

**LIVERPOOL JOHN MOORES UNIVERSITY
PARTICIPANT INFORMATION SHEET
(Control Participants)**

Title of Project:

Evaluation of a co-developed physical activity referral scheme

Name of Researchers and School/Faculty:

Principal Investigator: Benjamin Buckley

Research Supervisors: Dr Paula Watson, Prof Dick Thijssen,
Dr Rebecca Murphy

School/Faculty: Research Institute for Sports and Exercise
Sciences (RISES) / School of Sport and Exercise
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If you have any questions please contact:

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You are being invited to take part in a research study which forms part of a PhD. The study involves the evaluation of Liverpool's exercise referral scheme. Before you decide to participate, it is important that you understand why the research is being done and what it involves. Please take time to read through the following information and feel free to ask if there is anything that is not clear or if you would like more information. Take time to decide if you want to take part or not.

What is the purpose of the study?

The aim of this study is to evaluate Liverpool's exercise referral scheme, comparing different ways of delivering the scheme and measuring what effects the scheme has on participant health. You have been invited to

take part in the study as a control participant. This means your data will be compared with people who are taking part in an exercise referral scheme to see if the scheme is making any difference to their health.

Who can take part?

To be eligible for the study, you must be:

≥ 18 years old and have a health-related risk factor (e.g. high blood pressure, hyperglycaemia, obesity etc.) or a health condition (diabetes, cardiovascular disease, anxiety, depression etc.) that may be alleviated by increasing current PA levels.

You will not be eligible to take part if:

- You have an uncontrolled health-condition (Cardiac, metabolic, respiratory) and/or any recent traumatic events (e.g. heart attack). ***This means that if you are currently experiencing any symptoms from your condition or are having side effects from your medication you will not be able to take part.***
- Currently taking part in an exercise referral scheme

If you are unsure whether you are eligible to take part please speak to the person who gave you this form or contact the research team on the details above.

Do I have to take part in the research study?

No. It is up to you to decide whether or not to take part. If you decide to take part you will be asked to sign a consent form.

Can I take part if I have been on an exercise referral scheme in the past or might attend an exercise referral scheme in the future?

Yes. As long as you are not currently taking part in an exercise referral scheme and do not have any immediate plans to take part in an exercise referral scheme you may be a control participant. Please talk to the researcher if you are unsure about your eligibility.

If I consent to the study then change my mind, can I drop out?

Yes. You can withdraw at any time and without giving a reason. However, if you do decide to drop out, we will keep any data that has already been collected during the study.

What will happen to me if I take part?

You will be required to attend the laboratory at Liverpool John Moores University (LJMU), Tom Reilly Building, Byrom Street, on two separate occasions (free parking will be available). During each visit, you will take part in the activities outlined below. Visit 1 will take place in the next few weeks. Visit 2 will take place approximately 12 weeks after your first visit. Approximately 6 months after your first visit (3 months after visit 2) we will send out a questionnaire pack for you to complete and an activity monitor for you to wear for 7 days.

Each visit to LJMU will last approximately 1.5 to 2 hours. Three types of measurements will be conducted:

1. Questionnaires
2. Cardiorespiratory testing
3. Physical activity measurement

Questionnaires

You do not have to tell us anything you do not wish to.

The first booklet will include questions to gain information about yourself, such as your age, address, ethnicity, employment status, referral reason etc.

The second booklet will include questions related to your current lifestyle behaviours (e.g. smoking, alcohol intake and diet). Questionnaires will ask you about your motivation for PA, how you feel about the PA you are doing and how supportive you feel your exercise referral instructor is. There are no right or wrong answers and there will be a researcher available to answer any questions you have. The third set of questionnaires will ask you to recall your physical activity levels and wellbeing over a period of 1 – 2 weeks. Finally, the last set of questions will investigate your health-

related quality of life, and questions related to costs, this will help us to estimate the cost effectiveness of the scheme.

Cardiorespiratory testing

1) Brachial (arm) artery function:

you will be asked to lie on a bed and we will use an ultrasound probe (see picture) to look at the artery and the blood running through it. We will place a blood pressure cuff around your arm and inflate it for 5 minutes. We will then



let the air out of the cuff and scan your artery with the ultrasound for 3 minutes. You may feel a tingling/pins and needles sensation, but this is completely normal, and will stop when the cuff is released.

2) Carotid (neck) artery wall function: Cold test: you will be asked to put your left hand in ice slush (usually just below 4°C) for 3 minutes. While you do this and afterwards we will measure your blood pressure, heart rate, and blood flow via ultrasound.

3) Cardio-respiratory fitness: You will be asked to perform a short cycle-based fitness test. During the test we will measure heart rate using a chest strap and blood pressure using an automatic blood pressure device. The test is set at a low intensity so it is suitable for people who are not used to being physically active. You will cycle at 60 reps per minute for approximately 6 minutes while your heart rate is tracked. You can stop the test at any point. There are shower and changing facilities in the building that are free for you to use.

4) A blood sample (about a tablespoon) will be taken to look at your cholesterol, triglycerides, and blood sugar levels.

Physical activity measurement

At the end of the laboratory visits, and via post at 6 month follow-up, You will be asked to wear the monitor for 7 consecutive days on your right hip (see picture). The monitor is discreet and can be worn comfortably underneath clothing. We can send you an email or a text message each morning to remind you to wear the monitor if you wish. The monitor will then be returned to the researcher in person or by pre-paid postage.



What do I need to do to prepare for the lab visits?

- **Fast for at least 6 hours before testing**
- Do not exercise in the 24 hours before
- Do not drink alcohol in the 12 hours before
- Do not smoke in the 12 hours before
- Do not drink any caffeine/stimulants in the 8 hours before
- Continue to take your prescribed medication as usual

For example, if your appointment is at 9am on Tuesday morning, you must not do any exercise on Monday, the last alcoholic drink and cigarette you could have would be at 9pm on Monday evening, and the last drink of coffee or tea you could have would be at 1am Tuesday morning. Drinking water at any time is fine/encouraged.

If you feel this will be difficult for you to do or if you have any questions, please talk to the researcher.

What should I wear and bring with me to the lab visits?

- Please wear comfortable clothes to exercise in (e.g. t-shirt, shorts, trainers)
- Water and a healthy snack will be provided e.g. banana or snack bar.

Are there any risks / benefits involved in the research?

There are no known benefits in taking part in this study, however some participants may enjoy contributing to the development of the exercise referral scheme in Liverpool.

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

- a) Cold test (putting your hand in ice slush): You may feel discomfort or find this painful during this test, but this is short lived. If you become too uncomfortable or find it painful, we will stop the test immediately.
- b) Brachial (arm) artery function: you may feel some discomfort or slight pain which is short lived. As with the cold test, we will stop the test immediately at your request.
- c) Cardio-respiratory fitness test: You may feel your heart rate and breathing rate get faster and may feel hotter; however, these are completely normal responses and will go away when the test is finished. The test can be stopped at any time.

The researcher (Benjamin Buckley) is trained to deal with any medical emergencies that arise from the cardio-respiratory tests, a defibrillator is also available on site.

Will my GP be informed of my study participation or results?

No information will be passed on to your GP. The laboratory-based testing is not diagnostic in nature and is therefore not likely to find anything alarming. However, if any abnormal blood results (analysed following 12-week testing) are identified, the researcher will write to the individual participant and ask them to see their GP.

Will my taking part in the study be kept confidential?

You will be assigned a participant number, and only the researcher will know who is who. Data will only be accessible to the research team during the study. Once the study and data analysis is complete, personal data will be stored securely for 5 years and then destroyed.

Photography

Some photographs may be taken during this research study for LJMU promotional purposes. The photographs may be published on website

or print material for promotional purposes only, and will not be accompanied by any names. If you do not wish to have your photograph taken during the study please tick the opt-out box on the consent form. Consent for photographs will also be confirmed verbally prior to any photographs being taken.

This study has received ethical approval from North West – Preston Research Ethics Committee.

REC reference: 18/NW/0039 IRAS project ID: 238547

If you have 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.