Informed Consent

Promoting stretching exercise to reduce cardiovascular health risk in late pregnant women with obesity

NCT number NCT04291560
Document Date 11/03/2021

University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants Consent Form Version Date: November 03, 2021
IRB Study # 18-3091
Title of Study: Promoting stretching exercise to reduce cardiovascular health risk in late pregnant women with obesity
Principal Investigator: Seonae Yeo
Principal Investigator Department: School of Nursing
Principal Investigator Phone number: (919) 843-1245
Principal Investigator Email Address: syeo@email.unc.edu
Funding Source and/or Sponsor: NIH National Institute of Nursing Research (NINR)

What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary.
You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
The purpose of this research study is to test the effects of two types of exercise interventions on cardiovascular health in qualified pregnant women in the 3rd trimester. You are being asked to be in the study because you are pregnant and meet additional criteria approved by the IRB.

Are there any reasons you should not be in this study?
You should not be in this study if your health care provider asks you not to participate or several other study specific conditions which we have already asked you during screening.

How many people will take part in this study?
There will be approximately 200 people in this research study.

How long will your part in this study last?
You will be asked to take a part in the study activities for 13 weeks from 24 weeks' pregnancy.

For the first 3 weeks, we will call you for 10 minutes weekly at pre-arranged times that you agree. At 4th week (you will be 27 weeks pregnant), you are asked to visit the School of Nursing Biobehavioral Lab for approximately 2 hours for non-invasive tests that the IRB has approved. You are asked to visit two more times when you are 32 weeks and then 37 weeks pregnancy. In between these visits, we will check in weekly via text message, email, or phone call. There will be no follow up after the third visit. All of your information that we gather for the purpose of the study will be saved a safe area with passcode protected method. We will delete all information at the date the National Institutes of Health, our funding agency, specify.

What will happen if you take part in the study?

You will be assigned by chance, like flipping a coin, to a study group. One group is asked to engage in walking exercise and the other group is asked to engage in prescribed stretching exercise, both for 30 minutes a day 5 times/week.

After randomization, participants will receive a 1-hour in-person individual session, and a weekly phone call from the facilitator over the following 10 weeks.

You will wear a heart rate monitor while performing the assigned exercise. Additionally, you will enter physical symptoms into automated system via mobile phone.

Physiological measures will be assessed at three timepoints, 27, 32, and 37 weeks' pregnancy at the School of Nursing Biobehavioral Lab. You will be asked to avoid caffeine, food, and vigorous exercise for two hours before testing. If you do not comply, the assessment will be rescheduled. After arrival, you will change into a hospital gown without removing undergarments and be given the opportunity to void. Height and weight will be measured and recorded, and you will be asked to rest quietly without a pillow, in a slightly tilted supine position to avoid orthostatic hypotension due to the growing uterus. To achieve correct positioning, a rolled towel or small cushion will be placed under the left hip. While you are resting, electrodes will be affixed to the chest for heart rate variability and impedance cardiography wave form. Pulse wave verbosity will be taken. Blood pressure will be taken. Participants will quietly rest with normal breathing for 10 minutes while procedures are being prepared and completed. Before leaving the lab, you will be asked to fill out two surveys: one is about overall daily physical activity and the other is about overall anxiety.

The health records of your delivery and your baby will be accessed and collected for this study.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. There is little chance you will benefit from being in this research study.

What are the possible risks or discomforts involved from being in this study?

Potential risks to participating in the research include stress due to pressure to participate at clinics, injury due to exercise, stress and anxiety due to the hassle of visiting the lab, potential financial sacrifice during lab visits, and breech of privacy.

- Injuries may occur due to exercise.
- Although unlikely, exercise may result in adverse obstetrical events such as dizziness. To minimize such events, you will secure your prenatal care provider's approval to participate in physical activity. Obstetrical warning signs not to start exercise by American Congress of Obstetrics and Gynecology are provided.
- Anxiety may increase from arranging required phone calls, logging daily stretching exercise, and visiting the lab.
    - You will have three weeks (24-26 weeks' pregnancy) to experience the study by arranging a short phone interviews each week. This will give you time to self-assess whether you can make yourself available for three lab visits and 10 weekly phone calls. Logging exercise can be stressful. If facilitators recognize insufficient adherence they will apply motivational interviewing skills to encourage them to increase adherence. If any type of emotional response is observed by the research staff, you will be encouraged to report to your care provider.

In addition, there are additional measures specific to lab procedures:

- You will be asked to refrain from consuming large meals two hours prior to lab visits. Since this may cause dizziness during the lab visit, we will stock orange juice and crackers for you.
- Blood pressure measure. A cuff will squeeze an upper arm during assessment, which may cause a minor and temporary discomfort.
- Supine position during cardiac function measure. The supine position may cause hypotension due to the pressure of an enlarged uterus on the vena cava of pregnant women in the 2nd and 3rd trimesters. To avoid this potential adverse event, all participants will take a slightly tilted supine position with a rolled towel wedged under the left side between the back of the women and the bed.

There may be uncommon or previously unknown risks. You should report any problems to the researcher.

What are the risks to a pregnancy or to a nursing child?

To ensure safe exercise, we will follow ACOG recommendations by asking clinician care providers to evaluate *you* before starting to ensure that you do not have a medical reason to avoid stretching or walking exercise.

What if we learn about new findings or information during the study?

You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will information about you be protected?

The research team may accidentally expose private information to the public.
All research staff including graduate students will receive required training to handle private information. All computer systems are IRB approved and are secure systems provided by the

School of Nursing.

Key procedures for protecting the privacy and confidentiality of the individual's data are: Consent Form will be stored in a locked file cabinet in the password- protected lab. Temporary storage for some cases: A locked file cabinet in the research nurse's office in clinics where the access is protected by the hospital ID system.

Demographic and health data will be de-identified by removing private information, then stored in a passcode-protected computer system and in a locked file cabinet in the BBL.

Study measures: Data will be de-identified by removing private information, then stored in a passcode-protected computer system and in a locked file cabinet in the BBL.

Audio recording: After randomization, you will receive a 1-hour in-person individual session, and a weekly phone call from a nurse facilitator over the following 10 weeks. These communications will be audio-recorded for the purpose of program evaluation. Audio-files and transcribed document files will be de-identified by removing private information, then stored in a passcode-protected computer system and in a locked file cabinet in the BBL. Audio recordings may be requested to be turned off even when you check 'OK to record me during the study'.

Check the line that best matches your choice:

_____ OK to record me during the study

_____ Not OK to record me during the study

Project Coordinator, recruiters, PI (SY), and research nurses with appropriate training will have access to above information only when the study needs them.

Participants will not be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

What is a Certificate of Confidentiality?

This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information

that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The following information is regarding un-encrypted communication (e,g., texting or email) by study staff and should be read as an addition to the consent information you have already been provided. All information previously provided is still true and remains in effect. Your participation continues to be voluntary. You may refuse to participate or may withdraw your consent to participate at any time, and for any reason, without jeopardizing your future care at this institution or your relationship with your study team.

The study team would like to message you by text messaging, however you may say "no" to receiving these messages and still participate in this study. If you say "yes", messages may contain personal information about you and may be sent or received by the study team's personal electronic devices or in a method that is not able to be encrypted (protected) and there is the risk your information could be shared beyond you and the study team. This information may include information such as reminders and notifications to contact the study team.

If you wish to stop receiving unprotected communication from the study team or have lost access to your device, please notify the study team using the study contact information on the first page of this addendum to the consent. After the study is complete and all research activities finished, or you withdraw from the study or request to stop receiving unprotected communication, you will no longer receive un-encrypted (un-protected) messages specific to this study.

_____ Yes, I consent to the study team utilizing the following cell phone number to send communication:

List cell-phone #: _____

_____ No, I do not consent to receive un-protected communication from the study team.

What will happen if you are injured by this research?
All research involves a chance that something bad might happen to you. This may include the risk of personal injury. In spite of all safety measures, you might develop a reaction or injury from being in this study. If such problems occur, the researchers will help you get medical care, but any costs for the medical care will be billed to you and/or your insurance company. The University of North Carolina at Chapel Hill has not set aside funds to pay you for any such reactions or injuries, or for the related medical care. You do not give up any of your legal rights by signing this form.

What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

Will you receive anything for being in this study?
You will be receiving $150 ($50/visit x 3 visits) for taking part in this study. If you have a greater than 80% adherence to exercise and logging those behaviors, you will also receive an additional $80 after giving birth. Any payment provided for participation in this study may be subject to applicable tax withholding obligations

Will it cost you anything to be in this study?
It will not cost you anything to be in this study.

Who is sponsoring this study?
This research is funded by the National Institutes of Health. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

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

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____

Signature of Research Participant Date

_____

Printed Name of Research Participant

_____ _____

Signature of Research Team Member Obtaining Consent Date

_____

Printed Name of Research Team Member Obtaining Consent