The Impact of Prenatal Exercise Type and Intensity on Glucose Control in Women with Gestational Diabetes Mellitus

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UNIVERSITY OF CENTRAL ARKANSAS™ | RESEARCH COMPLIANCE

INFORMED CONSENT AGREEMENT

University of Central Arkansas
Informed Consent Agreement
The Impact of Prenatal Exercise Type and Intensity on Glucose Control in Pregnant Women

You are being asked to participate in a research study. Before you give your consent to volunteer, it is important you read the following information and ask as many questions as necessary to be sure you understand what you will be asked to do.

Investigators

Brittany R. Allman-Tucker, Ph.D. in Exercise Physiology with a Performance Nutrition emphasis
Department of Exercise and Sport Sciences
University of Central Arkansas
Doyne Health Sciences Center, Room 120
Email: rallman@uca.edu
Phone: (501) 852-7749

Purpose of the Research

This research study is designed to test how different types of exercise (cardio compared to weight lifting) and different intensities of exercise (low vs. moderate) affect how you control your blood sugar levels during pregnancy – and what might be causing this (like inflammation, fat burn). The data from this research will be used to help other professionals like personal trainers, OB/GYNs, etc. prescribe the best exercise to help you manage blood sugar levels.

Reasons for Exclusion from this Study

You will not be able to participate in the study if you are pregnant with more than one baby, have any metabolic diseases, before 24 weeks pregnant or after 30 weeks pregnant, younger than 18 or older than 35, currently active, used assisted fertility treatments to get pregnant, currently taking medication or supplements that impact blood sugar levels, take drugs, tobacco, or alcohol currently, or have a contraindication to exercise.

Procedures

If you volunteer to participate in this study, you will be asked to come to our laboratory five separate times. On the first visit, you will sign some paperwork, we will collect basic data (like age, gestational week, race, and ethnicity, and we will do some baseline tests (height, weight, heart rate, blood pressure). During this visit, we randomly select the order of your exercise visits. Those exercise visits will consist of:

1. Perform weightlifting at low intensity
2. Perform weightlifting at moderate intensity
3. Perform aerobic training at low intensity
4. Perform aerobic training at moderate intensity

Before each of your exercise visits, we will ask you to record what you eat for one day before the visit, and what physical activity you do for three days before the visit. To do this, we will give you printed out logs that

you will write on and return when you come to exercise. To prepare for the visit, we will ask you to not drink caffeine or exercise for the day before coming in.

When you come in for your exercise sessions, we will review your food and physical activity logs. Then we will connect a continuous glucose monitor (CGM) to the back of your arm. This CGM is a small device that tracks your blood glucose levels every five minutes with a very small and short needle that is inserted just below your skin. It should feel like a small finger prick. The CGM will stay on the back of your arm for two weeks. Then we will connect another one that will stay on your arm until you are done with your last visit. After we connect the CGM, we will measure your heart rate and blood pressure at rest to make sure that you are healthy that day. Then we will take some blood from your arm so we can measure how much glucose and insulin you have in your blood, as well as inflammatory markers. Finally, we will do the exercise.

During the cardio exercise, you will get to pick which piece of equipment you want to use. You can choose from a treadmill, an elliptical, a bike, or a rower. You will start will a light to moderate intensity warm-up for five minutes, and then you will exercise at either a low or a moderate pace for 45 minutes. A low pace should feel very doable – almost like if you were to take a casual walk outside. A moderate pace should feel challenging (not like a slow stroll in the park), but doable (you should be able to keep that pace the whole 45 minutes but be tired after). Throughout the 45-minute workout, every five minutes we will check your heart rate using a watch that will be placed on your wrist, and we will check how you feel by asking you to tell us a number on a scale from 1 to 10 (with 1 being very light effort, and 10 being your highest effort). This information will let us know that you are safe and at the right intensity. When you are done, you will do a series of stretches to cool down.

During the weight lifting visit, you will use dumbbells, and do eight exercises, done for four sets of 10 repetitions. The exercises will be a goblet squat, incline chest press, deadlift, shoulder press, step ups, bent-over row, biceps curls, and triceps extensions. After you get done the last set of each exercise, we will record your heart rate and your reported effort number (from 1 to 10) to make sure that you are safe and at the right intensity. For the low intensity visit, we will shoot for a 5 to 6 on the scale, and for the moderate intensity visit, we will shoot for a 7 to 8 on the scale. When you are done, you will do a series of stretches to cool down.

Your participation will take about one hour per visit, for a total of about five hours.

Potential Risks or Discomforts

We do not foresee any major risks or discomforts occurring. Most procedures are minimal risk. Exercise is recommended for you, and if you are accepted and agree to participate in the study, you will be healthy overall, which lowers your risk even more. Most big organizations recommend both weightlifting and cardio training for pregnant women and say that it is safe for you and your baby.

The exercise training will be closely supervised to make sure you are hydrated, you stay within the recommended exercise intensities, and you perform the exercises with safe techniques. The exercise training will be stopped right away if you report discomfort that is risky, like chest pain, uterine contractions, or vaginal bleeding. Participants will only be allowed to return to the study after their OB/GYN physicians have cleared them. You can stop training and testing at any time. The exercise training may leave you a little sore, but that is normal for any exercise routine. You will be trained one-on-one by a certified exercise professional at all times.

There is a trained phlebotomist that will take your blood. You may get a little bruising or feel light-headed. If you get sick, we will stop the visit until you are recovered. If needed, we will stop for the day. The CGM that will be used has a very narrow and short needle that is inserted under your skin on the back of your arm. To make sure we minimize infections, the professional that places the CGM will wash their hands and put on gloves. Also, the back of your arm will be cleaned using an alcohol wipe, and allowed to dry before placing the CGM. For the time that you wear the CGM, you will be asked to tell the research staff if any changes happen in the area that might make you think there is an infection, like redness or swelling. There is a very small chance that will happen, but if it does, you will be asked to report it to Dr. Allman-Tucker immediately. In these cases,

the CGM will be removed.

Overall, there are very minimal risks to participate in the proposed study; However, if they do happen, they will be reported to the appropriate people at UCA by Dr. Allman-Tucker.

Potential Benefits of the Research
You will get to see which type and intensity of exercise may be the best to help you manage blood sugar levels, and if there is a specific type or intensity of exercise that you may prefer and use for the rest of your pregnancy. You can also carry this information with you to any future pregnancies.

Society will benefit by getting a better understanding of the most precise prescription of exercise type during pregnancy. This research will fuel future research in the area of the exact exercise prescription that is needed to manage blood sugar levels. Professionals that commonly prescribe exercise to pregnant women, like OBGYNs, doulas, midwives, and fitness professionals, can use this information to most accurately prescribe exercise, the way a medical professional would prescribe drugs.

Incentives to Participate
You will get a fitness assessment (motivational interview, body composition, aerobic, muscular strength, muscular endurance, etc...) done by either Dr. Brittany Allman-Tucker or another research assistant. After that, you will be given up to two personal training visits per week for the rest of your pregnancy. To get the assessment set up, you will email Dr. Allman-Tucker at rallman@uca.edu.

In Case of Injury
It is unlikely that participation in this project will result in harm to you. If an injury happens, you may be seen by a local or regional medical facility. All expenses associated with care will be you and your insurance's responsibility.

Confidentiality and Data Storage
All staff will stay up-to-date with research training that will be needed to maintain your confidentiality.

When you begin in the study, you will be given a participant ID that will consist of "FITT-" (the acronym for Frequency, Intensity, Time, Type) and a number. For example, the first participant will be FITT-001. This unique identifier will be paired with any other identifiable information that we get from you in one master coded document that will be password protected and only accessible by Dr. Allman-Tucker. This file will be kept separate from the excel file of de-identified data collected from study visits. So, when we go to get the data for analysis, we won't be able to tell who you are – we will just see your participant ID.

All data and communications will be recorded in standardized forms that will be locked in a file cabinet in Dr. Allman-Tucker's office (Doyne Room 120 at UCA), and can only be accessed by Dr. Allman-Tucker.

Data will be entered into a password-protected file on Dr. Allman-Tucker's desktop computer in her office. This office is locked whenever Dr. Allman-Tucker is not there, and only she has a key.

Participation and Withdrawal
Your participation in this research study is voluntary. You may refuse to participate without penalty. If you decide to participate, you are free to stop at any time without penalty by just stopping and/or telling the investigator.

To withdraw from the study after data collection has been completed, contact Dr. Allman-Tucker by emailing her at rallman@uca.edu.

Questions about the Research

If you have any questions about the research, please ask them now. If you have questions later, you may contact Dr. Allman-Tucker at (501) 852-7749.

This research project has been reviewed and approved by the Institutional Review Board for the Protection of Human Subjects at the University of Central Arkansas. If you believe there is any infringement upon your rights as a research subject, you may contact the Research Compliance Coordinator at (501) 450-3451.

Subject's Agreement

I have read the information provided above. My signature below indicates my voluntary agreement to participate in this research study. Please return one copy of this consent form and keep one copy for your records.

_____ _____

Signature of Participant Date

_____ _____

Signature of Investigator (optional) Date