COMIRB
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Principal Investigator: Jenn Leiferman, PhD
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Study Title: My Baby, My Move+: A community wellness intervention

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You are being asked to be in a research study. This form provides you with information about the study. Please read the information below and contact the research team to ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

This study plans to learn more about wellness during pregnancy. You are being asked to be in this research study because we would like to better understand how wellness influences your health and the way you feel during your pregnancy.

Up to *100* people will participate in the study.

What happens if I join this study?

If you join the study, you will be asked to complete this electronic survey pertaining to your health behavior and feelings during pregnancy. The survey will take approximately 20-30 minutes. Once the survey is completed, you will be contacted by a member of the research team to identify a convenient time and place for them to drop off a Fitbit and a scale. You will be asked to wear the Fitbit (i.e. a small device that is worn on your wrist to count the amount of activity/steps and minutes of sleep you take each day) for seven days. It is important that you wear the Fitbit for seven consecutive days. Detailed instructions will be provided as to how to wear the Fitbit. You will be asked to return the Fitbit after the seven-day period. You will also be asked to weigh yourself three days during this 7-day period and email or text your weight to a member of the research team. A member of the research team will coordinate with you to pick up the Fitbit and scale. Due to COVID-19, you will not have any direct contact with the research team. The team is also following all safety protocols dictated by the University of Colorado-Anschutz. Medical Campus.

Once the Fitbit is picked up after the 7-day period, you will be randomly assigned (meaning assigned by chance, like flipping a coin ie. 50% chance) to one of two groups. You will not be able to decide which group you will be in. You will need to provide medical clearance for physical activity from your medical doctor prior to participating in

either group. A member of the research team will either email you a PDF version of the or leave you a hard copy of the curriculum for your group prior to start of the virtual group sessions.

Group I

One group will be asked to attend a 12-week program. During the first four weeks of the program you will receive weekly education materials on health and pregnancy such as information on healthy weight, eating, sleep, and physical activity. For the last 8 weeks of the program you will be asked to attend two group sessions per week with each session lasting approximately 45-60 minutes. Sessions will be conducted remotely using ZOOM, a free video conferencing platform. Each session will involve learning about wellness and other health information (e.g. nutrition, stress reduction) as well as participating in group activities involving stretching and yoga. You will be encouraged to walk for 30-minutes after each session or at a convenient time of your choosing. Four of the sessions will include yoga for an additional 45 minutes. The sessions will be supervised by an individual trained in exercise science who will make sure that all activities are safe and effective for pregnant women. There will also be women from the community helping with the program. These women will be available for you to talk to for support. Six-weeks after the start of the program and again at the end of the 12-week program, you will be asked to complete another electronic survey which is anticipated to take about 10-15 min for the 6 week measurement time and 20-30 minutes for the 12 week measurement time.

We will also collect information on your pregnancy outcomes such as birth weight, timeliness of delivery, APGAR scores and type of delivery intervention used, if any. We will contact you via electronic survey following the completion of the in person sessions to collect this information.

Group II

The second group will attend a 12-week program to learn more about pregnancy related topics including how to manage morning sickness, nutritional topics related to pregnancy, pain relief during labor and delivery, breastfeeding, postpartum care and responsive parenting such as infant sleep routines and responding to infant awakenings at night. The first 4 weeks you will receive this informational material in electronic form. For the last 8 weeks you will be asked to attend two group sessions per week to receive additional educational materials and instruction on these topics as well as training on infant CPR. Sessions will be conducted remotely using ZOOM, a free video conferencing platform. Each session will be approximately 30-45 minutes. Six-weeks after the start of the program and again at the end of the 12-week program, you will be asked to complete another electronic survey which is anticipated to take about 10-15 min for the 6 week measurement time and 20-30 minutes for the 12 week measurement time.

We will also collect information on your pregnancy outcomes such as birth weight, timeliness of delivery, and type of delivery intervention used, if any. We will contact you via electronic survey following the completion of the in person sessions to collect this information.

Participation will be up to 10 months.

Optional procedures
You may be contacted at the conclusion of the study and given the opportunity to choose to participate in a phone interview to better understand your thoughts about your participation in the program (to what extent you were satisfied with the program and parts of the program you enjoyed and parts you think could be stronger, etc). The interview will be approximately 45 minutes long and you will be compensated $30. Up to 15 women will be invited to participate in an interview.

What are the possible discomforts or risks?

Discomforts you may experience while in this study include mild muscle pain when beginning an exercise program involving walking and stretching. There is a small possible risk of injury to the muscles, ligaments, tendons and joint of the body. The study staff has expertise in designing activity programs for pregnant women and will monitor all activity session to reduce this risk. There are less common risks associated with physical activity that include but are not limited to abnormal blood pressure, fainting and dizziness, disorders of heart rhythm, heart attack, stroke or even death may occur.

Other possible risks include that you may become upset when completing questionnaires assessing feelings and mood. The study staff includes an obstetrician with expertise in psychosocial issues who can provide any necessary support for these questions. You will also receive information on local mental health resources.

The particular treatment or procedure may involve risks to the participant and fetus which are currently unforeseeable. There may be risks that are unknown at this time.

Participants who show signs of depression will be informed of their risk and given referral information for mental health providers experienced in the treatment of depression for pregnant women. If other treatments (such as therapy or medications) are necessary, you and your health insurance company will pay in the usual manner for those services.

If you experience a miscarriage during your pregnancy you will be asked to withdraw from the study. We will provide resources to help support you. You will also be given the option to receive any remaining program materials (e.g. informational handouts).

We respect your right to privacy. But there are some things we cannot keep private. If you give us information about child neglect or child abuse, we have to report that to

Social Services. If you give us information about someone hurting someone else, we have to report that to the police. If a court orders us to hand over your study records, we have to hand them over to the court.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about how wellness influences health during pregnancy.

Who is paying for this study?

This research is being paid for by the National Institute for Child Health & Development.

Will I be paid for being in the study? Will I have to pay for anything?

You will be paid $30 for completing the first survey, wearing the fitbit for at least four days, and sending pictures of your weight to the study coordinator via email before the program begins. You will receive another $30 for completing the survey, wearing the fitbit for at least four days, and sending pictures of your weight to the study coordinator via email at the end of the 12-week program. For completion of the survey at 6 weeks you will receive tickets from a random drawing for a chance to win free diapers. You will be asked to complete three surveys for a total of $60 and a chance to win free diapers over the course of the study duration. Participants in Group 1 will also receive a yoga mat and pedometer, and both groups will have the opportunity to participate in drawings for free diapers. If selected for an interview at the conclusion of the program you will be compensated $30 for your participation.

It is important to know that payments for participation in a study are taxable income.

It will not cost you anything to be in the study.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

What happens if I am injured or hurt during the study?

We will arrange to get you medical care if you have an injury that is caused by this research. However, you or your insurance company will have to pay for that care.

Who do I call if I have questions?

The researcher carrying out this study is Dr. Jenn Leiferman. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Dr. Jenn Leiferman at 303-723-4386. You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call the Colorado Multiple Institutional Review Board (COMIRB). You can call them at 303-724-1055.

Who will see my research information?

The University of Colorado Denver | Anschutz Medical Campus (the University) and the health systems it works with have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.
The institutions involved in this study include:

- University of Colorado Denver | Anschutz Medical Campus
- University of Colorado Health

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University and its affiliate health systems may not be covered by this promise.

We will do everything we can to keep your records a secret. It cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Primary Investigator, at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no

further information about you will be collected. Your cancellation would not affect information already collected in this study.

Jenn Leiferman, 13001 East 17th Place, Mail Stop B119, Aurora, CO 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information.

- Federal offices such as the Food and Drug Administration (FDA) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study doctor and the rest of the study team.
- National Institutes of Health, who is the company paying for this research study.
- Officials at the institution where the research is being conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

- Some things we cannot keep private. If you give us any information about child abuse or neglect we have to report that to Social Services. Also, if we get a court order to turn over your study records, we will have to do that.
- Some things we cannot keep private: If you tell us you are going to physically hurt yourself or someone else, we have to report that to the police.. Also, if we get a court order to turn over your study records, we will have to do that.

You have the right to request access to your personal health information from the Investigator. [To ensure proper evaluation of test results, your access to these study results may not be allowed until after the study has been completed

Certificate of Confidentiality

This study has been issued a Certificate of Confidentiality from the federal government to help protect your privacy. The Certificate prohibits the researchers from disclosing your name, or any identifiable information, document or biospecimen from the research, with the exceptions listed below. A certificate provides protections against disclosing research information in federal, state, or local civil, criminal, administrative, legislative or other proceedings. These protections apply only to your research records. The protections do not apply to your medical records.

The researchers may disclose your name or identifiable information, document or biospecimen, under the following circumstances:

- To those connected with the research,
- If required by Federal, State or local laws,
- If necessary for your medical treatment, with your consent,
- For other scientific research conducted in compliance with Federal regulations,
- To comply with mandated reporting, such as a possible threat to harm yourself or others, reports of child abuse, and required communicable disease reporting, or
- Under other circumstances with your consent.

A Certificate of Confidentiality does not protect information you or a member of your family voluntarily release.

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, phone number)
- Portions of my previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results
- Research Visit and Research Test records
- Psychological tests

What happens to Data that are collected in this study?

Scientists at the University and the health systems involved in this study work to find the causes and cures of disease. The data collected from you during this study are important to this study and to future research. If you join this study:

- The data are given by you to the investigators for this research and so no longer belong to you.
- Both the investigators and any sponsor of this research may study your data collected from you.
- If data are in a form that identifies you, the University or the health systems involved in this study may use them for future research only with your consent or IRB approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

HIPAA Authorization for Optional Additional Study Procedures

In this form, you were given the option to agree to additional, optional research procedures. You must also give us your permission, under HIPAA rules, to use and disclose the information collected from these optional procedures, as described above. If you decline to give us permission to use and disclose your information, you cannot take part in these optional procedures, but you can still participate in the main study.

Please initial next to your choice:
_____ I give permission for my information, from the optional procedures I have agreed to above, to be used and disclosed as described in this section.
_____ I do not give permission for my information for any optional procedures to be used and disclosed; I understand that I will not participate in any optional procedures.

Agreement to be in this study and use my data
I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I can print a signed and dated copy of this consent form.

Signature:_____ Date:_____

Print Name:_____