Meals for Moms

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Meals For Moms Pilot Study

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I. Background, Rationale and Context

Pregnancy and the peripartum period can function as a "stress test" for future development of cardiometabolic disease,[1] with and gestational diabetes (GDM) and excessive gestational weight gain (GWG) portending worse outcomes later in a mother's life.[2,3] The prevalence of both conditions continues to increase with the obesity epidemic,[4,5] highlighting the urgent need for successful interventions to reverse maternal weight gain and promote normoglycemia. The early postpartum period provides a critical opportunity to address dietary behaviors that underlie both weight and dysglycemia. Postpartum medically-tailored meal (MTM) delivery is a novel intervention approach that may allow for improved glycemic control and weight loss in a traditionally hard-to-engage patient population. There is currently no available data on the cost, feasibility, or effectiveness of providing MTM to postpartum women.

A. GDM Plus Excess GWG Increases Risk of Adverse Maternal & Child Health Outcomes

Incidence of GDM has substantially increased over the past two decades,[4,5] and there is a need for interventions to reduce its long-term health impacts for mother and baby. Excess retained weight after pregnancy, impacting up to 80% of women, has important health consequences including development of Type 2 Diabetes Mellitus.[6] GDM and gestational weight retention confer higher risk of complications in subsequent pregnancies and cardiovascular disease in the future.[6,7]

B. The Postpartum Period: A Opportunity to Improve Maternal Metabolic Health

Most cardiometabolic perturbations from pregnancy will either resolve or persist within 12 weeks after delivery.[8] Further, the first 6 months after a baby is born are generally the period of most rapid weight loss for new mothers.[6] Weight plateau and even regain typically occur by 12 months postpartum, with consequences for short and long-term glycemic control.[9] Despite the opportunity to improve women's cardiometabolic health trajectories during the early postpartum period, many aspects of traditional weight loss and glycemic control interventions, such as intensive in-person visits and meal planning/preparation are quite difficult to implement and sustain while caring for a newborn infant. Attendance rates at postpartum clinical visits are low,[10] only 50% for Medicaid patients,[11] exemplifying the fact that new mothers have limited bandwidth for self-care activities. Postpartum dysglycemia & weight retention pose both an opportunity and a challenge for primary and secondary prevention of obstetric and cardiometabolic outcomes in women.

C. MTM programs are promising for treating Type 2 Diabetes, but there has been little uptake in practice

MTMs are designed with nutritional content (caloric density, macronutrient breakdown, and other features) tailored to a specific chronic disease state,[12] and typically operationalized by community-partners experienced in food preparation and delivery at the request of health systems or payers. Intervention studies using MTM to treat diet-related disease have shown great promise, especially for Type 2 Diabetes Mellitus where initial studies have found that MTM have been effective in improving diet quality and glycemic control.[13,14] Despite growing evidence that MTM programs can improve health and decrease medical care costs,[15] few of them have been translated from research into routine clinical practice, likely due to the high cost.[16] Where MTM programs are available, they are often restricted to short periods of time despite the chronic nature of the diseases they are intended to treat. Such high costs are not viewed as sustainable for long-term chronic disease management by health systems or payers. To our knowledge, MTM programs have not been used for primary prevention. Use of MTM for a time-limited but critical period, such as the first 3 months postpartum, may have greater translational potential among health systems & payers.

II. Objectives

The purpose of this proposal is to test the feasibility of providing medically tailored meals for postpartum women who had gestational diabetes and gestational weight gain that exceeds the IOM guidelines. The first objective is to understand the **feasibility** (n/% of meals successfully ordered & delivered, program cost per participant, and completion rate of CGM data collection) and **acceptability** (using participant surveys and interviews with key stakeholders) of the intervention and outcome measures. The second objective is to explore the preliminary **effectiveness** of the program, via 3-month changes in CGM markers of dysglycemia (primary) as well as: maternal diet quality, maternal weight and infant weight change, initiation and maintenance of breastfeeding, household food insecurity, and validated measures of financial and overall stress (exploratory).

III. Methods and Measures

A. Design

The Meals for Moms study is a pilot study to test the feasibility and acceptance of using continuous glucose monitors to measure changes in glucose associated with providing medically tailored meals to postpartum women who had gestational diabetes. A schematic of study enrollment, intervention design, and follow-up is included in Figure 1.

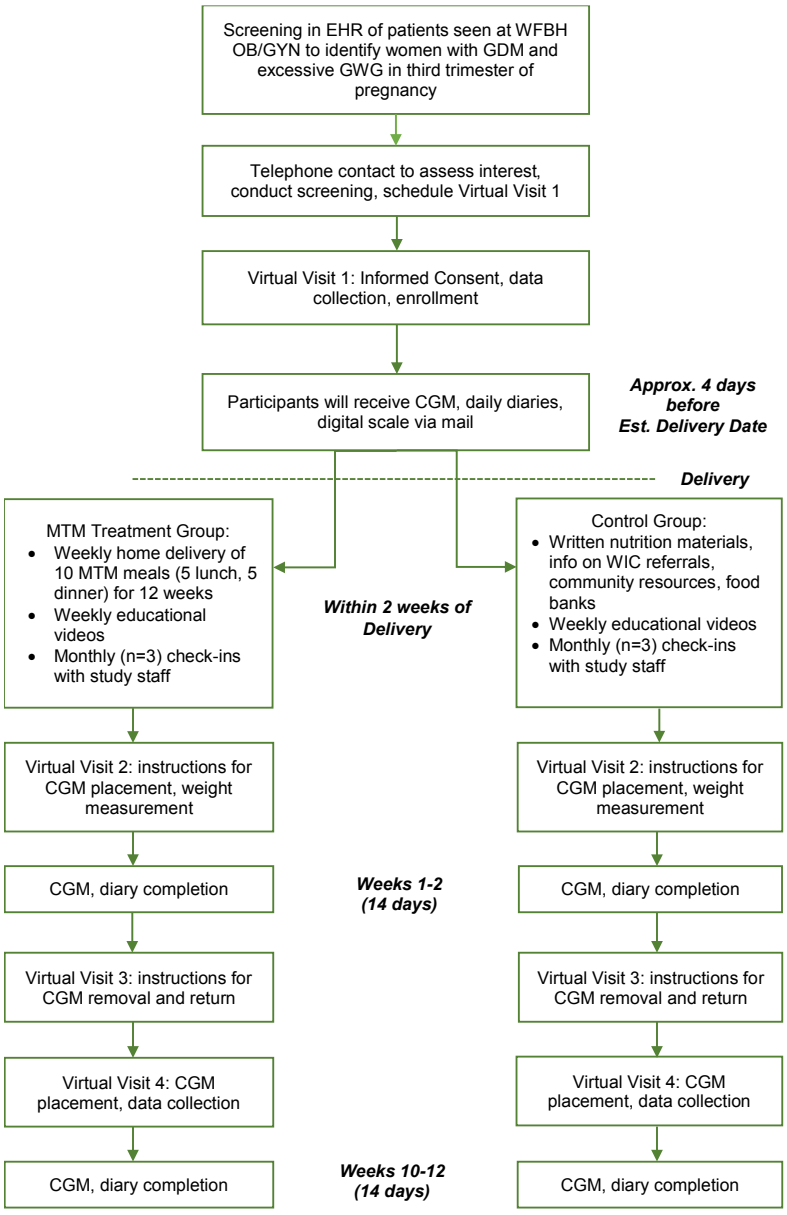

Figure 1. Schematic of Study Participation

B. Setting

The Meals for Moms pilot study is a collaborative partnership between researchers and clinicians from Wake Forest Baptist Medical Center and Providence Community Kitchen, a subsidiary of the Second Harvest Foodbank of Northwest North Carolina.

C. Subjects selection criteria

The principles guiding the selection of the following inclusion and exclusion criteria are to ensure the enrollment of participants who meet 2 major criteria: 1) high risk for future adverse health outcomes due to the diagnosis of GDM and excessive GWG; and 2) no medical contraindications to participate in a medically tailored meal program. Participants will include 30 women in the third trimester of a singleton pregnancy or who have recently given birth (within the previous 14 days) who receive obstetric care at a Wake Forest Baptist Health clinic and reside in Forsyth County, NC.

Inclusion Criteria

- Demographics: Women 18 years of age and older who reside in Forsyth County, NC

- Pregnancy: Currently 24 or more weeks into a singleton pregnancy or who have given birth within the past 14 days
- Clinical evidence of GDM defined as either:
    - 3-hour oral glucose tolerance test (OGTT) results obtained in the second trimester of pregnancy that show at least 2 abnormal values in any of the following combinations:
        - Fasting glucose > 95 mg/dL and 1h > 180 mg/dL
        - Fasting glucose > 95 mg/dL and 2h > GE 155 mg/dL
        - Fasting glucose > 95 mg/dL and 3h > 140 mg/dL
        - 1h > 180 mg/dL and 2h > 155 mg/dL
        - 1h > 180 mg/dL and 3h > 140 mg/dL
        - 2h > 155 mg/dL and 3h > 140 mg/dL
    - A diagnosis of "gestational diabetes" included on the Problem List in Wake One during current pregnancy, regardless of OGTT values
- Pre-gravid overweight or obesity or excessive GWG: Overweight or obese (BMI $\geq$25.0 kg/m^2) prior to current pregnancy OR most recent weight exceeds predicted weight gain for current weeks gestational age based on starting BMI defined as:
    - Pre-pregnancy BMI of 30 kg/m^2 or more and weight at most recent clinical visit 20+ pounds over pre-pregnancy weight
    - Pre-pregnancy BMI of 25-29.9 kg/m^2 and weight at most recent clinical visit 25+ pounds over pre-pregnancy weight
- English Proficiency: Able to read/understand English at or above a level sufficient to comprehend recruitment, informed consent, and intervention materials.
- Access to a smart phone/tablet/computer capable of connecting to video calls or teleconferencing software.
- Access to freezer space to store 10 frozen meals delivered to the home each week.
- Willingness to Accept Treatment Assignment: Prospective participants must be willing to accept assignment to either the medically tailored meal intervention or the comparison intervention condition.

Exclusion Criteria

- Clinical history of diabetes (type 1 or 2) pre-pregnancy
- Non-singleton pregnancy
- Other chronic diseases or medical conditions that would increase risk or make participation otherwise unsafe, including special dietary needs. A clinician investigator will review the medical record for all potential participants to determine if any such conditions exist.
- Known food allergies or sensitivities. Potential participants who report special dietary requirements including vegetarians, vegans, those who follow kosher or other specialized diets will be excluded due to the small nature of this pilot study.
- History of allergic skin reaction to adhesive tape
- Unable or unwilling to wear a CGM device
- Is scheduled for an MRI during the study weeks, making use of the CGM device unsafe
- Other: Conditions/criteria likely to interfere with participation and acceptance of treatment group assignment, including the following: inability/unwillingness to give informed consent, major psychiatric or cognitive problems (schizophrenia, dementia, self-reported substance or alcohol abuse), participation in another research study that would interfere with Meals for Moms

D. Sample Size

We anticipate recruiting a sample of 30 women (12 African-American, 10 Hispanic, 8 Non-Hispanic White). This is a pilot study and is not powered to test the effect of the MTM intervention on any outcome. The

estimates obtained in this study will be used to design a fully powered randomized controlled trial assessing the effect of a post-partum MTM intervention on blood glucose. Estimates of retention and adherence will be used to modify the sample size to account for dropouts and poor adherence. Estimates of the participation and accrual rates will be used to judge the feasibility of the subsequent trial given the required sample size relative to patient availability and our ability to recruit them into our trial.

E. Screening and Enrollment

We will generate weekly datasets using the Clarity reporting relational database in WakeOne to identify potentially eligible women within the electronic health record (EHR). The EHR data pulls will identify women, age 18 years or older, in their third trimester of pregnancy seen for obstetric care in a WFBH clinic in the past week who had a diagnosis of GDM with excessive GWG, and for whom English is the documented primary language. Datasets of up to 50 women who meet these criteria will be output weekly to a secure folder on the PHS network which only IRB-approved study staff may access. Datasets will also include patient name, age, MRN, expected delivery date, pre-gravid height and weight (to calculate BMI), current weight, diagnosis of GDM, and OGTT results. Research staff will then access individual EHR data to identify contact information and will place a telephone call to potential participants to discuss the study and to assess additional eligibility criteria. As we anticipate that some women who meet eligibility criteria may not appear in these datasets until very close to their expected delivery date and may not be reached for recruitment pre-partum, we will also attempt to contact women who appear in the dataset who have recently given birth (within the past 14 days). Additionally, a physician investigator will review diagnostic codes associated with recent encounters for all potential participants to identify any potential diagnoses or health conditions that may make participation unsafe or increase risk, including diagnosis of Type 1 or Type 2 diabetes pre-pregnancy, cardiovascular disease, essential hypertension, and dyslipidemia.

Potential participants who 1) satisfy the inclusion/exclusion criteria previously described, and 2) indicate that they are willing to provide written informed consent will be invited to complete a virtual baseline visit and be enrolled in the study. Informed consent will be obtained at the beginning of this visit (see Section I.b. Informed Consent for details). Given current patient volumes, we anticipate recruiting 1-2 women per week over a period of 3-4 months. As the study timeline is brief, 20 participants will be recruited into a MTM treatment group to ensure the feasibility of the intervention approach is tested. If sufficient time remains, an additional 10 participants will be recruited into a usual care comparison condition.

After enrollment, participants will be routinely monitored via the EHR to determine when they are admitted for delivery and to check for any potential problems during the delivery. To standardize anticipated contacts across all participants, the Estimated Date of Delivery (EDD) will be used to schedule meal deliveries, mailings, and email contacts for both treatment groups. Our plan is to initiate participant data collection post-partum within 2 weeks of delivery. Study staff will contact the participant approximately one week after the EDD to check on delivery status. We will also collect contact information during the enrollment process for an alternative contact person in

Table 1. Outline of Weekly Video Emails

Week	Video
1	The 4th Trimester (St. Louis Children's Hospital video)
2	HELP -Mindfulness
3	HELP - ABCs of emotions
4	*Phone visit with study team (no email)*
5	HELP - Tipping the calorie balance
6	HELP - Healthy Eating
7	HELP - More About Healthy Eating
8	*Phone visit with study team (no email)*
9	HELP - Physical Activity 101
10	HELP - Problem solving
11	HELP - Creating an environment for success
12	*Phone visit with study team (no email)*

the case of negative outcomes during or after delivery. Study staff will make at least five (5) attempts by phone, email, or text message to reach enrolled participants or their alternate contacts in the 2 weeks following the EDD. Continuous glucose monitors, readers, daily diaries, digital scales, and informational materials about the study and healthy diet resources will be delivered to participants by mail after the participant has been reached and continued participation is confirmed. Those participants who do not respond to study contact after delivery or who decline further participation will not receive study-related materials or meal delivery and will be considered as drop-outs. For those participants who are recruited and enrolled after giving birth, data collection will begin from the date of recruitment and informed consent.

Table 2. Outline of Monthly Phone Contacts

Month	Topic and Progress Check	Research Study	Health-related Goal Setting
Month One	General Check In- Self Care: • Sharing the importance of self-care and ideas for self-care activities • How are you prioritizing self-care? • "Goods and Bads" exercise for self-care • Encourage to attend 6 week postpartum visit o Help with concerns about healing body o Ideas for contraception o Help with breastfeeding or feeding concerns o General health help and advice	• Meal delivery (MTM group only) • Meal prep (MTM group only) • Weekly videos from study team • Problems with digital scale / tips on weighing • Other feedback	• SMART goal setting • Help participant set a modest goal for self-care
Month Two	General Check In- Dietary Awareness: • Brief primer on label reading (food label exercise) • Practice with food labels • Encourage to teach other family members (esp. those that do shopping)	• Meal delivery (MTM group only) • Meal prep (MTM group only) • Weekly videos from study team • Self-weighing on digital scale • Other feedback	• SMART goal setting • Help participant set a modest goal for dietary habit change • Eat breakfast • Try to notice when I am hungry • Have a healthy snack option in the house • Practice label reading
Month Three	General Check In- Physical Activity: • Brief primer on walking for exercise • Discuss what they have liked and not liked about exercise in the past? • What are their current barriers to exercising?	• Meal delivery (MTM group only) • Meal prep (MTM group only) • Weekly videos from study team • Self-weighing on digital scale • Other feedback	• SMART goal setting • Help participant set a modest goal for exercise habit change

F. Interventions and Interactions

Although frequent in-person sessions for nutrition education and lifestyle change counseling are typically part of glycemic control and weight loss interventions, our unique patient population does not allow for a traditional "intensive lifestyle intervention" (recovery from delivery, infant child at home, frequent newborn doctor visits). Accordingly, we focus on meal delivery as the main intervention component, coupled with the provision of nutrition and lifestyle information to increase the knowledge base and build a foundation for further improvements in lifestyle behaviors after the 3-month post-partum period in both treatment groups. Participants in both treatment groups will receive an educational email each week (unless there is a scheduled phone visit with the study team) with resources for women post-partum. These emails will include short informational videos, developed as part of a community-based translation of the Diabetes Prevention Program (HELP PD, IRB00000613), that contain core content on the physiological, emotional, cognitive, and behavioral basics of losing weight as well as adopting and

maintaining an active lifestyle. We will also include videos developed specifically for post-partum women on self, care, diet, and physical activity as appropriate. In order to address potential issues with access to availability of food and to increase the representation of diverse populations across the socioeconomic spectrum, all participants will be provided information on WIC access, local food banks, and other resources for healthy eating to address potential food insecurity. An outline of the weekly video emails is included in Table 1.

All participants will be scheduled for monthly individual visits with a member of the study team to discuss progress to date, potential barriers, and set goals for the upcoming month. During the first month, these visits will focus on self-care; in month 2, the focus will be dietary awareness; in month 3, participants will discuss physical activity with a member of the study team. A complete outline of the monthly phone calls is included in Table 2.

a. Medically-Tailored Meal (MTM) Intervention

A standardized series of MTMs appropriate for women with GDM will be developed in partnership with Providence Community Kitchen chefs. Participants will receive 10 meals each week (5 lunch, 5 dinner) over the course of 12 weeks for a total of 120 meals. Meals will be designed to create a slight caloric deficit in order to promote gradual weight loss, but with sufficient energy intake and macronutrient balance to allow breastfeeding. These meals will be roughly 40% carbohydrate, 30% protein, and 30% fat in composition and will be consistent with recommendations from the American Diabetes Association for women who have been diagnosed with GDM. We will plan up to 20 unique lunch and dinner recipes for the series. Providence will prepare each meal to be between 450-600 kcal and to contain 6 ounces of protein, 4 ounces of vegetable and I cup of whole grain (at a minimum). An example menu of 10 meals (1 week) is included in Appendix A and an example of the nutritional information that will be provided with each meal is included in Appendix B. In addition to receiving the MTMs, participants will be advised to supplement their own breakfast +/- snacks to reach a total daily calorie goal determined by starting BMI category. Note that we will provide participants with lists of healthy, low-cost ADA compliant snacks and breakfast ideas that would meet the caloric requirements, so that they do no need to track calories on their own. We do not expect the women to keep track of calories, but rather are providing them with a meal structure that should help them remain within the designated calorie range for their BMI category. Using the snack lists plus consuming provided lunches and dinners, the daily dietary structure we will advise will include 5 eating episodes, structured as follows:

BMI 30-39.9 – 1600 kcal daily (so long as breastmilk production not reduced)

- Breakfast 200-300 kcal
- Lunch (provided most days; on own 2d per week) 450-600 kcal
- Mid-Afternoon snack (on own) – 100-200 kcal
- Dinner (provided most days; on own 2d per week) 450-600 kcal

BMI 40-49.9 - 1800 kcal daily

- Breakfast 200-300 kcal
- Mid-morning snack: 200 kcal
- Lunch (provided most days) 450-600 kcal
- Mid-Afternoon snack (on own) – 200 kcal
- Dinner (provided most days) 450-600 kcal

BMI 50+ - 2000 kcal daily

- Breakfast 200-300 kcal
- Mid-morning snack: 200 kcal
- Lunch (provided most days) 450-600 kcal
- Mid-Afternoon snack (on own) – 200 kcal

- Dinner (provided most days) 450-600 kcal
- After-dinner snack: 200 kcal

Table 3. Measures to be Collected

	Visit			
Primary Measures or Constructs	**Screening**	**Baseline**	**Intervention**	**Follow-Up**
Study evaluation of acceptability				x
Process measures				x
CGM		x		x
Secondary Measures of Constructs				
Maternal and infant anthropometrics		x	x	x
Rapid Eating Assessment for Participants (REAP-S)		x		x
Food Insecurity		x		x
Awareness of GDM, management		x		
Diet-related comorbidities	x			
Infant feeding plans and practice		x		x
Financial stress		x		
Overall stress		x		
Confusion Hubub and Order Scale (CHAOS)		x		
Plans for weight-loss		x		
Health literacy		x	x	
Social support		x		x
Data collection for recruitment and retention				
Pregnancy, delivery history		x		
OGTT	x			
Demographics		x		

As described previously, study staff will run weekly EHR reports to identify when a participant is admitted to the hospital for delivery. About one week post-EDD, a member of the study team will contact the participant via text or phone call to ensure that she has delivered and is still planning to participate. We will coordinate with the participant and/or other household member to initiate home delivery of MTMs within 2 weeks (14 days) of delivery. Once per week, for a period of 3 months, 10 MTM (5 lunches and 5 dinners) portioned to feed one adult and frozen for ease of storage will be delivered directly to the participant's home by Providence Kitchen staff. MTM deliveries will include reheating instructions and recipe cards with nutritional information. During the monthly phone visits with a member of the study team, participants in the MTM treatment group will also be given the opportunity to provide feedback on the weekly meal delivery, food preparation, and troubleshoot any potential issues with this component of the intervention.

b. Usual Care Comparison Group

As in the MTM group, participants will be contacted by a member of the study team via text or phone call to ensure that she has delivered and is still planning to participate before the email/phone visit schedule is initiated. The current standard of care for Wake Forest patients who had GDM during pregnancy includes no additional follow-up or intervention in the postpartum period. The monthly phone visits and weekly emails described above will therefore be significantly more intervention than they would normally receive. In addition, participants in the comparison group will receive written materials on self-care, nutrition, and exercise after pregnancy and community resources for healthy living. They will also receive specific information about following a diet consistent with recommendations from the American Diabetes Association for women who have been diagnosed with GDM, including forming their meals with roughly 40% carbohydrate, 30% protein, and 30% fat in composition and what their calorie goal should be for the day based on their BMI category. Participants in the comparison group will also receive the ADA placemat and electronic scale, as mentioned above.

Participants will receive $50 and $75 grocery store gift cards upon return of the CGM devices at the end of the first and second CGM data collection, respectively ($125 total). Additionally, participants in the comparison

group will also receive 2 weeks (20 meals) of medically tailored meals from Providence Community Kitchen at the conclusion of their participation in the study. These meals will be delivered to the participant's home in a single delivery or will be available for pick-up.

G. Measures

Measures in this study have been selected to reflect the feasibility, acceptability, and preliminary effectiveness objectives of this pilot study and include participant self-reported constructs, existing medical history and pregnancy history information from the EHR, and data collected directly via CGM. A table outlining the time points at which each measure is collected and the mode of collection is included in Table 3.

Demographics: We are collecting self-reported data on gender, race, ethnicity, highest level of education, marital status, and the number of adults and children living in the home.

Continuous Glucose Monitoring: Participants will wear a blinded FreeStyle Libre Pro CGM at baseline (first 2 weeks after delivery) and at follow up (after 3 months). CGM devices will be mailed to participants and a member of the study team will video call participants to provide instructions and real time guidance on attachment and activation of the CGM. In order to facilitate collecting baseline post-partum CGM data and weight, this call will occur as close to the actual date of delivery as is possible. The participants will wear the CGM for 14 days at the beginning (initial month) and end (3 months) of the study. They will also keep a daily diary of the timing of meals, sleeping, and exercise (Appendix C). Study staff will call participants on day 14 to remind them to remove the sensor and provide instructions and guidance if needed for removal. At the conclusion of the 3 months, an abbreviated remote virtual visit to aid in placement and activation of the second continuous glucose monitor will be conducted. Participants will return the continuous glucose monitors, readers, and daily diaries to the study coordinator by mail using prepaid mailers. A 1-page report with a summary of the 14-day glucose data (graph of glucose values with information on the normal range) will be provided back to participants together with a cover letter for them to share with their health care provider if they choose.

Table 4 shows the guideline-based CGM measures that we will analyze,[17] using time in range 70-180 mg/dL, expecting that deviations in time in range will be lower both in duration and in amplitude for those with GDM than is typically seen in those with Type 2 Diabetes Mellitus. We will also investigate changes in glucose management indicator, an estimated measure of HbA1c from the CGM.[18] We will also combine timestamped CGM data with diary responses about sleep and meal timing to describe: maximum postprandial glucose peak, steepness of glucose trajectories including increase and decrease, and nighttime hypoglycemic dipping during sleep and response to exercise.

During CGM wear time, participants will complete daily diaries documenting the timing of sleeping, waking, eating, and exercise. Only the time of the activity start will be recorded with no additional details. Start time of the CGM device will be recorded for the purpose of combining these data sources. These diaries were unanimously considered easy to complete by participants in a previous study.[19] The diaries will allow us to investigate additional diurnal glucose metrics that might be related more strongly to MTMs including postprandial glucose spikes, nocturnal dipping

Table 4. Standardized CGM Metrics for Clinical Care

Measure	Explanation
Mean Glucose	
Glucose Management Indicator (GMI)	Roughly equivalent to HbA1c
Glycemic Variability (% coefficent of variation)	Target ≤ 36%
Time in range (%)	70 mg/dL ≤ time ≤ 180 mg/dL
Time above range (%)	180 mg/dL , time
Time below range (%)	Time < 70 mg/dL

during sleep, and response to exercise.

Anthropometrics: Maternal height, infant weight, and infant length will be collected from the EHR at baseline. Maternal weight will be collected within 2 weeks of delivery, at 2 months, and at 3 months using a digital scale mailed to the participant and facilitated by a member of the study team during the study telephone/virtual visit. In addition to collecting a maternal weight, participants will be provided instructions to weight their infant at the initial post-partum visit. We anticipate that some participants may not want to know their post-partum weight or could experience a negative emotional response to seeing that weight; therefore, participants will be provided with digital scales (BodyTrace) that will transmit weight data via cellular connection. These scales will transmit the data electronically to a digital platform (Carium) that will then provide aggregate data on all study participants to the study team. The display feature of the scale will be covered to prevent either the maternal weight or infant weight being displayed to the participant.

Medical History: Information on history of chronic diseases and other serious health conditions will be collected from the EHR in order to implement the eligibility criteria. Additionally, we will ask participants about their diagnosis of GDM during the current pregnancy, the strategies they may have employed to manage GDM, and their past pregnancy history.

Home environment: Participating women will complete the Confusion, Hubbub, and Order Scale (CHAOS). The CHAOS measure includes 15 items and is designed to capture environmental confusion in the home.[20] In addition, participants will be asked to answer a series of questions about financial stress and food insecurity.[21]

Dietary Habits and Quality: We will evaluate diet quality and dietary habits using a short, validated questionnaire, the Rapid Eating and Activity Assessment for Participants Short Version (REAP-S).[22] The REAP-S was originally developed as a tool for primary care to providers rapidly assess and discuss nutrition and physical activity patterns with patients and consists of 16 questions and designed to focus making it more practical for use with low-literacy populations in clinical settings. The REAP-S can be used to quickly assess the relative intake of fat, cholesterol, fiber, sugar, and selected food groups.

Overall Stress: We will use the Stress Overload Scale-Short (SOS-S), a self-report measure that has demonstrated accuracy in identifying people who will develop stress-related pathology in the wake of stressful experiences.[23] The SOS-S is also frequently used as a viable diagnostic tool for stress and stress-related disorders across diverse populations in the clinical setting.[23]

Plans for Weight-Loss: We will collect a series of questions on satisfaction with weight-status, plans to lose weight post-partum, motivation level for weight-loss, and self-efficacy for weight-loss at baseline for all participants.

Health Literacy: We plan to use a series of single-item questions to assess confidence in filling out medical forms, frequency with which participants need help to read health information, and to rate their own reading ability. These questions have been validated for identifying patients with inadequate and marginal literacy in healthcare settings with limited time for administration.[24]

We will also administer the Newest Vital Sign (NVS) to participating women as part of the monthly phone visit in month 2. The NVS is based on a nutrition label from an ice cream container and is designed to gauge ability to understand food labeling and nutrition literacy.[25] Women will be provided the label via mail or email prior to the visit then asked 6 questions about it.

Social Support: We plan to collect the Lubben Social Network Scale (LSNS-6) to assess social support in study participants at both baseline and 3-months post-partum.[26] Originally developed as a measure of social isolation in seniors, this measure has been previously validated in post-partum populations.[26]

Process measures: In order to assess the feasibility of the MTM intervention, we will collect information from Providence Kitchen on the number of meals successfully delivered, the cost of meal preparation and meal delivery, any problems encountered with meal delivery, and nutritional information on the meals (kCal per meal, macronutrient composition and sodium content). In both treatment groups, we will assess the acceptability of other intervention components including the number of videos watched and the number of monthly phone visits completed. To assess the feasibility of CGM in this population, we will quantify the number of days the CGM was worn by each participant and collect data on any technical problems with the CGM devices or Adverse Events reported.

Study Evaluation: Follow-up data collection will also include a brief exit evaluation to determine general satisfaction/dissatisfaction with the MTM intervention, written/video education materials, CGM monitoring, and overall study experience.

H. Analytical Plan

Since this pilot study is primarily about feasibility, analysis will be limited. We will describe baseline characteristics including demographics and cardiometabolic risk factors by CGM metrics. We will use mixed models with a random subject effect to estimate change in glucose metric variables across follow up with adjustment for demographics and other relevant confounders of dysglycemia. We will assess differences in CGM metric changes between participants receiving the MTM intervention and controls with independent sample t-tests. We will conduct similar analysis for change in weight.

I. Data Management

Case report forms and interviewer-administered questionnaires will be collected on paper and will be reviewed for completeness and accuracy in real time by the study staff during the visit. These forms will then be data entered by the study team member. Participant self-administered questionnaires will be emailed directly to the participant for completion prior to each data collection visit. We will use the Research Electronic Data Capture (REDCap) system for secure, web-based data entry and management. Use of the REDCap system allows real-time monitoring and reporting of study accrual, data collection, and retention rates. If needed, data can be securely downloaded directly by study team members for use in analyses. All data will reside securely within REDCap, and will not be linked to any other servers or analytic programs.

Electronic data are managed centrally, with a feedback mechanism through e-mail and web-based reporting. After reviewing forms for gross errors and missing data, study staff enters data from case report forms and interviewer-administered questionnaires through a web browser. No electronic data are housed locally, but automated data reports are available for the staff to request on-line. Validation checks are applied during the data entry process. These checks include intra- and inter-form checks for consistency of responses, range checking, and checks for required fields and skip patterns.

Participants will be enrolled and assigned IDs through the REDCap interface. Once inclusion and exclusion criteria are verified and the informed consent is completed, study staff will enroll participants and receive IDs immediately. Data collection and participant status will be tracked with a web-based interface.

The REDCap data management system will also provide confidentiality and data security. A very high level of data encryption during transmission (128 bit) coupled with the use of IDs, rather than subject names, provides adequate data security. The use of text containing identifying information is avoided.

J. Human Subjects Protection

Potential risks to participants due to the proposed research are minimal. The medically tailored meals will be designed in consultation with a dietitian from the Endocrinology Department to follow American Diabetes Association guidelines and be appropriate for the initiation and maintenance of breastfeeding. Continuous glucose monitoring systems are considered minimally invasive, involving a sensor probe placed in the subcutaneous tissue to measure glucose levels in the interstitial fluid, with risks primarily including infection at device insertion site and skin irritation from tape used to secure the device.

Setup and removal of the continuous glucose monitors will happen with real time virtual support and guidance from a highly trained study coordinator. Dr. Joseph Aloi is a practicing endocrinologist with extensive experience managing continuous glucose monitor devices. He will supervise the continuous glucose data collection and assess each resulting report for safety concerns. If necessary, he will contact participants directly with results that indicate the need for medical follow up; However, there are no alerts as the data are not available in real-time and the data collected are not clinically actionable at the time of the data download.

The investigators for the proposed research will receive only de-identified data and will have no contact with participants unless necessitated by participant need. This study poses minimal risk of loss of confidentiality for participants, but we will use data safety best practices to ensure that participant data remain secure and confidential.

a. Subject Recruitment Methods

Participants will be screened for eligibility through the Obstetric Department at Wake Forest Baptist Health by obtaining a list of eligible patients from the EHR. The study coordinator will call potential participants to confirm eligibility and determine interest in volunteering for the study. All communication between the study coordinator and potential participants will be kept strictly confidential. Any information obtained during recruitment and screening from individuals who decline to participate will be destroyed at the end of the study.

b. Informed Consent

Informed consent will be obtained remotely for all participants. We will use a Zoom (or other web-based platform) meeting to perform web-based informed consent. At the outset of the consent meeting, we will email prospective participants a link to a pdf version of the informed consent document. We will ask them to share their screen and open the consent form, which we will review with them, reviewing all required elements of consent, the content of the study, assessing for understanding and answering any questions they have. If the participant requests additional time to review the consent form, we will schedule a follow-up meeting as needed for signing. In order for weight to be measured remotely, we are planning to provide participants with a digital scale that will be used to transmit weight measurements directly to Carium, Inc., an internet-based platform used in the clinical setting to deliver telehealth or remote patient monitoring. In order to link the digital scale to a specific participant, members of the study team will register the scale and sync it to the Carium website before shipping to the participant. Only the study identification number will be registered to link the scale; no identifying information for participants will be provided to Carium The consent form includes information on the digital scale and Carium website. We have also included an option for participants to receive study communication via SMS text message in the consent form.

Once that process is complete, we will ask the participant to sign the consent document using the “pencil” function in their iPhone or computer’s pdf viewer, save the signed copy and email it back to our research staff.

At that point, the staff member will also sign and date the consent form, and save the form with both signatures in the study folder on the secure network drive to which only IRB-approved study staff have access. A copy of the signed consent will also be emailed or printed and mailed (participant preference) to the participant for their records.

c. Confidentiality and Privacy

Confidentiality will be protected by collecting only information needed to assess study outcomes, minimizing to the fullest extent possible the collection of any information that could directly identify subjects, and maintaining all study information in a secure manner. To help ensure subject privacy and confidentiality, only a unique study identifier will appear on the data collection forms. Any collected patient identifying information corresponding to the unique study identifier will be maintained on a linkage file, store separately from the data. The linkage file will be kept secure, with access limited to designated study personnel. Following data collection subject identifying information will be destroyed one year after study completion consistent with data validation and study design, producing an anonymous analytical data set. Data access will be limited to study staff. Data and records will be kept locked and secured, with any computer data password protected. No reference to any individual participant will appear in reports, presentations, or publications that may arise from the study. In order to complete data collection and intervention activities, participant names and contact information will be provided to Providence Kitchen for meal delivery in the MTM arm. The consent form includes language notifying the participants of this process and assuring them that no health information will be provided to Providence Kitchen.

K. Data and Safety Monitoring

The principal investigator will be responsible for the overall monitoring of the data and safety of study participants. The principal investigator will be assisted by other members of the study staff. In addition, the Institutional Data and Safety Monitoring Board (I-DSMB) available through the Wake Forest Clinical and Translational Science Institute will provide independent oversight for this study. Adverse events and safety alerts that are reported during any participant contact or study activity will be logged and submitted to the DSMB and IRB.

L. Reporting of Unanticipated Problems, Adverse Events or Deviations

Any unanticipated problems, serious and unexpected adverse events, deviations or protocol changes will be promptly reported by the principal investigator or designated member of the research team to the DSMB, IRB, and sponsor or government agency where appropriate.

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Appendix A. Example Weekly MTM Menu (10 meals)

All items include 6 ounces of protein, 4 ounces of vegetable and I cup of whole grain at a minimum.

Grilled Chicken w/Sundried Tomato Pesto Brocolli w/lemon WG Pasta w/Roasted Red Peppers & Garlic	Beef Pot Roast Mashed Potatoes Glazed Carrots
Salisbury Steak w/Mushrooms & Onion Roasted Potatoes Southern Green Beans	Cheese & Turkey Pepperoni Pizza Squash Medley
White Bean Chicken Chilli Brown Rice Corn Niblets	Roast Turkey Stuffing, Gravy Butternut Squash
Alaskan Salmon w/lemon butter Asparagus Spears Quinoa Pilaf	Chicken Parm WG Pasta Marinara Roasted Brussel Sprouts
Pork Loin w/Apples Braised Red Cabbage Noodles (WG)	Pit Ham Yams Green Breans

Appendix B. Example Nutrition Information

Pizza with Cheese and Turkey Pepperoni, Squash Medley

Calories (kcal):	365
% Calories from Fat:	35.9%
% Calories from Carbohydrates:	47.7%
% Calories from Protein:	16.5%

Per Serving Nutritional Information

Total Fat (g):	15g	23%
Saturated Fat (g):	6g	30%
Monounsaturated Fat (g):	5g	23%
Polyunsaturated Fat (g):	3g	12%
Cholesterol (mg):	28mg	9%
Total Carbohydrate (g):	44g	15%
Dietary Fiber (g):	5g	20%
Protein (g):	15g	31%
Sodium (mg):	1354mg	59%
Potassium (mg):	750mg	16%
Calcium (mg):	209mg	16%
Iron (mg):	4mg	21%
Zinc (mg):	2mg	21%
Vitamin C (mg):	29mg	32%
Vitamin A (i.u.):	948IU	19%
Vitamin A (r.e.):	105RE	12%

Vitamin B6 (mg):	.4mg	22%
Vitamin B12 (mcg):	.6mcg	23%
Thiamin B1 (mg):	.6mg	48%
Riboflavin B2 (mg):	.4mg	31%
Folacin (mcg):	62mcg	16%
Niacin (mg):	6mg	35%
Caffeine (mg):	0mg	N/A
Alcohol (kcal):	0	N/A
% Refuse:		

Food Exchanges

Grain (Starch):	28
Lean Meat:	0
Vegetable:	0
Fruit:	0
Non-Fat Milk:	0
Fat:	0
Other Carbohydrates:	0

**The Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 2000 calories a day is used for general nutrition advice.*

Appendix C. Continuous Glucose Monitoring Diary

Study Diary

Participant ID: _____

Which glucose monitor? 1st?_____ OR 2nd?_____

Date of glucose monitor placement:_____

Time of glucose monitor placement:_____

Date of glucose monitor removal:_____

Time of glucose monitor removal:_____

Day 1

What time did I wake up today? _____

What time did I eat today? (include all meals and snacks)

Time	Meal	Time	Meal
Ex: 8:00am	Breakfast	3:00pm	Snack
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

What time did I exercise today? ☐ I did not exercise today.

Time	Activity
_____	_____
_____	_____

What time did I nap today? ☐ I did not nap today.

Time	Activity
_____	_____
_____	_____

What time did I go to sleep today? _____

Day 2

What time did I wake up today? _____

What time did I eat today? (include all meals and snacks)

Time	Meal	Time	Meal
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

What time did I exercise today? ☐ I did not exercise today.

Time	Activity
_____	_____
_____	_____

What time did I nap today? ☐ I did not nap today.

Time	Activity
_____	_____
_____	_____

What time did I go to sleep today? _____

Day 3

What time did I wake up today? _____

What time did I eat today? (include all meals and snacks)

Time	Meal	Time	Meal
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

What time did I exercise today? ☐ I did not exercise today.

Time	Activity
_____	_____
_____	_____

What time did I nap today? ☐ I did not nap today.

Time	Activity
_____	_____
_____	_____

What time did I go to sleep today? _____

Day 4

What time did I wake up today? _____

What time did I eat today? (include all meals and snacks)

Time	Meal	Time	Meal
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

What time did I exercise today? ☐ I did not exercise today.

Time	Activity
_____	_____
_____	_____

What time did I nap today? ☐ I did not nap today.

Time	Activity
_____	_____
_____	_____

What time did I go to sleep today? _____

Day 5

What time did I wake up today? _____

What time did I eat today? (include all meals and snacks)

Time	Meal	Time	Meal
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

What time did I exercise today? ☐ I did not exercise today.

Time	Activity
_____	_____
_____	_____

What time did I nap today? ☐ I did not nap today.

Time	Activity
_____	_____
_____	_____

What time did I go to sleep today? _____

Day 6

What time did I wake up today? _____

What time did I eat today? (include all meals and snacks)

Time	Meal	Time	Meal
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

What time did I exercise today? ☐ I did not exercise today.

Time	Activity
_____	_____
_____	_____

What time did I nap today? ☐ I did not nap today.

Time	Activity
_____	_____
_____	_____

What time did I go to sleep today? _____

Day 7

What time did I wake up today? _____

What time did I eat today? (include all meals and snacks)

Time	Meal	Time	Meal
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

What time did I exercise today? ☐ I did not exercise today.

Time	Activity
_____	_____
_____	_____

What time did I nap today? ☐ I did not nap today.

Time	Activity
_____	_____
_____	_____

What time did I go to sleep today? _____

Day 8

What time did I wake up today? _____

What time did I eat today? (include all meals and snacks)

Time	Meal	Time	Meal
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

What time did I exercise today? ☐ I did not exercise today.

Time	Activity
_____	_____
_____	_____

What time did I nap today? ☐ I did not nap today.

Time	Activity
_____	_____

_____ _____

What time did I go to sleep today? _____

Day 9

What time did I wake up today? _____

What time did I eat today? (include all meals and snacks)

Time	Meal	Time	Meal
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

What time did I exercise today? ☐ I did not exercise today.

Time	Activity
_____	_____
_____	_____

What time did I nap today? ☐ I did not nap today.

Time	Activity
_____	_____
_____	_____

What time did I go to sleep today? _____

Day 10

What time did I wake up today? _____

What time did I eat today? (include all meals and snacks)

Time	Meal	Time	Meal
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

What time did I exercise today? ☐ I did not exercise today.

Time	Activity
_____	_____
_____	_____

What time did I nap today? ☐ I did not nap today.

Time	Activity

_____ _____
_____ _____

What time did I go to sleep today? _____

Day 11

What time did I wake up today? _____

What time did I eat today? (include all meals and snacks)

Time	Meal	Time	Meal
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

What time did I exercise today? ☐ I did not exercise today.

Time	Activity
_____	_____
_____	_____

What time did I nap today? ☐ I did not nap today.

Time	Activity
_____	_____
_____	_____

What time did I go to sleep today? _____

Day 12

What time did I wake up today? _____

What time did I eat today? (include all meals and snacks)

Time	Meal	Time	Meal
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

What time did I exercise today? ☐ I did not exercise today.

Time	Activity
_____	_____
_____	_____

What time did I nap today? ☐ I did not nap today.

Time Activity

_____ _____

_____ _____

What time did I go to sleep today? _____

Day 13

What time did I wake up today? _____

What time did I eat today? (include all meals and snacks)

Time	Meal	Time	Meal
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

What time did I exercise today? ☐ I did not exercise today.

Time Activity

_____ _____

_____ _____

What time did I nap today? ☐ I did not nap today.

Time Activity

_____ _____

_____ _____

What time did I go to sleep today? _____

Day 14

What time did I wake up today? _____

What time did I eat today? (include all meals and snacks)

Time	Meal	Time	Meal
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

What time did I exercise today? ☐ I did not exercise today.

Time Activity

_____ _____

_____ _____

What time did I nap today? I did not nap today.

Time Activity

_____ _____

_____ _____

What time did I go to sleep today? _____