

SweetMama: Testing of a novel technology for diabetes education and support to pregnant women

NCT03240874

This supplement contains the following items:

1. Informed Consent Form: Focus Group Usability Testing (approved 7/12/2017)

Permission to Take Part in a Human Research Study

Do not sign this consent if today's date is later than the stated expiration date above.

Title of Research Study: SweetMama: Usability testing of a novel technology for diabetes education and support to pregnant women – FOCUS GROUP

Investigator: Lynn M. Yee, MD, MPH

Supported By: Northwestern University and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you are pregnant and have a diagnosis of diabetes.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team you can call us with questions or concerns.

Lynn M. Yee, MD, MPH, is the person in charge of this research study. You can reach her by pager (312-695-9210) Monday through Friday from 8am to 5pm, or by email at lynn.yee@northwestern.edu with questions about this research study.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Why is this research being done?

This study is being done to investigate how we can make it easier for you and women like you to care for yourself when you have diabetes during pregnancy. There are many tasks that you are asked to perform during your pregnancy in order to care for yourself, and some of these tasks take time and effort. Many women feel that having reminders and educational tips sent to them will help them with the challenges of being diabetic during pregnancy. We hope to test a new program, called a smartphone "app", and learn if this helps pregnant women with diabetes think about and cope with these tasks. We have just developed this new app and are hoping to get some feedback on what you like and don't like about so that

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we can improve it before we make it available to a large group of people. We hope that when this program is fully developed that its use will help improve the health of mothers and babies.

How long will the research last?

We expect that the focus group you will participate in as part of this research study will last no more than 1 hour.

How many people will be studied?

We expect about 20 people will be in this phase of the research study.

What happens if I say “Yes, I want to be in this research”?

If you choose to participate in this study, we will ask you to interact with the new app we have developed; it is called “SweetMama.” You will participate in a group interview with a research assistant where you will describe what you like and do not like about the app. We will also ask you questions about your experience with diabetes during pregnancy and your preferences for resources. The interview will last approximately 1 hour and will happen in a private room on the Northwestern campus. These interviews will be audio recorded and transcribed and will only be shared with the immediate research team. Audio recording is required for your participation. Nothing about your participation will affect your medical care. After the focus group, no further information or participation will be required.

What happens if I say “Yes”, but I change my mind later?

You can leave the research at any time and it will not be held against you. However because you are participating in a group, it will not be possible to delete your individual comments in the audio recording, and we will analyze the information you have provided up until the point that you decide to leave the group. Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment.

Is there any way being in this study could be bad for me?

There is no physical risk to you or to your fetus from being in this study. You may feel uncomfortable answering some questions on the survey or interview. If you do not wish to answer a question, you may skip it and go to the next question. It is okay if you do not know the answers to any question. There is also the risk of a confidentiality breach but we have taken multiple measures to secure your information.

Will it cost me anything to participate in this research study?

Taking part in this research study will not lead to any costs to you.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include feeling increased support and knowledge about diabetes during pregnancy. Your involvement in this study will help investigators understand how smartphone apps can assist women in managing their diabetes during pregnancy. The

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results will hopefully assist research in designing an improved app that may benefit pregnant women diagnosed with diabetes in the future.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution.

What else do I need to know?

If you agree to take part in this research study, we will give you a \$30 Visa gift card for your time and effort.

HIPAA Authorization

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- All information in a medical record
- Results of physical examinations
- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition as well diaries and questionnaires

During this study you may be coming to a Northwestern Memorial Healthcare Corporation entity (for example, Northwestern Memorial Hospital, Prentice Women's Hospital) for research appointments or to get clinical services, such as lab tests, needed for the study. When that happens, you will be scheduled for these services through the NMHC computer system. When a clinical exam or lab is done by NMHC or one of its employees for the purpose of this research study, that information will be kept in both NMHC's clinical records and in the study records.

The following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), Northwestern Lake Forest Hospital (NLFH).

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

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Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Clinical affiliates, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), Northwestern Lake Forest Hospital (NLFH), and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.
- Clinical affiliates, including but not limited to Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH), for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- Other University research centers and University contractors who are also working on the study,
- Study monitors and auditors who make sure that the study is being done properly,
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it will expire at the end of the research study.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

PI's Name: Lynn Yee, MD, MPH

Institution: Northwestern University

Department: Department of Obstetrics and Gynecology

Address: 250 E. Superior Street #5-2175, Chicago, IL 60611

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

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Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

I agree I disagree

_____ _____ The researcher may contact me in the future to see whether I am interested in participating in other research studies by the principal investigator of this study.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of participant

Date

Printed name of participant

Signature of person obtaining consent

Date

Printed name of person obtaining consent