Official Title: Meals for Moms: A Postpartum Medically-Tailored Meal Program to Promote Weight Loss and Blood Glucose Control Among Women With Hyperglycemia in Pregnancy
NCT04866823
IRB -Approved Date: 5/23/22

MEALS 4 MOMS PILOT STUDY

Informed Consent Form to Participate in Research
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SUMMARY

You are invited to be in a research study. The purpose of this research study is to test whether delivery of medically tailored meals (meals designed to be healthy) can be used to help reduce high blood sugar and promote weight loss after delivery of a baby. You are being asked to take part in this study because you are in the third trimester of pregnancy, screened positive for gestational diabetes based on an oral glucose tolerance test, and have gained more weight than is ideal during your pregnancy. Your participation in this research will involve 4 virtual visits (including this one) and last for about 3 months after your baby is born. If you decide to take part, you may enroll in the study while you are still pregnant and your total participation will last for 4-5 months. If we approached you about taking part in this study after your baby was born, your total participant will last for about 3 months.

Participation in this study will involve completing study surveys and wearing a device to monitor your blood sugar (glucose). You will also receive medically tailored meals and information about healthy eating, exercise, and self-care after your baby is born. All research studies involve some risks. A risk to this study that you should be aware of is a rare chance of infection at the site where the glucose monitoring device is inserted and skin irritation from tape used to secure the device. You may not benefit from participation in this study.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. Since this is not a treatment study, your alternative is to not participate in this study. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Dr. Morgana Mongraw-Chaffin. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study you can contact her by email at [redacted] or by telephone at [redacted].

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted].

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because during the third trimester of pregnancy, you were diagnosed with gestational diabetes or screened positive for gestational diabetes based on an oral glucose tolerance test. You have also gained more weight than is ideal during your pregnancy. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to test whether delivery of medically tailored meals (meals designed specifically to be healthy) can be used to help reduce high blood sugar and help mothers lose weight after delivery of a baby. Gestational diabetes and excessive weight gain during pregnancy, especially if you do not lose that weight after your baby is born, can put you at risk for diabetes, heart disease, and other chronic diseases later in life.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

There will be 30 people at this research site who will take part in this study. In order to identify the 30 participants needed, we may need to screen as many as 60 because some people will not qualify to be included in the study or will decide not to volunteer.

WHAT IS INVOLVED IN THE STUDY?

If you qualify and decide to take part in this study, you will have four (4) virtual study visits, including this one, and you will be asked to wear a small sensor on the back of you upper arm that records information on blood sugar (glucose). This sensor has a tiny filament (smaller than a needle) that will go under your skin. The sensor is placed on the skin on the back of the upper arm using a special applicator. Most people do not feel the sensor when it is applied or when they are wearing it. You can go about your daily activities while wearing the sensor. You will be asked to wear this sensor for 2 weeks in the first month after your baby is born and for 2 weeks after about 3 months.

You will receive medically tailored meals for 12 weeks after your baby is born. You will also receive weekly information videos with nutrition, exercise, and healthy lifestyle tips for women after pregnancy and a monthly phone visit each month with a member of the study team.

<u>Virtual Visit 1: Baseline Visit</u>

During this visit, we will discuss this Informed Consent form and answer any questions you have about the study. If you decide to participate in this study, we will have you sign the Informed Consent electronically. After you have signed the Informed Consent, we will ask you a series of questions about your health, pregnancy, eating habits, and your ability to pay for food and access to it during this visit. We will also email you a link to complete a set of surveys online that ask you questions about the confusion and order in your home environment, your levels of personal

and financial stress, your food habits, plans for feeding your baby, your plans for losing weight, and support from your family and friends. These surveys should take about 20 minutes to complete.

You will receive 10 (5 lunch, 5 dinner) medically tailored meals for you to eat each week. You will receive 120 total meals. These meals will be delivered to your home once a week for 12 weeks after your baby is born. Providence Community Kitchen, a local restaurant and catering company, will professionally prepare these meals. Each meal will be prepared according to recommendations from a nutritionist and the American Diabetes Association. The meals are designed for healthy eating for women who had gestational diabetes. With each delivery, you will also receive instructions for reheating the meals and nutrition information and recipe cards. You will also receive information about how to choose healthy breakfast options and how to supplement the meals you receive with healthy snacks.

You will also have monthly individual check-ins with a member of the study team to discuss the medically tailored meals, check your progress to date, discuss healthy changes to your lifestyle, and to set a small goal for the upcoming month. During the first month, this will focus on self-care. In month 2, the focus will be on healthy eating and in month 3, we will discuss physical activity. Each week, you will also receive an email with a short video about self-care, healthy eating, or exercise.

Confirmation Phone Call

After your baby is born, we will contact you to confirm that you are still willing to take part in the study. We will also ask you to provide your baby's name so that we can collect birth weight and length on him or her from the medical record. If we approached you about taking part in this study after your baby was born, you will not have this confirmation phone call. Instead, we will ask you to provide your baby's name during your visit today.

Please circle your answer: I agree to provide my baby's name so that you can collect birth weight and length after he or she is born.

YES NO

After this phone call, we will send you a package in the mail that includes a special sensor for measuring blood sugar (glucose), called a continuous glucose monitor, and instructions to place it. This package will also include a digital scale to weigh yourself during the study. This scale has a cellular connection that will transmit your weight measurement directly to a patient website called Carium. At the end of the study, the weight measurements for all participants will be provided back to the study team by Carium

Virtual Visit 2

After you have received this package, we will contact you to guide you through the placement of the continuous glucose monitor and explain to you how it works. The continuous glucose

monitor includes a sensor that you will insert into the lower level of your skin with an applicator. You will be asked to place this glucose monitor on the back of your arm. During this virtual visit, you will also be asked to weigh yourself and your baby. You will be expected to wear the continuous glucose monitor for 14 days while you continue with your normal routine. During that 14 days you will be asked to write down when you wake up and go to sleep, when you eat, and when you exercise every day in the diary provided to you. Completing your diary each day should take 5-10 minutes.

Virtual Visit 3

On day 14, you will receive a phone call from study staff reminding you to remove and return the continuous glucose monitor. We will answer any questions you have about removing the device. We will also conduct your first individual check-in to discuss the medically tailored meals, check your progress to date, discuss self-care, and to set a small goal for the upcoming month.

During the second month of the study, we will call you for your second individual check-in to discuss the medically tailored meals, check your progress to date, discuss healthy eating, and to set a small goal for the upcoming month.

Virtual Visit 4

About 3 months after your baby is born, study staff will guide you through placement and activation of a second continuous glucose monitor. You will be expected to wear the continuous glucose monitor for 14 days while you continue with your normal routine. During that 14 days you will be asked to write down when you wake up and go to sleep, when you eat, and when you exercise every day in the diary provided to you. Completing your diary each day should take 5-10 minutes. We will also conduct your third individual check-in to discuss the medically tailored meals, check your progress to date, discuss physical activity, and to set a small goal for the upcoming month.

We will also ask you to weigh yourself and your baby again, and repeat many of the questions from your baseline visit. We will email you a link to complete surveys online that ask you questions about your food habits, support from your family and friends, and feeding your baby. We will also ask you to complete a short survey about your time participating in the study and any suggestions you have for improvement. These surveys should take about 20 minutes to complete.

After 14 days of wearing the continuous glucose monitor, we will call to remind you to remove and return the continuous glucose monitor and any other study materials. We will answer any questions you have about removing the device. At the end of this time, we will also send you a report with the results from your continuous glucose monitor. If there are any safety concerns, one of the study doctors will contact you to recommend that you follow-up with your primary care doctor.

How Long Will I Be in the Study?

You will be in the study for 4-5 months. You will complete Virtual Visit 1 (this visit, Baseline Visit) before your baby is born. Then you will have 3 more virtual visits over about 3 months after your baby is born.

You can stop participating at any time. If you decide to stop participating in the study, we ask you call the Study Coordinator immediately to receive information on removing and returning the continuous glucose monitor and scale. There are no potential health or safety consequences to withdrawing from the study.

What Are the Risks of the Study?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff.

Risks and side effects related to wearing the continuous glucose monitor include a rare chance of infection at device insertion site and skin irritation from tape used to secure the device. The risk of infection will be minimized by cleaning the skin on the back of your upper arm with alcohol before placing the sensor.

There is a slight risk that you may have an unknown allergy to some of the foods provided to you. During the screening process for this study, we asked you about any allergies or sensitivities to food to reduce this risk. If you do have an unknown allergy, you could have an allergic reaction. Mild allergic symptoms that can occur include: raised red bumps of skin – hives, swelling of the lips, tingling of the throat and mouth, itchy skin and rash, runny nose, tightening of the throat, and digestive symptoms –cramps, stomach pain, nausea or vomiting. If you feel you are experiencing one of these mild allergic reactions, please contact the study team. Symptoms of a severe allergic reaction include: difficult or noisy breathing, swelling of the tongue, swelling or tightness of the throat, difficulty talking or a hoarse voice, wheeze or persistent cough, or persistent dizziness or collapse. If you feel you are experiencing one of these severe allergic reaction symptoms, please call 911 and seek immediate medical care. After treatment, please contact the study team.

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

There also may be other side effects that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks.

To contact you in this study, we would like to send you text messages to your cellular or smart phone. If you decide to receive these text messages, standard data and messaging rates will

apply.

Please circle your answer: I agree that I would like to receive text messages from members of the study team.

YES NO

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future. The continuous glucose monitor can provide information about your patterns of glucose over a two-week period. We will send you a report of your glucose results and you can share this report with your doctor if you wish.

WHAT OTHER CHOICES ARE THERE?

This is not a treatment study. Your alternative is to not participate in this study.

WHAT ARE THE COSTS?

All study costs, including any procedures related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

WILL YOU BE PAID FOR PARTICIPATING?

If you complete the study, you will receive $125 in grocery gift cards for your time and participation. You will receive $50 in grocery gift cards after you have completed Virtual Visits 1, 2, and 3 and returned the first continuous glucose monitor device and you will receive $75 in gift cards after you have completed Virtual Visit 4 and returned your second continuous glucose monitor. To receive payment, you must provide your social security number, name and address so that we can comply with IRS (Internal Revenue Service) reporting requirements. When payments are reported to the IRS we do not let them know what the payment is for, only that you have been paid. If you do not wish to provide this information, you can still take part in this study but you will not be paid.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by the North Carolina Diabetes Research Center. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year. The Wake Forest University School of Medicine, and the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management, at [redacted].

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call *Dr. Morgana Mongraw-Chaffin at* [redacted] *, or after hours* [redacted].

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any information we collect from you about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:** your name and contact information, your weight, your blood glucose levels, the information you report in the study diary including symptoms and eating and exercise patterns, information about your stress levels, home environment, and plans for feeding your baby, and information you report about your eligibility to participate and any medical conditions you report. In addition we will also collect information from your medical record about your medical history, pregnancy, and delivery.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study may be placed in your medical record,

and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products. For you to receive weekly meal deliveries, your home address and phone number will be shared with Providence Community Kitchen. However, no other information or study data will be provided to Providence Community Kitchen. You will be provided with a digital scale to collect your weight at different time points in the study. This scale will send your data to a website, go.Carium.com, which will then send the data to us. No information to identify you will be provided to the website. We will use a study identification number instead. None of your health information other than weight will be collected or stored by Carium.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records for six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified. You will not be able to obtain a copy of your Protected Health Information in the research records until all

activities in the study are completely finished.

You can tell Dr. Morgana Mongraw-Chaffin that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Dr. Morgana Mongraw-Chaffin
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

What Are My Rights as a Research Study Participant?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because you develop a condition that excludes you from the study, you had an unexpected reaction to wearing one or more of the study devices or decided not to wear one or more of the devices, you failed to follow instructions, or the entire study has been stopped.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

Whom Do I Call if I Have Questions or Problems?

For questions about the study or in the event of a research-related injury, contact the study investigator, **Dr. Morgana Mongraw-Chaffin at [redacted], or after hours [redacted]**.

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the **Chairman of the IRB at [redacted]**.

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm