



LIVERPOOL JOHN MOORES UNIVERSITY PARTICIPATION INFORMATION SHEET

Title of Project: Can physical activity during pregnancy improve mother and baby blood vessel health?

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If you have any questions, please contact:

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You are invited to take part in a student-led research study looking at the effect of physical activity on blood vessels in the body during pregnancy. Before you decide on whether you would like to be a part of this study, it is important that you understand why the research is being done and what it involves. Please take your time to read the following information and feel free to ask if there is anything that is not clear or if you would like more information. Please take the time to decide if you want to take part or not.

What is the purpose of the study?

Your heart and blood vessels are responsible for transporting nutrients and oxygen around your body. During pregnancy, they have to work much harder as they need to get blood to you and your growing baby, so it is very important that they are kept healthy. Being physically active is one way to improve the health of your heart and blood vessels. We know that being active during pregnancy can reduce the risk of pregnancy complications like diabetes and high blood pressure, and can help to stop excessive weight gain. Pregnancy activity can also be good for the baby. We would like to test whether being active during pregnancy can improve mum and baby's heart and blood vessel health.

Who can take part?

To take part in the study, you must be:

- A healthy pregnant female
- Carrying only 1 baby
- Free of current cardiovascular disease, gestational diabetes or pre-eclampsia, and have no history of these conditions.
- Aged 18-45 years
- Not on medication
- A non-smoker for at least 6 months
- Participating in structured exercise less than twice/week
- BMI less than 35kg/m²

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do you will be given this information sheet and asked to sign a consent form. You are still free to withdraw at any time and without giving a reason. A decision to withdraw will not affect your rights/any future treatment/service you receive.

What will happen to me if I take part?

You will come to the Research Institute for Sport and Exercise Sciences at John Moores University (LJMU), Tom Reilly Building, Byrom Street, L3 3AF on 4 occasions during your pregnancy. During each visit you will have a number of tests done to assess how healthy your blood vessels are, your fitness and your body weight. After you have given birth, we will also collect information from your medical notes at the hospital on relevant information about your labour.

The visits to the University will occur at the end of each Trimester of your pregnancy as follows:

Visit	When?	Why?	How long for?	Where?
1	Trimester 1 (week 10 – 12)	Your blood vessel assessments	3 hours	Liverpool John Moores University
2	Trimester 2 (week 24 – 27)		3 hours	
3	Trimester 3 (weeks 36 - 38)		3 hours	
4	Within 4 weeks of delivery	Your baby's blood vessel assessment, a short questionnaire and interview	1 hour	Liverpool John Moores University <u>OR</u> At your own home

Details about what will happen during each visit to LJMU are given in the next section.

On **visit 1** you choose to be a part of either an exercise group, or a control group who will not take part in exercise. If you are in the exercise group, you will complete a 24-week, partially supervised exercise programme during trimesters 2 and 3. You will exercise 3-4 times/week. You will complete 2-3 sessions per week at your local Lifestyles Centre gym, and the final session will be completed at the gym in Liverpool John Moores University (City Centre). Prior to your first exercise session, you will partake in a short interview carried out by the researcher on the topic of physical activity and exercise during pregnancy. Unfortunately, travel expenses cannot be covered.

Details about what will happen during the exercise sessions are provided on page 5.

What will happen during the visits to the University?

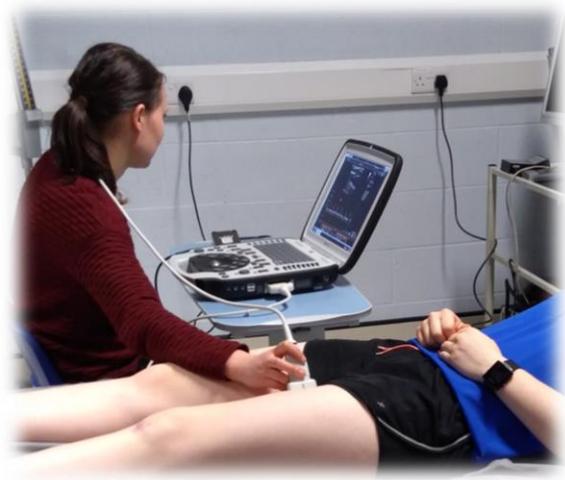
Visits 1-3:

Before each visit to LJMU you will be required to:

- ✓ Drink plenty of water in the 24 hours before
- ✓ Fast for 5 hours (no food or drinks except tap water)
- ✓ Avoid caffeine, chocolate, fizzy/energy drinks and alcohol for 8 hrs
- ✓ Avoid strenuous physical activity for 24 hrs

Below is a detailed description of the assessments that will be taken during LJMU visits 1-3:

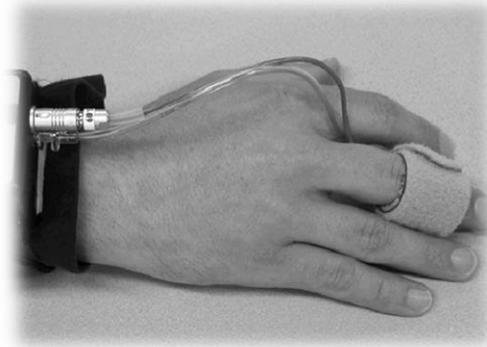
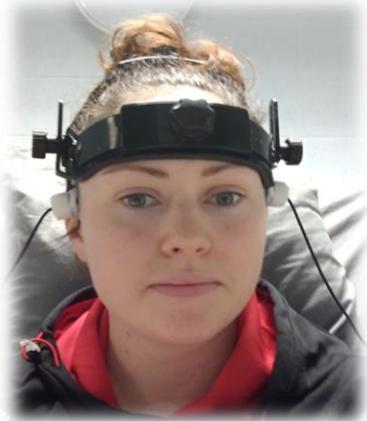
- 1) **Weight, height, waist and hip size** will be taken. **Body fat** will be measured using skinfolds. Skin folds will be measured by gently pinching the skin at three points - the front and back of the upper arm and below the shoulder blade. (15 mins)
- 2) **Neck and leg blood vessel size:** An ultrasound probe will be placed on your neck to scan the main blood vessel feeding the brain called the carotid artery. An image of this vessel will be recorded. This will take approximately 5 minutes. The same will be done on the main artery in the upper leg called the femoral artery.(10mins) See images below.



- 3) **Blood vessel function test:** We will use ultrasound to look at the blood vessels in your upper arm and thigh for 10 minutes. During this time, we will inflate a cuff, (just like one used to measure blood pressure; see image on the right), below your elbow and above your knee for 5 minutes. This is painless but you may get pins and needles, this will resolve when the cuffs are released. (15mins)
- 4) **Blood pressure:** will be measured using an automatic blood pressure monitor around the upper arm. (3mins)



- 5) **Blood vessel stiffness:** we will measure the pulse at the neck and in the upper leg, near the groin, using a painless probe. During this test, we also measure heart rate through 3 stickers on the stomach and chest. (30mins)
- 6) **Brain blood flow:** Participants will wear a head band fitted with small ultrasound probes at either side of the head to measure brain blood flow (see picture below). We will also attach a small finger cuff to monitor your blood pressure (see picture below):



You will then complete 3 different tests:

- a) **Eye closing task:** You will be asked to close your eyes for 30 seconds, following this you will be shown an image on an iPad for 30 seconds. This will be repeated 5 times. (10mins)
 - b) **Breathing test:** You will be fitted with a nose clip and will breathe room air through a tube for 5 minutes. You will then be asked to take a big breath in and breathe into a large bag. You will continue to breathe through this bag for 5 minutes. You will then breathe room air for a 3 minute period. This test is painless, but may make you feel slightly light headed towards the end of breathing via the bag. As soon as you return to room air the light headedness goes. (13mins)
 - c) **Posture change test:** You will be asked to repeat a series of sit to stand moves (coached by a member of the research team) for a 6-minute period. (6mins)
- 7) **Fitness test:** We will ask you to do an exercise test on a bike to find out how fit you are. You will start with a 5 minute warm up at a level chosen by you. We will then increase the resistance you pedal against until we get your heart rate to a target set by the researcher. Once this target has been met, we will get you to cool down for 5 minutes on the bike by pedalling at a light resistance. Water will be available on completion of the test. (20mins)
 - 8) **Physical Activity/Sedentary time measurement:** At the end of your visit to the University, you will be given 2 activity monitors to wear. One monitor sits on the right hip using an elastic belt and it reports the number of steps taken (see picture below left). The other monitor is worn on the right thigh via a sticky pad and measures the amount of sitting time (see picture below right). You will wear them for a total of 7 days.



This monitor will count your steps.

This monitor will calculate your sitting time.

Visit 4

This visit will happen within 4 weeks of delivery and will involve 3 parts

1. Baby assessment
2. Mum's Quality of Life assessment
3. Short Interview [For those in the exercise group only]

Off-spring assessment

1.) *Baby blood vessel wall size:* you will be asked to provide separate written consent for this assessment. This section of the study will require an ultrasound scan of your baby's tummy to view a blood vessel that lies below the ribs. This painless scan is the same measurement that will have been done on your neck and leg at each of your visits to LJMU. This measure will be carried out within 4 weeks following delivery and will be the only measurement taken from your baby. (20mins)

Mum's Quality of Life Assessment

2.) *Questionnaire:* You will be provided with a questionnaire to complete to assess your quality of life following the delivery of your baby. You can complete this questionnaire during this visit to the University, or you can take it home and send it to the research team via post or email. The research team will be available to contact should you have any queries regarding this. (20mins)

3.) *Short Interview:* For participants who are in the exercise training group only. The researcher will ask you some questions about your experience throughout the study and your thoughts on exercise during pregnancy. (20mins)

Note: The measures taken during this study are for purely for research purposes and cannot be used as diagnostic tests.

The Exercise Intervention

On the first visit to LJMU you will choose to be a part of either an exercise, or a non-exercise control group. If you choose the exercise group, you will complete a 6 month partially supervised exercise programme consisting of 3 aerobic exercise sessions/week of 15 minutes in duration gradually building to 30minutes 4 times/week. You will complete 2 exercise sessions/week at your most conveniently located Liverpool Lifestyles Leisure centre, which you will be given free access to for the duration of this study. One other session per week will be held at the dedicated gym based at LJMU which will be supervised by the researcher. During each exercise session you will be required to wear a heart rate monitor to allow the research team to monitor your heart rate during the exercise. The researcher will be available to provide ongoing support as necessary, and will be in weekly contact throughout the exercise intervention.

Checking your health prior to each session:

Prior to each exercise session, you will complete a short questionnaire to make sure it is safe for you to exercise. The questionnaire will contain a question related to the 20-week scan prompting you to disclose anything of note to the research team. It will be your responsibility to disclose any information you feel is relevant following your 20-week scan regarding the health of your pregnancy. If anything is highlighted in the screening at any point, you will be instructed to contact your midwife to check whether you are fit to exercise.

****Note:** If any abnormality is detected at the 20-week scan, you can either inform the research team or withdraw from the study at this point.

Participants not choosing the exercise group will have contact with the research team on 4 different occasions during their pregnancy during their laboratory visits along with their routine clinical appointments. Following delivery, these participants will be given information on the importance of physical activity for general health. They will also be given a walking programme that they can engage in after birth and will have the chance to discuss this topic with the researchers.

Are there any benefits/risks involved?

Benefits

We will provide you with feedback on your physical activity level throughout your pregnancy so you can see if you achieve the national guidelines. The research team are not qualified to provide you with diagnostic feedback on the results of the tests, however if you have any concerns, we advise you to consult your GP.

****Note:** Unfortunately, we are unable to reimburse you with travel expenses during this study. This includes travel to and from the University and exercise sessions

Risks

All testing procedures are risk assessed and conducted by qualified and trained researchers. Nonetheless, discomforts may occur:

- **Blood vessel function test:** You may experience a tingling sensation in your leg and hand during cuff inflation. However, this will be short lived and will return to normal shortly after cuff deflation.
- **Breathing Test:** You may feel a little light headed towards the end of this test however this will subside once you return to breathing room air.
- **Fitness test:** The test aims to increase your heart rate, which is normal during exercise. The exercise may cause you to feel tired and breathless. These symptoms go once the test is completed but may return over the following few days (also known as delayed onset of muscle soreness). To alleviate these symptoms, you will complete a short cool down after the test and will be advised to stretch regularly throughout the day.
- **Fasting:** Before each of the 3 visits to the University we will ask you to fast. Irregular, short term fasts are not harmful for your pregnancy, however there is a risk that this may cause you to feel a little weak, tired or lightheaded. Under these circumstances, food (fruit and cereal bars) will be made available to you and we will stop the tests.

Water will also be available for you during the sessions, and we advise that you are well hydrated before your visit.

- **Exercise training:** You may become out of breath during the exercise intervention. However, this is normal during exercise and will be short lived and will not have any long-term consequences. Due to the simplicity of the exercise intervention, the risk of injury is minimal. If, however, you begin to feel unwell either prior to or during your exercise session, we would encourage that you avoid/terminate the planned exercise and call the triage nurse for further advice related to engaging in the exercise.

Will my taking part in the study be kept confidential?

You will be assigned a participant number, and only the researcher will know the details of this. Data will only be accessible to the principal researcher only during the study and all data will be anonymised at the time of collection. Once the study is complete, the data will be stored for up to 10 years and will then be destroyed.

If you any concerns regarding your involvement in this research, please discuss these with the researcher (contact details on the first page). If you wish to make a complaint, please contact researchethics@ljmu.ac.uk and your communication will be re-directed to an independent person as appropriate.