COVER PAGE

Official Title: Feasibility Trial of a Lifestyle Intervention for Pregnant People with Gestational Diabetes

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Consent Form for Participation in a Research Study

UCONN
UNIVERSITY OF CONNECTICUT

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Title of Research Study: "Feasibility Trial of a Lifestyle Intervention for Pregnant People with Gestational Diabetes"

Sponsor: Clinical Research and Innovation Seed Program (CRISP)

Name of Research Participant:

Overview of the Research

You are being asked to provide consent to participate in a research study. Participation is your choice. You can say yes or no. If you say yes now you can still change your mind later. Some key points to consider are summarized in this overview, but you should consider all the information in this document carefully before making your decision.

This research is being done to assess the feasibility of a lifestyle intervention called Meals 4 Moms (M4M) for pregnant persons diagnosed with gestational diabetes (GDM).

Participation in this study will last approximately 8 to 11 weeks (dependent on your delivery date).

A total of 40 participants will be enrolled in the study. 20 of the participants will be randomized (like a coin flip) into a group to participate in the Meals 4 Moms program, and the other 20 will be randomized to receive no additional intervention. Participants in both conditions will continue to receive their usual prenatal care by their prenatal care provider.

Before deciding about whether to participate in this research, you should know that you have the option to not participate in this study and this will in no way affect your present of future medical care at UConn Health or St. Francis Health.

A more detailed description of this research follows.

Purpose of This Research

Gestational diabetes mellitus, or GDM, affects 2-10% of pregnancies in the United States (CDC). Approximately 50% of patients with GDM will progress to develop Type 2 diabetes in their lifetime. Patients must have immediate access to nutrient-rich food, and ongoing education and support regarding healthy-meal preparation. GDM, therefore, is a window of opportunity for prevention of diabetes.

The purpose of this study is to test whether a healthy living program that includes continued GDM education, physical activity level monitoring, and delivery of medically-tailored GDM meals is feasible for the management of gestational diabetes in pregnant patients.

Voluntary Participation

Participation in this study is your choice. Before deciding about whether to participate in this research study, please read this consent form carefully and discuss any questions you have with the researcher. You may also want to talk with family members, your primary care physician, prenatal care provider or a friend before deciding.

You can choose to not participate in this study. If you choose to participate in this research study, you can choose to withdraw from it at any time. If you decide not to participate or choose to withdraw from participation, your decision will not affect your present or future medical care and there will be no penalty or loss of benefits to which you are otherwise entitled.

Why Am I Invited To Participate?

You are invited to take part in this study because you are/have:

- Aged between 18-49 years old
- Currently pregnant with one baby
- Been diagnosed with Gestational Diabetes Mellitus (GDM) after 24 weeks in your pregnancy
- Currently receiving gestational diabetes care from a provider at the UConn Health Maternal Fetal Clinic, St. Francis Hospital Women's Health clinic, or Hartford Healthcare Women's Ambulatory Health Services (WAHS)
- Intending to deliver your baby at either UConn Health, St. Francis Hospital or Hartford Hospital

How Many Other People Do You Think Will Participate?

We estimate that a total of 40 pregnant persons with gestational diabetes will participate in this study.

How Long Will My Participation In This Study Last?

Participation in this study will last 8-11 weeks depending on when during your pregnancy you join the study and when you deliver your baby.

What Are the Costs To Me For Participating In This Study?

There is no cost for you to be a part of this study.

What Will I Be Asked to Do?

Your participation will involve:

1) **Baseline Data Collection**

    a. The baseline data collection will begin after you decide if you'd like to participate and will include 1) the completion of an online survey 2) completion of 3 diet recall surveys, and 3) obtaining permission to contact your prenatal care provider for medical clearance.

    We will email you a link to the online survey via email so that you can complete the survey at home. In this survey, we will ask about your demographics (marital status, education, etc.), feelings/mood, access to food and physical activity levels. The survey should take 20-30 minutes to complete.

    We will ask you to complete 3 diet recalls – a special kind of survey in which you will be guided through reporting everything you ate in the previous 24 hours. You will complete these diet recall survey using a web-based program called the "Automated Self-Administered 24-hour (ASA24®) Dietary Recall System". Three recalls will be completed over a week (specifically, 2 weekdays and 1 weekend day that are chosen at random). You may enter the food recalls on your home computer and will be provided instructions for logging into the system and completing the recall. If you have any difficulties completing the food recalls, a member of the study team will be available to administer the recall to you. Each recall should take about 20-30 minutes to complete.

    We will ask for your permission to contact your prenatal care provider to obtain medical clearance for you to participate in the study. Medical clearance is required as you could be asked to increase your physical activity levels. The study team wants to confirm it is safe for you to do so during your pregnancy. If your prenatal care provider does not provide approval, you will not be able to participate in the study.

2) After baseline data collection is complete, you will be randomly selected (like a coin-flip) to receive "**Meals 4 Moms**" lifestyle intervention or continue to receive "**Usual GDM Care**." You have a 50/50 chance of being in one group or the other. You should only agree to participate in this study if you are OK with being assigned to either intervention.

    <u>If you are randomly selected to receive the **Meals 4 Moms** lifestyle intervention you will receive or be asked to complete the following:</u>

- You will continue to receive your current management of gestational diabetes that is currently provided by your prenatal care provider.

- Access to the Meals 4 Moms Lifestyle platform.
    - The Meals 4 Moms (M4M) platform is a secure platform within the My Local Chefs website (www.mylocalchefs.com). Only study participants will have access to the M4M platform. The email address you provide to the study team will serve as your username/login. Upon your initial log-in, you will be asked to create and remember a password. You will be asked to create a password that is unique to you and one that you will remember.
    - Once you are registered on the M4M platform, you will be able to order GDM meals using a $266 food credit per week. Meals can be ordered and delivered weekly and up to 1 week after the delivery of your baby.
        - My Local Chefs, a local medically tailored meals food delivery services will professionally prepare the meals.
        - The meals will be prepared based on guidelines from the American Diabetes Association for people with GDM. In addition, meals can be prepared based on any preferences (e.g., vegetarian) and allergies (e.g., gluten) you indicate during registration.
        - The prepared meals will be delivered to your home address that you provide. Prepared meals will include the recipes, tips for meal preparation and education on the nutrients that are being provided.
        - My Local Chefs may send text or email reminders to you if you have not placed an order for your meals.
        - You will have the option to self-purchase additional meals if you wish to do so. The study team will not collect your credit card information.
    - The M4M platform also hosts a variety of resources to assist in the management of your gestational diabetes including GDM-friendly recipes, GDM related blog posts and podcast recordings and exercise videos.
- Meet virtually or over the phone with an exercise trainer every two weeks during your study participation.
    - At the beginning of your participation, the exercise trainer will assess your physical activity level and provide guidance as to which exercise videos on the M4M platform may be appropriate for you to participate in.
    - The exercise trainer will recommend that you try to be physically active for at least 150 minutes (2 and a half hours) per week or walk 6,000 steps per day.
- Be provided with an activity tracker (used to count the amount of activity/steps and minutes of sleep) and asked to wear the tracker on your wrist as often as possible (including when you sleep) during your study participation.

  - You will be asked to download a free app to go with your activity tracker (Fitbit app) as a tool to help track your physical activity. The information you enter into the app or allow the app to access from their phone is subject to the tracker's terms of use and privacy policy. We suggested you review these terms and the privacy policy carefully before choosing to download and use the app or use the website. During the study, if we become aware of any changes made to applicable privacy policies, we will notify you promptly that this has occurred and will encourage you to review the updated privacy settings.
  - You will be asked to sync the activity tracker with the mobile application to ensure your activity data is downloaded on a regular basis. The downloaded data will be reviewed by the exercise trainer who may provide appropriate modifications to maintain or increase your activity levels.
  - The activity tracker will be shipped to your home or provided to you at a prenatal visit. At the end of your study participation, you will be allowed to keep the activity tracker.
- Be provided with a Wi-Fi scale (such as a Fitbit Aria Air scale). You will be asked to weigh yourself daily, preferably in the morning, or at least weekly if you do not want to weigh yourself every day. You will be provided with instructions on how to download the scale's mobile application, create a profile and download the data from the scale to a database.
  - The Wi-Fi scale will be shipped to your home or provided to you at a prenatal visit. At the end of your study participation, you can keep the Wi-Fi scale.
  - A member of the study team will monitor your weight measurements. If you experience a weight gain greater than 1.0 kg (2.2 lbs.) in a week or any weight loss in a week, the study team will contact your prenatal care provider to inform them.

If you are randomly selected to receive "**Usual GDM Care",** you will continue to receive the current prenatal care including GDM care that is provided by your prenatal care provider. This will include regular prenatal care visits with your prenatal care provider as well as your care provider who is monitoring your gestational diabetes.

3) Follow-up Data Collection

Follow-up data collection will occur anywhere from 37 weeks' gestation and up to within 2 weeks of delivery.

The study team will email you a link to the online survey via email so that you can complete the survey at home. The survey will include the same measures collected at the

baseline data collection. The survey will also ask you to rate your experience with the study. The survey should take 20-30 minutes to complete.

Similar to baseline, we will ask you to complete 3 dietary recall surveys using the ASA24 system.

If you are randomized to the Meals 4 Moms condition, we will ask you to complete an follow-up interview post-delivery (conducted over the phone or via a videoconferencing platform such as Zoom) with a study team member to better understand your thoughts about your participation in the M4M program such what parts of the program you enjoyed and your suggestions for making the program better. We will record this interview and then transcribe (write down) what you said, so that we have your feedback in your own words. The interview will take approximately 30-45 minutes.

4) **Telephone and Email contact:**

You may also receive phone calls or emails from the study team. The purposes of these calls and contacts will be to:

- Follow up with you about the completion of study assessments.
- To answer your questions or provide assistance with completing study activities, for example, to help you complete the dietary recall surveys or to help you set up the activity tracker or Wi-Fi scale.

Communication via email is not absolutely secure. We do not recommend that you communicate sensitive personal information via email.

What information will be collected?

For all participants:

The study team will perform a medical chart review to collect information your demographic, medical history, pregnancy, GDM management and delivery outcomes including your baby's birth weight, type of delivery and if your baby experienced any low blood glucose levels.

The ASA24 is an online questionnaire that was developed by the U.S. National Cancer Institute (NCI). Please note that the online survey is hosted by a company named Westat, which stores survey data on servers located in the United States of America (USA). You will need to provide an email address to create an account. Your data collected for the ASA24 will not be shared with other researchers.

For participants randomized to the Meals 4 Moms condition:

We will download data about how you interacted with the Meals 4 Moms website, including what pages you looked at and what meals you ordered.

We will work with a company called Fitabase to download information recorded by your activity tracker and Wi-Fi scale such as total number of steps taken, the intensity of activity, heart rate, information about your sleep, and weight measurements.

What are the potential risks of participating in this study?

Minimal risks to participants are expected.

There is a potential risk of confidentiality due to collection of protected health information at research visits and storage of this information in the research record.

Risks Associated with Completion of Study Surveys: There are no physical risks associated with answering questions in the baseline survey or dietary recall surveys. There are possible mild psychological risks in that you may feel uncomfortable answering some of the questions. You may also feel upset when answering these questions.

Safeguards Taken: You may always choose not to answer a question that makes you feel uncomfortable or upset. If you feel discomfort or distress at anytime, you can skip the question(s).

If you report that you are a safety concern to yourself or someone else, we will need to release your confidential information for emergency care purposes. You'll be asked to answer some questions about your mood (i.e., depressive symptoms). If we find that answers on the survey are concerning, we will ask you to consult with your primary care provider or obstetrician/gynecologist to discuss your symptoms. The study team will also contact your prenatal care team and let them know what you told us about your mood. We may also determine that you need psychiatric care immediately and we'll make arrangements for you, and also consult with your prenatal care provider. We also encourage you to talk to prenatal care provider if you feel depressed or experience any unexpected mood changes at any point during the study.

Risks Associated with Participating in the Meals 4 Moms Lifestyle Intervention:

There is a slight risk that you may have an unknown allergy to some of the foods provided to you. If you do have an unknown allergy, you could have allergic reaction. There is a slight risk that you may become ill from consuming foods that have not been prepared correctly. Meals will be prepared within commercial kitchens by chefs affiliated with My Local Chefs. The kitchens have been inspected and certified in the prevention of the spread of food borne illnesses by the State of Connecticut Department of Public Health. You will receive instructions to keep meals refrigerated or frozen to prevent food borne illness. You will also receive instructions on how to appropriately reheat the meal for consumption.

There are mild risks associated with increasing your physical activity levels. You could experience muscle soreness, fatigue, increasing in heart rate and blood pressure and injury. The exercise videos available to you will not increase the likelihood of injury or other risks beyond what would occur when you engage in physical activity on your own.

There are no anticipated physical or emotional risks associated with accessing and interacting on the Meals 4 Moms website.

Risks Associated with Participating in the Usual GDM Care:

There are no additional risks to physical risks associated with participating in the current care provided by your prenatal care provider.

Risks Associated with Confidentiality:

There is a slight risk of a breach of confidentiality. We will do our best to protect the confidentiality of the data you provide. 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.

For participants randomly assigned to the M4M intervention, information posted to the intervention website hosted by MLC, is subject to terms of use and privacy policy, including terms of use for their website and mobile application. We will instruct participants to review these terms and the privacy policy. Participants will be able to post comments to blog posts and rate recipes within the My Local Chefs platform. If participants choose to comment on posts on MLC website, other participants may be able to see the real name or email name used for MLC website sign-up. Participants will be able to send in questions about meals, meal prep, etc. that will be answered by MLC chefs. Participants location or contact information will not be posted on the platform. The MLC support community will be private and comments or reactions on website content (e.g., recipe post) made by participants will only be available to participants randomized to the M4M intervention.

Safeguards

Safeguards Taken for Completion of Study Surveys or Interview: You may always choose not to answer a question that makes you feel uncomfortable or upset. If you feel discomfort or distress at any time, you can skip the question(s).

Safeguards Taken for Participating in the Meals 4 Moms Lifestyle Intervention:

During the screening process, we asked you about any allergies or sensitivities to food to reduce the risk of experiencing an allergic reaction. Mild allergic reactions include: raised red bumps on the 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 these mild allergic reactions, please contact your prenatal care provider. 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. If you feel you are experiencing these severe allergic reactions symptoms, please call 911 and seek immediate medical care.

The exercise videos made available to you on the M4M platform have been reviewed by the study PI and has confirmed the exercises to be safe for use during pregnancy. If at any time you do not feel comfortable performing an exercise, do not perform it. The study team will remind you about the importance of warming up and cooling down to prevent injury. If you do become injured during the study, you should call your prenatal care provider immediately. You should also alert the study team to inform them you have been injured. The study team will also teach you to measure your blood sugars prior to exercising.

- If your blood sugar reading prior to exercise is below 100mg/dl, you will be instructed to consume a GDM friendly snack before you exercise.
- If your blood sugar reading prior to exercise is above 250 mg/dl, you will be instructed not participate in exercise and contact your prenatal care provider.

Safeguards Taken to Protect Confidentiality:

Study documents (Informed Consent Form, HIPAA Authorization, etc.) that contain your name or signature will be kept in a secure location accessible only to authorized members of the study team (i.e., REDCap).

The REDCap (Research Electronic Data Capture) platform is a data collection system for research studies. The REDCap® platform is hosted on premise at UConn Health and managed by Academic IT Services and the Clinical Research Center. It is secured using the technical controls stipulated by HIPAA. These controls include (but not limited to): protection behind the firewall in the IT data center with controlled physical access, servers kept up to date with operating system and application patches and upgrades, role-based access to projects, data encrypted while in transmission, daily backup, and regular audits of system events and logs. REDCap® is not certified as HIPAA-compliant since annual cybersecurity audits, necessary for the certifications, are not performed.

A master key/password that links your name and other identifiers and the PID will be maintained in a separate and secure location by the study staff at the UConn Health Obstetrics and Gynecology Clinic.

How Will My Personal Information Be Protected?

The study team will protect the confidentiality of the information participants provide. However, confidentiality cannot be guaranteed. Recordings of the follow-up interviews will be kept in a password-protected computer drive with access limited to designated researchers. These recordings will be destroyed after they are transcribed and completion of data analysis.

The following security protocols will also be applied to all data:

- The information you provide during baseline and follow-up data collection will be linked to you only by a randomly assigned identification number, which cannot be used to identify you personally. All data will be labelled with the identification number only and will not be directly traceable to you.
- All data and interview recordings will be stored on secure servers behind firewalls (e.g., REDCap hosted by UCHC, password-protected computer drives such as OneDrive). All hard copy files will be locked in secure cabinets; logical protections – all recordings and data will be password protected and/or encrypted; and access protections – access will be granted to data on a need-to-know basis only. All records consisting of personal identifiers will be destroyed upon completion of the study by shredding of the hard paper copy, redacting the PHI/PII from the hard paper copy, and/or destruction of the electronic files. Only relevant study staff will have access to participant PHI/PII. Analytic datasets will not include PHI/PII. Interview recordings will be deleted after transcription.

Other Considerations of Physical or Psychological Risks

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

What Are the Benefits of Participating In This Study?

If you are randomized to the Meals 4 Moms condition, we hope that you benefit by: learning about how to manage your GDM, becoming more physically active, and eating the GDM-tailored meals. Any of these may help you manage your GDM and benefit you and your baby. Receiving meals at no cost may also provide financial benefit to your family. However, we cannot promise a benefit.

If you are randomized to the Usual GDM Care condition, there is no anticipated benefit to you for participating in this study.

Results of this study may help persons with GDM in the future.

Will I Be Compensated For Participating In This Study

If you are randomized to the **Usual GDM Care** condition:

- You will receive a $10 gift card (Amazon, Target, Walmart or gas) for completion of the baseline assessments and a $20 gift card for completion of the follow-up assessments.
- You will receive a $10 gift card (Amazon, Target, Walmart or gas) for each completed dietary recall survey at baseline and follow-up assessment timepoints (for a total of $60).
- In total, you may receive up to $90 in gift card for participating in this study.

If you are randomized to the **Meals 4 Moms** condition:

- You will receive a $10 gift card (i.e., Amazon) for completion of the baseline assessments and a $20 gift card for completion of the follow-up assessments.
- You will receive a $10 gift card (i.e., Amazon) for each completed dietary recall at baseline and follow-up assessment timepoints.
- In total, you may receive up to $90 in gift card for participating in this study.
- You will receive a $266 food credit per week to order GDM meals for up to 11 weeks (up to a total of $2,926 worth of food credits).
- You will be able to keep the activity tracker and Wi-Fi scale.

What Alternative Procedure or Treatments Are Available To Me?

You have the option not to participate in this study. There is no risk to you from choosing not to participate.

Will my information be shared?

We anticipate publishing the findings of this research and publishers often require that we have a plan in place to share the information we collect during this study.

Sharing research data helps to translate research results into knowledge, products, and procedures that improve human health. Your information will be stripped of the PID and any other identifiers and will be given a new code not linked to the PID or any information that would be able to uniquely identify you before sharing.

Recoded information from this study may be placed in a public, unrestricted databases that makes your de-identified (all direct identifiers removed) information freely available for anyone to use for future research. This information will not be labeled with your name or other information that could be used to easily identify you. If you provide permission now to share your anonymized information and change your mind later we will not be able to withdraw your data as we will have no way to link data with you. Please indicate whether we may share your anonymized information in public, unrestricted databases by initialing your preference:

Yes, my anonymized information may be shared for future research in public, unrestricted databases: _____

No, do not included my anonymized information in the data that is shared in public, unrestricted databases: _____

Publication of Study Results

Your name or other information that might identify you will not appear when the results of this study and future research are presented or published.

Withdrawing from Participation

You may decide to withdraw your participation at any time. If you decide to stop taking part in the study, your relationship with your doctors or UConn Health will not be affected. If you

decide to withdraw, we ask that you let us know by calling at Dr. Andrea Shields at 860-679-3331or by sending a written notice to Dr. Andrea Shields, UConn Health, Dept. of Obstetrics & Gynecology, 263 Farmington Avenue, Farmington, CT 06032-8071.

Will I Find Out the Results of This Research Study?

You will not be told any of the results of the research, nor will the results be added to your medical record. Results will not be made available to you because they will not have relevance to your individual medical care. If you would like to know the overall results of the study at its conclusion, you may contact the principal investigator to find out.

Can Someone Else Make Me Stop Participating In This Study?

The researcher may prevent you from continuing in this study. This may happen under any of the following circumstances:

- Failure to follow the instructions of the study staff
- The Principal Investigator decides that continuing your participation could be harmful to you.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

Injury from Participation

UConn Health does not provide insurance coverage to compensate for injuries incurred during this research. However, compensation may still be available. A claim may be filed against the State of Connecticut seeking compensation. For a description of this process contact a representative of the UConn Health's Institutional Review Board at 860-679-4849 or 860-679-8729. UConn Health does not offer free care. However, treatment for a research related injury can be obtained at the UCHC for the usual fee.

Questions

The Principal Investigator is willing to answer any questions you have about the research. You are encouraged to ask questions before deciding whether to take part. You are also encouraged to ask questions during your study participation. If you have questions, complaints, or concerns about the research, you should call the Principal Investigator, Dr. Shields at 860-679-3331.

If you have questions about your rights as a research subject you may contact a coordinator at the Institution Review Board at 860-679-4849 or 860-679-8729.

You may also call a coordinator at the Institutional Review Board if you want to talk to someone who is not a member of the research team to pass along any suggestions, complaints, concerns or compliments about your involvement in the research, or to ask general questions or obtain information about participation in clinical research studies.

Please do not call the IRB number for medical related issues or to schedule or cancel an appointment.

Consent To Participation:

By signing this form you (the participant, legally authorized representative, parent(s) or guardian) acknowledge that you have read, or have had read to you, this informed consent document, have talked with research personnel about this study, have been given the opportunity to ask questions and have them satisfactorily answered, and voluntarily consent to participate in this project as described in this form.

By signing this form the individual obtaining consent is confirming that the above information has been explained to the subject (and/or legally authorized representative, parents or guardians) and that a copy of this document, signed and dated by both the person giving consent and the person obtaining consent, along with a copy of the Research Participant Feedback Form, will be provided to the participant.

Role	**Printed Name**	**Signature**	**Date**
Participant			
Person Consenting			