low as we are using an experienced company (Nourish Kitchen) that operates in compliance with local, state, and federal food safety regulations. All meals will be kept cold in transit and delivery times will be scheduled with you to ensure meals do not sit out too long. Meals also come with reheating instructions and are marked clearly with their expiration date.
- Some questions on the study surveys ask about personal information, such as income and information about your health. There is a small risk that you will feel uncomfortable or not want to answer these questions. If this happens, you can choose to skip any questions at any time.
- We will have to share your name, phone number, email address, and the address where you want your study meals delivered with a private meal delivery company we are contracting to provide study meals, Nourish Kitchen. By participating in this study, your name and contact information will be shared with Nourish Kitchen staff and delivery drivers to allow them to schedule and deliver your study meals. As such, there is a risk of loss of confidentiality associated with the information we provide to Nourish Kitchen. Only necessary information to provide you with the study meal delivery will be shared with Nourish Kitchen (this information is limited to your name, phone number, email address, and the address where you want your meal delivered).
- There is a risk of potential loss of privacy and confidentiality. This risk is small. We will take precautions to minimize this risk and assure confidentiality of data managed and stored at UAB. All self-reported questionnaire responses will only be identified by ID number. All interviews will be audio-recorded and transcribed but your name will not be used in transcripts. You do have the options to choose an anonymous name or nickname at the beginning of the interview. All data collected during this study will be securely stored as paper records in locked storage cabinets as well as electronic records. All electronic records will be stored on a secure, password-protected server. Only staff involved in the project will have access to records related to this research study.

Information for Women of Childbearing Potential, Nursing Mothers, and/or Men Capable of Fathering a Child

To be eligible to participate in this study, you must have had a baby within the last 5-45 weeks. The study is specifically designed for and targeting postpartum women. The provision of 10 healthy meals per week does not cause any extra risk to mothers who may be nursing.

Benefits

You may benefit from participating in this study, as all participants in the study will receive 10 healthy meals per week. These meals may make it easier for you to eat a healthier diet and lose weight after having a baby. Providing you with 10 meals per week free of charge may help you feel less stress by saving you time on planning, grocery shopping, and preparing meals; giving you access to healthier foods; and improving your food security (not having to worry about having enough food). Together, a healthier diet and less stress could have some benefits to your mental and physical health postpartum.

Because not much is known about how meal delivery postpartum can benefit mom's health, your participation in this study may provide valuable information to the medical community to help us better understand if meal delivery-based programs could be used to improve mom's weight and health after having a baby.

Alternatives

Your alternative is to not participate in this study.

Confidentiality and Authorization to Use and Disclose Information for Research Purposes

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you.

What protected health information may be used and/or given to others?
All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of any kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills; any other information related to or collected for use in the research study, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes; records about any study drug you received or about study devices used; and consent forms from past studies that might be in your medical record.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Who may use and give out this information?
Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study.

Who might get this information?
All individuals/entities listed in the informed consent document(s), including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere). Your information may also be given to the sponsor of this research. "Sponsor" includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor, or are providing support to the sponsor (e.g., contract research organization).

Information about you and your health which might identify you may be given to:

- the Office for Human Research Protections (OHRP)
- the U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Governmental agencies in other countries
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- the University of Alabama at Birmingham - the physicians, nurses and staff working on the research study (whether at UAB or elsewhere); other operating units of UAB, UAB Hospital, UAB Highlands Hospital, University of Alabama Health Services Foundation, Children's of Alabama, Eye Foundation Hospital, and the Jefferson County Department of Health, as necessary for their operations; the UAB IRB and its staff
- the billing offices of UAB and UAB Health Systems affiliates and/or Children's of Alabama and its billing agents

Why will this information be used and/or given to others?
Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the

sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

This research will be covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the UAB Forge AHEAD Center which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse and neglect, or harm to self or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

Information obtained during the course of the study which, in the opinion of the investigator(s), suggests that you may be at significant risk of harm to yourself or others will be reportable to a third party in the interest of protecting the rights and welfare of those at potential risk.

What if I decide not to give permission to use and give out my health information?
By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research.

May I review or copy the information obtained from me or created about me?
You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

May I withdraw or revoke (cancel) my permission?
Yes, but this permission will not stop automatically. The use of your personal health information will continue until you cancel your permission.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Is my health information protected after it has been given to others?
If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others. Including others outside of UAB, without your permission.

Voluntary Participation and Withdrawal

Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in it. If you decide not to be in the study, you will not lose any benefits you are otherwise owed.

You are free to withdraw from this study at any time. Your choice to leave the study will not affect your relationship with this institution. Contact the study investigator, Camille Worthington (205-975-7274), if you want to withdraw from the study.

You may be removed from the study without your consent if the sponsor ends the study, if the study doctor decides it is not in the best interest of your health, or if you are not following the study rules.

If you are a UAB student or employee, taking part in this research is not a part of your UAB class work or duties. You can refuse to enroll, or withdraw after enrolling at any time before the study is over, with no effect on your class standing, grades, or job at UAB. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation

There will be no cost to you for taking part in this study. All study meals and study-related assessments will be provided to you at no cost during the 11 week study period.

The costs of your standard medical care will be billed to you and/or your insurance company in the usual manner.

Payment for Participation

You will be paid $25 for each study visit, plus an additional $30 for completing all six 24-hour dietary recalls (if you complete less than 6 of the 24-hour recalls, you will be compensated $5 per recall you completed). If you withdraw from the study, you will be paid $25 for each study visit and $5 for each 24-hour dietary recall you completed. Payments will be made within 7 days of completing each study visit (one payment within 7 days of completing Study Visit 1 procedures and within 7 days of completing Study Visit 2 procedures) if you complete the entire study. The total payment you may receive is $80. If you do not finish the entire study, you will be paid at the time you decide to stop taking part in the study. Ask the study staff about the method of payment that will be used for this study (e.g., check, cash, gift card, direct deposit).

Payment for Research-Related Injuries

UAB has not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

UAB and the UAB Obesity Health Disparities Research Center have not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

New Findings

You will be told by the study investigator or the study staff if new information becomes available that might affect your choice to stay in the study.

Questions

If you have any questions, concerns, or complaints about the research or a research-related injury including available treatments, please contact the study investigator. You may contact Dr. Camille Worthington at (205) 975-7274.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.

Legal Rights

You are not waiving any of your legal rights by signing this consent form.

Signatures

Your signature below indicates that you have read (or been read) the information provided above and agree to participate in this study. You will receive a copy of this signed consent form.

_____

Signature of Participant Date

_____

Signature of Person Obtaining Consent Date

Reviewed by:

_____

Signature of Principal Investigator Reviewing Consent Document Date