Official Title:	Prenatal Starting Early Program: Randomized Controlled Trial of an mHealth Intervention in Prenatal Care and WIC to Improve Nutrition and Physical Activity During Pregnancy
NCT Number:	NCT06087133
Study Number:	s23-00902
Document Type:	Informed Consent Form
Date of the Document:	• August 30, 2023

NYU Langone Health

Research Subject Informed Consent Form

Title of Study:	Prenatal Starting Early Program: Randomized Controlled Trial of an mHealth Intervention in Prenatal Care and WIC to Improve Nutrition and Physical Activity During Pregnancy s23-00902
Principal Investigator:	Mary Jo Messito, MD Department of Pediatrics NYU Grossman School of Medicine 462 First Avenue, New York, NY 10016 (212) 263-6424
Emergency Contact:	Mary Jo Messito, MD (212) 263-6424

1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “subjects”, “research subjects” or “participants”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

Some of the people who may be able to take part in this study may not be able to give consent because they are under 18 years of age (a minor, in this case, your baby). Instead, we will ask you, their parent or legal guardian, to give consent. When we say “you” in this consent form, we mean you or your baby, the “subjects” or “participants”.

2. What is the purpose of this study?

The purpose of this study is to learn whether a program beginning in pregnancy with meetings delivered remotely using zoom can help pregnant people develop healthy eating habits and lifestyle behaviors during pregnancy. You are being asked to be a part of this study because you plan to get your prenatal and pediatric care at this hospital.

3. How long will I be in the study? How many other people will be in the study?

As part of this study, you will be assigned by chance to a group. This means, like flipping a coin, you will be assigned to one of the groups. There are no special reasons for you to be in either group. You will have a 50/50 chance of being in either group. The groups will either be the "**Prenatal Starting Early**" group or the "**Control**" group.

- If you are assigned to the "**Prenatal Starting Early**" group, your participation will include about 14 hours in the next 15 months.
- If you are assigned to the "**Control**" group, your participation will include about 6 hours in the next 15 months.

Up to 300 pregnant people will be in this study.

4. What will I be asked to do in the study?

If you choose to take part in the study, here is what will happen:

First, we will ask you to sign this consent form using a REDCap link.

Next, you will complete your first interview with one of our research assistants.

After completing your first interview, you will be assigned by chance to a group. The groups will either be the "**Prenatal Starting Early**" group, who will be part of a program to help pregnant people develop healthy habits in addition to getting their regular prenatal care, or the "**Control**" group, who will get their regular prenatal care but will not be part of the additional program.

- **For the Prenatal Starting Early Group**: Participants in this group will be asked to attend up to 8 nutrition and lifestyle counseling sessions with our Program Nutritionist. Sessions 1, 2 and 7 will be individual sessions with you and the nutritionist. Sessions 3, 4, 5, 6, and 8 will take place in a group setting with the nutritionist and other pregnant people around the same trimester of pregnancy as yours. The sessions will be delivered remotely using a secure video conferencing platform, called Zoom. You will be able to join the Zoom sessions using your own smart phone, computer or other mobile device. Zoom links will be sent through email or text. The sessions will be scheduled about every 2 to 4 weeks and will take about 45 minutes to 1 hour. Each nutrition and lifestyle counseling session will have a topic. Some of the topics include healthy eating and physical activity during pregnancy, how to deal with stress, breastfeeding and bonding with your baby. Participants will also get their regular prenatal care.

- **For the Control Group**: Participants will get their regular prenatal care. Participants will not be part of the added nutrition and lifestyle counseling sessions provided by the Starting Early Program.

All participants in the Prenatal Starting Early and Control groups will be asked to complete a set of interviews with our Research Assistants. The interviews will include questions about your health, diet, physical activity, sleep and stress. The interviews may be completed in-person or over the phone. It can take about 1 to 2 hours to complete each interview. You are free to skip any questions that you do not want to answer. There will be 3 interviews during this study: when you enroll in the study, during your third trimester of pregnancy, and about 3 months after your baby is born.

In addition to the interviews, our research team will be doing chart review of your medical records in order to collect information about weight gain during pregnancy, vital signs (like blood pressure), and medical problems. We will also review your baby's medical records in order to collect information about their birth, weight, length, vital signs, and medical problems.

In summary:

At time of enrollment	You will sign informed consent.
	You will complete Interview #1.
	You will be assigned by chance to either the "Prenatal Starting Early" or "Control" groups.
Throughout your pregnancy	If you are part of the "Prenatal Starting Early" group, the Nutritionist will contact you to be part of up to 8 nutrition sessions during your first, second and third trimesters of pregnancy. You will also get your regular prenatal care.
	If you are part of the "Control" group, no additional Starting Early nutrition sessions will be offered. You will get your regular prenatal care.
	You will complete Interview #2 during your third trimester.
After your baby is born	You will complete Interview #3 when your baby turns about 3 months old.

Any identifiable private information collected and/or used for the purposes of this research will not be used or distributed for future research studies.

Communicating with the Research Team via Text Message:
We may need to communicate with you about information relevant to the research study. The research team will usually contact you for these purposes by phone, but if you have given us your email address and mobile/cell phone number and permission to send a text message, the research team may contact you that way. When the research team sends email messages that include identifiable health information, they will use encrypted messaging (e.g. sendsafe). When the research team uses texting over mobile/cell phones there is no way to encrypt the message. This means that information you send or receive by text message is unencrypted and could be intercepted or viewed by an unintended recipient, or by your mobile/cell phone provider or carrier. Therefore, text messages carry security and privacy risks.

Below are some important points about texting in this research study.

- Text messages are not encrypted, and therefore are unsecure and may result in a breach of your confidentiality.
- You will be responsible for all fees charged by your carrier's service plan for text messaging. This research study and NYULH/Bellevue will not cover the cost related to any increased charges, data usage against plan limits or changes to data fees from the research texts.
- Text messages will only be read during regular business hours. However, if you have a scheduled survey outside of business hours, you may receive a text in relation to this survey outside of regular business hours.
- Text messaging should not be used in case of an emergency. If you experience a medical emergency, call 911 or go to the nearest hospital emergency department.
- You may decide to not send or receive text messages with staff associated with this research study at any time. You can do this in person or by sending the research number a text message that says "Stop Research Text."
- Your agreement applies to this research study only. Agreeing to other texts from NYULH/Bellevue, for example appointment reminders, is a separate process. Opting out of other texts from NYULH/Bellevue is a separate process as well.

Please make sure to keep the research team updated if your mobile/cell phone number changes during the study.

_____ Yes, I agree to receive texts from this research group. _____ Initial here
Cell phone number:_____

_____ No, I do not agree to receive texts from this research group. _____ Initial here

5. What are the possible risks or discomforts?

Risk of Study

There is a minimal or small risk in any study, including this one, of loss of confidentiality or privacy. This could be a small risk that people may get to see your information who are not supposed to. Our team has taken many steps to keep your information confidential. To decrease this risk, all identifying information will be kept private. Data will be uploaded or put immediately after the interviews onto a secure computer network drive on a password protected NYU server. Researchers will identify all information by a code number, not by name. Only members of the research team will have access to study information.

In this study you may receive texting over mobile/cell phones and this method of communication may result in a breach of your confidential information because text messages to mobile/cell phones are not encrypted. This means that information you send or receive by text message could be intercepted or viewed by an unintended recipient, or by your mobile/cell phone provider or carrier.

Other Risks

Some participants may feel uncomfortable answering certain questions. Our interviewers are well-trained and will explain what we are doing at each step. You are free to skip any questions that you do not want to answer.

In the interviews, we will ask you questions about your wellbeing and your feelings. Please be aware that we may inform your provider if we learn that additional services are needed (for example, meeting with the social worker). We are also required to let responsible authorities know if we encounter evidence of child abuse or maltreatment. Child maltreatment is defined as physical or mental injury, sexual abuse or exploitation, negligent treatment, or maltreatment of a child by a guardian, under circumstances that indicate that the child's health or welfare is harmed or threatened.

Unforeseeable Risks: The research may involve risks that are currently unforeseeable.

6. What if new information becomes available?

During this study, we may find more information that could be important to you.

This includes information that might cause you to change your mind about being in the study. We will let you know as soon as possible if such information is found.

7. What are the possible benefits (or good things) from being part of the study?

We cannot promise that you will benefit from being in this study. It is hoped the knowledge gained will be of benefit to others in the future. If you receive the Starting Early program you may improve your knowledge about nutrition, physical activity, and ways to deal with stress. This may result in a having a healthy pregnancy, a healthier diet, and lifestyle.

8. What other choices do I have if I do not participate?

You do not have to be part of this research study. What you decide will not affect your health care or your baby's health care.

9. Will I be paid for being in this study?

You will be paid for your time being in this study. You will receive a total of $120 in gift cards to pay you for your time over the next 15 months.

- A $40 gift card following completion of the first interview.
- A $40 gift card following completion of the third trimester interview.
- A $40 gift card following completion of the interview when your baby is about 3 months old.

If you chose to leave or are withdrawn from the study for any reason before finishing the entire study, you will only be paid for the completed interviews.

Please let us know if you are enrolled or plan to enroll in additional research projects at NYU Langone Health that offer cash/card payments as you are required to track all payments made to you by NYU Langone Health for your participation in any research for this calendar year. You must let Dr. Messito and/or her research team know immediately if/when the total research payments (for one or more studies) presently equal or is likely to exceed $600.00 total (not including travel reimbursements) for this calendar year.

10. Will I have to pay for anything?

There are no costs to you for being a part of this study.

11. What happens if I am injured from being in the study?

There are no risks of physical injuries from being in this study. Although being part of this study is considered minimal risk, for medical emergencies contact 911. If you think you have been injured as a result of taking part in this research study, please contact the Principal Investigator Dr. Mary Jo Messito at the following telephone number 212-263-6424.

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the NYU Langone Health to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

12. When is the study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all parts of the study, and all information has been collected. Your participation is expected to last about 15 months. This study may also be stopped or your participation ended at any time by your physician, or the study sponsor without your consent because:

- The principal investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The study sponsor, the principal investigator, or other body responsible for monitoring the safety of the study has decided to stop the study.

If you decide to participate, you are free to leave the study at anytime. Leaving the study will not affect your future care or your baby's care, how your health care is paid for, or what kind of health insurance you or your baby can get.

13. How will you protect my confidentiality?

Your medical information is protected health information, or "PHI", and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record and your baby's research record, as well as information in your medical record at NYU Langone Health. In compliance with NYU Langone Health policies and procedures and with HIPAA, only those people who have a reason to look at your health information and your baby's health information because of their job can look at this information.

Medical information created by this research study will not be entered into the medical record.

However, we may include your research information in your medical record for several reasons, including for the billing of services provided in connection with the study, to securely document any medical services you receive, and so that other members of the NYU Langone Health community who may treat you have access to important information about your health.

You have a right to access information in your medical record. In some cases, when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Health policies and applicable law.

14. HIPAA Authorization

As noted in the Confidentiality section above, federal law requires us, and the NYULH researchers working with us, health care providers, and your physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information and your baby's health information with others in connection with this study, in other words, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not give permission or authorize the use and disclosure of your information for this study.

What information may be used or shared with others in connection with this study?
All information in your research record for this study may be used and shared with those individuals listed in this section. Also, information in your medical record and your baby's medical record that the research team believes may be important to the study may be accessed by those listed here. This includes, for example, results from your physical examinations, laboratory tests, procedures, surveys, and diaries.

Who may use and share information in connection with this study?
The following individuals may use, share, or receive your information for this research study:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study
- The study sponsor: United States Department of Agriculture (USDA)

- Governmental agencies responsible for research oversight (e.g., the U.S. Food and Drug Administration or FDA).
- The Institutional Review Board or IRB that oversees the research and the research quality improvement programs.
- Health care providers, including your doctors and others who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.
- Other study sites involved in the research:
    - H+H personnel responsible for the support or oversight of the study at Bellevue

Your information may be re-disclosed (shared) or used for other reasons if the person who gets your information is not required by law to protect the privacy of the information.

What if I do not want to give permission to use and share my information for this study?
Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to be part of this study.

Can I change my mind and withdraw permission to use or share my information?
Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

How long may my information be used or shared?
Your permission to use or share your personal health information for this study will never end unless you withdraw it.

15. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The Institutional Review Board (IRB) reviews all research involving people before it can be started and then as long as the study continues. The main concern of the IRB is to protect the people who are part of the study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU Langone Health IRB Office number is 212-263-4110. The NYU Langone Health IRB is made up of doctors, nurses, non-scientists, and people from the community.

16. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at 212-263-4110.

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

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date

Signature of Parent(s)/Guardian for Child

I give my consent for my child to take part in this research study and agree to allow his/her health information to be used and shared as described above.

Name of Parent (Print)	Signature of Parent	Date