Mobile Health Biometrics to Enhance Exercise and Physical Activity Adherence in Type 2 Diabetes

NHS Research Ethics Committee Approval Reference: 20/SS/0101

School/Faculty: School of Sport and Exercise Sciences, Faculty of Science, Liverpool John Moore University (LJMU)

Chief investigator: Dr Matt Cocks (LJMU)

UK Investigators: Katie Hesketh LJMU, Dr Robert Andrews (Medical Doctor, University of Exeter), Prof Helen Jones (LJMU), Dr Tori Sprung (LJMU), Prof Ceu Mateus (University of Lancaster)

Collaborators from The University of British Columbia (UBC), Canada: Prof Ali McManus, Dr Jonathan Little, Dr Mary Jung, Dr Charlotte Jones (Medical Doctor), Prof Joel Singer

You are being invited to participate in a research project. However, before you give consent to participate in the study, it is important that you completely understand why this research is being completed and what will be required of you. Please take time to read through this information sheet. If there are any areas that are not clear, or that you would like more information on, feel free to contact the researchers who will be happy to provide this information for you.

What is the purpose of the study?
Being physically active and exercising is important for the treatment of Type 2 diabetes, as it helps control your blood sugar and prevent complications. Lots of people find it hard to be physically active and begin or stick to exercising regularly. Research is needed to help identify effective methods to help people with Type 2 diabetes increase their everyday physical activity levels and start exercising regularly to benefit their diabetes management, particularly in the early stages after diagnosis.

In this project we will investigate two strategies to support people with Type 2 diabetes to increase and then maintain a physically active lifestyle, which includes exercising regularly. Participants in one group (exercise counselling) will complete a 6-month structured exercise and physical activity programme supported by regular contact with an exercise specialist. Participants in the second group (mobile health technology (mHealth)) will receive the same 6-month exercise and physical activity programme supported by an exercise specialist, but participants in this group will also receive a fitness watch that links to a mobile phone application (App). The fitness watch and mobile App will allow your exercise specialist to provide greater support and feedback throughout the programme.

Am I eligible for this study?
You are likely to be eligible for this study if you fulfil the following criteria:

- Diagnosed with T2D within the previous 5–24 months
- Male or Female
- Aged 40-75
- Treat your diabetes with only Metformin or lifestyle modifications (diet and exercise)
- For those prescribed Metformin: have used a stable dose for 3-months or more

Meeting any of the following criteria will prevent you from participating in the study:

- Aged under 40 or over 75
- HbA1c more than 10%
- Blood pressure higher than 160/110 mmHg
- Treat your diabetes with an antidiabetic drug other than Metformin
- Unstable angina (frequent chest pain)
- Myocardial infarction (heart attack) within the previous 3 months
- Transient ischemic attack (TIA) within the previous 6 months
- Heart failure ≥class 2
- Arrhythmia (heart rhythm problems)
- Inability to increase activity
- Pregnancy or planning to become pregnant
- Less than 6 months post childbirth or stopped breastfeeding less than 1 month ago
- Not owning a smartphone/ or having no data plan or access to WiFi
- currently meeting the recommended exercise guidelines (150 min of moderate intensity exercise per week).

If you are unsure on any of these, then please contact the research team and we will help.

If you become pregnant during the study you will need to inform the research team and withdraw from the study.

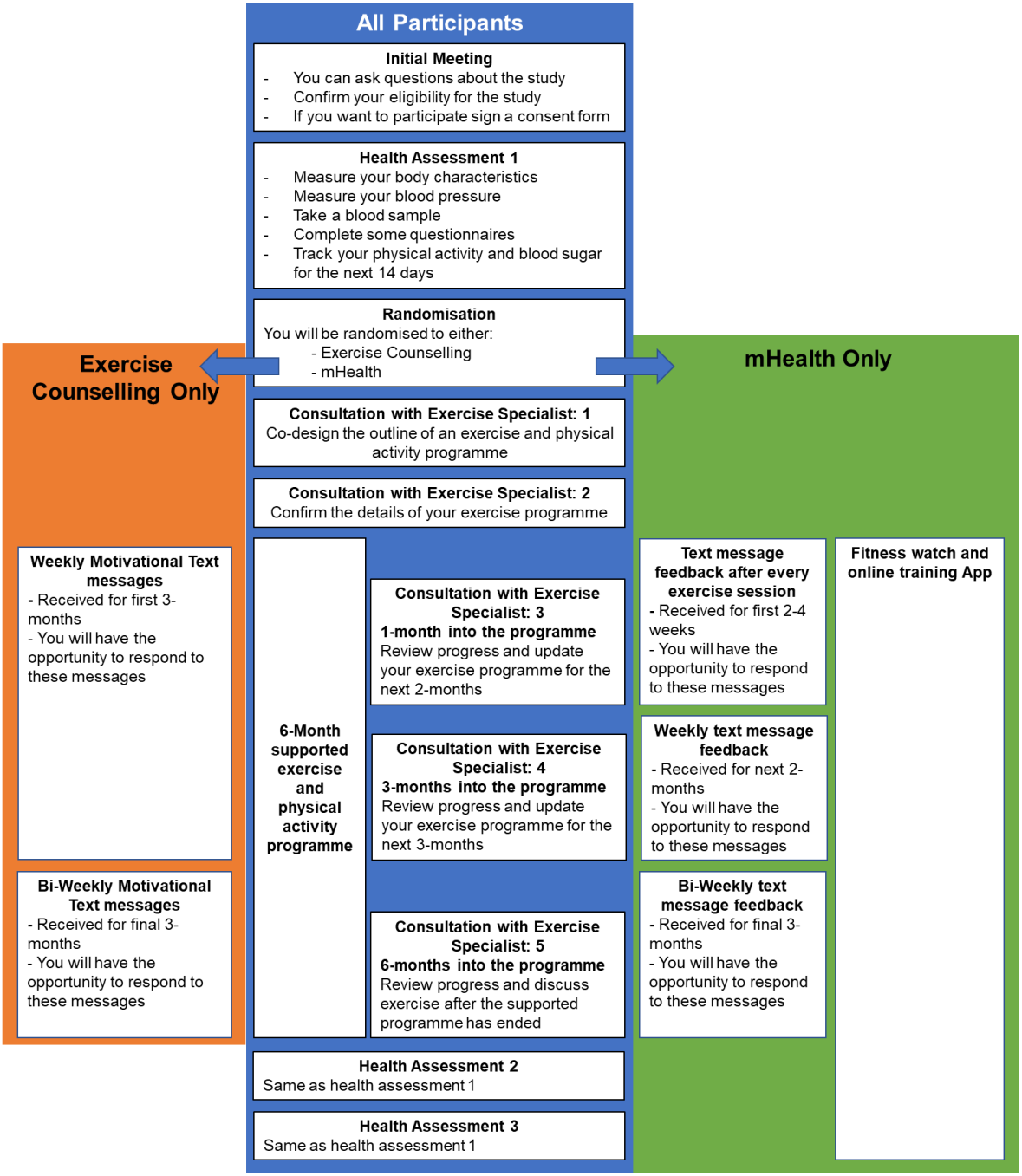
Do I have to take part?
No. Taking part in this study is entirely voluntary. If you would like to participate you will be given this information sheet to keep and be asked to sign a consent form. You are still free to withdraw at any time and without giving a reason. A decision to withdraw will not affect your rights, or any future treatment or service you receive.

Benefits:
All participants will co-design their own 6-month personalised exercise and physical activity programme with an exercise specialist and have 5 exercise consultations with an exercise specialist, spread across the 6-month programme (more details below). You will also complete three basic health assessments. To do these assessments you will be given, to keep, a tape measure, set of scales and a blood pressure monitor.

Participants in the mHealth group will also be given a wrist worn fitness watch (Polar Ignite), to keep, and access to a free online training application (Polar Flow). The fitness monitor will act as a personal trainer on your wrist providing live feedback on how to exercise. The training app will help you track your exercise and enable your exercise specialist to follow your progression and provide regular personalised feedback.

You will receive a £5 Amazon voucher each time you complete the study questionnaires. You will be asked to complete the questionnaires 3 times in total (total £15).

What do I have to do?



Due to COVID-19, all aspects of the study will be remote. Therefore, you can do everything from the comfort of your own home. If you agree to take part, you will have three health assessments (each taking approx. 45 minutes); 1) before the start of the exercise programme (Baseline), 2) immediately after the exercise programme (Post-Intervention, 6 months) and 3) 6-months following the end of the exercise programme (Follow-up, 12 months). All participants will complete these health assessments, and details of what you can expect are outlined below. We will provide you with detailed written and video instructions on how to take the measures, alongside support from a member of the research team via phone or video-call. We will post all the equipment you need to an address of your choosing (you will keep all the equipment used).

Initial meeting

We will arrange an initial meeting, via telephone or video call (depending on your preference), so you can ask any questions you may have about the study. We will also assess your eligibility for the study using a screening questionnaire. If you wish to take part in the study and are eligible, we will ask you to sign the document using the digital signature tool HELLOSIGN.

Health assessment
Baseline, post-intervention and follow-up health assessments will be identical unless stated below. Prior to the health assessments a member of the research team will call/video-call you to go over what you need to do for each measurement, and gain information about your current medication use and ethnicity. You will be given written and video resources to help you with the measurements. A member of the research team will also be available for a call/ video call if you need help when you complete the measures. All equipment will have been set-up and pre-programmed by the research team before you receive it.

You will complete the health assessments in the morning having completed an overnight fast, without caffeine and without alcohol or vigorous exercise the day before testing. Before completing the measurements, you will drink a glass of water. The measurements should take about 45 minutes.

Body characteristics
You will measure your height, weight and waist circumference. We will send you a tape measure and scales to do this.

Blood Pressure
You will measure your blood pressure with a home use blood pressure monitor that we will send to you, it's similar to what is used at GP surgeries. You will wrap the blood pressure cuff around your upper arm and press the start button then note the reading. You will do this 3 three times.

Blood sample
Using a commercially available home testing kit (www.MonitorMyHealth.org.uk) you will collect a small blood sample from your finger. Using a lancet (like a small pin), you will make a small cut on your finger (you will feel a small scratch). You will then fill a tube with 500ul of blood (equivalent to 4-5 drops of blood). You might need to repeat the process on more than one finger to get enough blood. You will then post the sample to the lab for analysis in the pre-paid/pre-addressed envelope on the day you took the blood sample. It is really important that it is posted the same day.

14-Days physical activity and blood sugar monitoring
You will wear two devices to track your physical activity and blood sugar levels for 14 days after you performed the above measurements.

1. A physical activity monitor will be worn on your wrist (similar to a digital watch).
2. You will wear a flash glucose monitor. This device uses a small sensor inserted under the skin on your upper arm to check sugar levels throughout the 14-day period. You will insert this yourself. Like the blood sample described above, you will feel a small scratch when the sensor is inserted. To start the sensor we will ask you to scan it with a reader device. After the 14-day recording period we will ask you to scan the sensor again before removing it.

Following the 14 day recording period we will ask you to return the physical activity monitor and the flash glucose monitor sensor and reader by putting them in a pre-paid/pre-addressed envelope.

Questionnaires

As part of the health assessment, you will complete 6 online questionnaires. You can decide not to complete a questionnaire or any specific questions. The questionnaires will ask about: 1) the impact of your health status on your everyday life, 2) your use of healthcare over the previous 12 weeks, 3) your satisfaction with your diabetes treatment, 4) your typical exercise levels over the past week, and 5) your motivation for regular exercise.

During post-intervention and follow-up testing two additional questionnaires will be used to assess 1) how your satisfaction with your diabetes treatment has changed and 2) your rapport with your exercise specialist.

Measures during the exercise programme
Every month throughout the study (12-months in total) you will be asked to complete an online questionnaire about the amount of exercise you completed over the last week.

Interviews
You **may** be asked to take part in a phone/video (as preferred) interview to talk about your experience of the research project 1) following the baseline health assessment, 2) post-intervention or 3) at follow-up. We will select a diverse range of participants to take part in the interview discussions. These discussions will be recorded and pseudonymised so that no one can be identified from them. As soon as possible the audio files will be moved to secure storage and deleted from the recording device.

Mobile Apps
We will ask all participants to download the video calling App, Zoom. No personal information or sign-up is required for the Zoom App to work. Participants in the mHealth group will be asked to download the training App, Polar Flow. The research team do not own the data recorded on the Polar Flow mobile apps or downloaded to Polar Flow website. The data is owned by POLAR Electro. However, no personal data will be provided to the company as a unique login and password will be created for you using a study code. We will provide you with a copy of the privacy policies before consenting to the study. We will then ask for your permission to use the mobile App and website.

The Polar Flow App requires information to be downloaded from your phone to cloud storage. This will use your mobile phone data and as such could cost you money which the research team will not reimburse. To avoid using your mobile data this process can be done using Wi-Fi.

6-month personalised exercise and physical activity programme
You have a 50/50 chance of being in the exercise counselling or mHealth groups. Groups will be chosen randomly, the same as tossing a coin, so that it is as fair as possible. We will randomise you to a group after the first health assessment. Much of the 6-month programme is the same for participants in both groups.
All Participants
The aim of the programme will be to slowly increase the amount of exercise you complete until you reach government guidelines for weekly exercise (150 minutes of moderate-to-vigorous exercise per week). You will work with your exercise specialist to co-design an exercise programme that works for you, choosing from a wide selection of exercise types including: traditional exercise like walking, cycling or swimming; weight training; time efficient online classes; dance classes or sports like walking football. To help the programme fit with your lifestyle you will be able to exercise in a number of environments including: at home; outdoors; in a gym or while commuting to work or the shops. Importantly, many of the exercises will require no equipment or money to do.

To support you through the 6-month programme you will have 5 consultations with an exercise specialist. The sessions will be conducted using the mobile App ZOOM (we will help you download the App).

Consultation 1: The week after health assessment 1
You will have a conversation with your exercise specialist about your current beliefs on exercise, the benefits of exercise and your concerns about exercising. This conversation will help you and the exercise specialist make a plan for your exercise programme.

Consultation 2: The week after consultation 1
From the conversation had in consultation 1 your exercise specialist will develop an initial exercise programme. Together you will discuss the programme and how to achieve it.

Consultation 3: 2-4 weeks into the exercise programme
You will review your progress and make changes to the exercise programme if required.

Consultation 4: 3 months into the exercise programme
You will review your progress and make changes to the exercise programme if required.

Consultation 5: at the end of the 6-month programme
You will review your progress and discuss how you can continue exercising after the structured programme has finished.

Exercise Counselling Only

To support your exercise programme you will receive weekly text messages for the first 3-months. These messages will be motivational statements encouraging you to exercise.

After the first 3-months these text messages will be sent every other week.

You will be able to contact your exercise specialist (via text or email) or reply to the weekly/bi-weekly text messages throughout the programme to ask any questions you may have.

mHealth Only

You will be given a fitness watch (Polar Ignite) and access to a free online training App (Polar Flow). The fitness watch will act as a person trainer on your wrist, giving you feedback during exercise on how to complete the planned session. The training App will allow you to plan your training programme (with the help of your exercise specialist) and monitor your progress towards your goals. Data recorded by the fitness watch will also be available to your exercise specialist to help them provide personalised feedback throughout the programme.

During the first month of the programme you will be asked to provide feedback on your exercise sessions via the training App. Your exercise specialist will then send a message based on what you did in the session and your feedback. You will be able to reply to these comments. If necessary, your exercise programme will be modified based on these conversations.

After the first month of the programme you will receive weekly text messages from your exercise specialist. These will be based on the training you have done. You will have the opportunity to reply to these comments to ask any questions you may have.

After the first 3-months these text messages will be sent every other week.

Data from the fitness watch and your ongoing feedback will also be used to help personalise the conversations had during consultations 3, 4 and 5.

What Testing Equipment Will You Keep
Following the study you will keep the tape measure, scales and blood pressure monitor. Participants in the mHealth group will also keep the fitness watch (Polar Ignite). You will need to return the physical activity monitor and the flash glucose monitor sensor and reader to the research team.

Are There Any Risks?

- Blood Sampling: You will collect a finger prick blood sample at three time points during the 12-month study (baseline, post-intervention and follow-up). You may experience some sensitivity where the blood sample is taken, but this will be short-lived and normally only lasts ~24 hours. The research team will provide detailed information on how to do this and all the necessary equipment. You will also have a meeting (phone or video as preferred) where you can discuss this test and any other aspects of the programme, ask questions, and get expert information before agreeing to be a participant.
- Exercise: You will experience fatigue during the exercise sessions. This is normal and will be short-lived and you should fully recover within hours of the process. However, during exercise there is a very minimal risk of unforeseen heart failure. Although specific figures are not available for people with Type 2 diabetes, the risk of a cardiac event or complication in adults without existing heart disease ranges from 1 in 400,000 – 800,000 hours of exercise. Even in patients with heart disease, who are recognised as high risk, the risk equates to 1 death every 176,000 hours of exercise. As such, the risk is deemed extremely small. You are also free to stop exercising at any point if you feel uncomfortable.

At any stage throughout the study you are free to withdraw and stop the testing immediately.

Will I be recorded and how will the recorded media be used?
You may be asked to complete an interview discussing your experiences of the intervention and study process. If you are interviewed the audio/ video recording will be made on a password protected device and transferred to secure storage and deleted from the recording device as soon as possible.

We will also record your interactions with your exercise specialist. As above, these audio/ video recordings will be made on a password protected device and as soon as possible the recording will be transferred to secure storage and deleted from the recording device. You are free to decline to be audio/video recorded in this manner. You should be comfortable with the recording process and you are free to stop the recording at any time.

What will happen to my blood sample?
The blood samples provided at baseline, post-intervention and follow-up will be used to assess your HbA1c, total cholesterol, HDL cholesterol, and triglycerides. Your blood samples will be sent by you to be analysed in an NHS laboratory (via a prepaid envelope provided with the testing kit). Your identity will not be available to the laboratory analysing the sample. The only

information provided to the laboratory will be your study ID (number you will be given when you enrol in the study). Only the direct research team will have access to your personal information. During the study samples will be stored in the freezers managed by Dr Tim McDonald (Clinical Director and Consultant Clinical Scientist of the Blood Sciences Laboratories at the Royal Devon and Exeter Hospital) at the Royal Devon and Exeter Hospital.

With your permission, at the end of the study, your home blood samples and data will be transferred to the Peninsula Research Bank at the University of Exeter to ensure their safe use in the future research. We will not store any of your DNA (the material from which genes are made) or any live cells. All personal identifying information will be kept separately and may only be accessed by the Peninsula Research Bank data management team. The Peninsula Research Bank steering committee will approve the use of samples for research into common disease, healthy ageing and other relevant medical research. This research may form part of collaborations in the UK or overseas including collaborations with scientists within companies.

Specifically samples:
a) Will not be sold for profit
b) Will not be used in animal research
c) Will not be shared with non-research organisations, such as the police.

Will my General Practitioner/family doctor (GP) be informed of my participation?
With your permission we will inform your GP about your participation in the study. In this letter we provide them with the results from your baseline blood test (HbA1c, total cholesterol, HDL cholesterol, and triglycerides).

What will happen to the data provided and how will my taking part in this project be kept confidential?
The information you provide as part of the study is the **study data**. Any study data from which you can be identified (e.g. from identifiers such as your name, date of birth, audio recording etc.), is known as **personal data**. This includes more sensitive categories of personal data (**sensitive data**) such as your ethnic origin or health. Personal data collected from you will be recorded using a linked code – the link from the code to your identity will be stored securely and separately from the coded data. Any data transferred to the Canadian research team will be labelled with the specific study ID code, not with your name. You will not be identifiable in any ensuing reports or publications. Audio recordings will be transferred to a computer file, encrypted and saved using pseudonyms immediately after the testing visit. This data will be kept on a password-protected folder on the LJMU network. Once data has been saved, it will be immediately deleted from the recording device. Audio recordings will be transcribed by a member of the Canadian research team. All audio recordings transferred to the Canadian team will be processed in accordance with the UK data protection act. To ensure this a data processing agreement incorporating model clauses regarding audio data has be agreed between LJMU and UBC. The blood samples that you collect throughout the study will be given to the laboratory to analyse without any link to your personal details. With your permission, at the end of the study, your blood samples and data will be transferred to the Peninsula Research Bank at the University of Exeter to ensure their safe use in the future research.

When you agree to take part in a study, we will use your personal data in the ways needed to conduct and analyse the study and if necessary, to verify the process and outcomes of the study. Personal data will be accessible to the research team only. When we do not need to use personal data, it will be deleted or identifiers will be removed. Personal data does not include data that cannot be identified to an individual (e.g. data collected anonymously or where identifiers have been removed). However, your consent form and contact details will be retained for 10 years. Responsible members of Liverpool John Moores University may be given access to data for monitoring and/or audit of the study to ensure that the study is

complying with applicable regulations.

De-identified data might be used for additional or subsequent studies and we might share de-identified data with other investigators running other studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or private companies. All personal information that could identify you will be removed or changed before information is shared or results are made public. This information will not be combined with other information in a way that could identify you.

When you agree to take part in a study, the information collected may be provided to investigators running other studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or private companies in this country or abroad. Your information could be used for research and could be combined with information about you from other sources held by investigators, the NHS or government. Where this information could identify you, the information will be held securely with strict arrangements about who can access the information. The information may be used to contact you about future opportunities to participate in studies. It will not be used to make decisions about future services available to you, such as insurance. Where there is a risk that you can be identified your data will only be used in studies that has been independently reviewed by an ethics committee.

What will happen to the results of the research project?
We aim to present the outcomes of the study in scientific journals and at conferences, but names of participants will never be published.

What if we find something unexpected?
There is a chance one of our tests will pick up an unexpected finding. Should this occur our study medic (Dr Robert Andrews who is an expert in Diabetes) will send this information to your GP, and we will advise you to speak with your GP.

Who is organising and funding the study?
This study is organised by Liverpool John Moores University and funded by the UK (Medical Research Council) and Canadian (Canadian Institute of Health Research) governments.

Who has reviewed this study?
This study (IRAS project ID: 283225) has been reviewed by, and received ethics clearance through, an NHS Research Ethics Committee (Reference number: 20/SS/0101). In addition, Liverpool John Moores University has approved and supported this study as a sponsor.

What if something goes wrong?
If you have a concern about any aspect of this study, please contact the relevant investigator who will do their best to answer your query. The investigator should acknowledge your concern within 10 working days and give you an indication of how they intend to deal with it.

If you are harmed due to someone's negligence then you may have grounds for legal action for compensation against LJMU but you may have to pay your legal costs. LJMU holds Professional Indemnity insurance to cover the legal liability of the University as Research Sponsor and as the employer of staff/students engaged in the research, for harm to participants arising from the design of the research, where the research protocol was designed by the University. This does not in any way affect an NHS Trust’s responsibility for any clinical negligence on the part of its staff.

Please report concern to Dr Dave Harriss,
Research Governance Manager
Research Innovation Services

Exchange Station
Tithebarn Street
Liverpool
L2 2QP
Email: Sponsor@ljmu.ac.uk
Phone: 0151 231 2121

Data Protection Notice
Liverpool John Moores University is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Liverpool John Moores University will process your personal data for the purpose of research. Research is a task that we perform in the public interest. Liverpool John Moores University will keep identifiable information about you for 10 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the study to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at by contacting secretariat@ljmu.ac.uk.

If you are concerned about how your personal data is being processed, please contact LJMU in the first instance at secretariat@ljmu.ac.uk. If you remain unsatisfied, you may wish to contact the Information Commissioner's Office (ICO). Contact details, and details of data subject rights, are available on the ICO website at: https://ico.org.uk/for-organisations/data-protection-reform/overview-of-the-gdpr/individuals-rights/

Thanks for your time. If you have any further questions or want to participate in the study please contact:

Contact Details of Researcher:
Katie Hesketh (post-doctoral Researcher)
Email: K.Hesketh@2012.ljmu.ac.uk

If you would like an independent source of information and advice on the study please contact Dr Dave Harriss (see above for contact details).

Note: A copy of this participant information sheet should be retained by the participant with a copy of the signed consent form.