Mobile Health Biometrics to Enhance Exercise and Physical Activity Adherence at LJMU: A Pilot Study

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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 regularly is important for a healthy body and mind. Nevertheless, lots of people find it hard to be physically active and/or stick to an exercise programme. Research is needed to identify more effective methods to help people increase and maintain their everyday physical activity levels and start exercising regularly, in order to benefit their physical and mental health. This will also reduce the risk of many chronic health conditions such as diabetes, cardiovascular disease, and even dementia.

In this project we want to see if mobile health (mHealth) technology (i.e. the use of smartphones, wearable technology and apps to support the delivery of interventions) when combined with exercise support makes it easier for people to begin and maintain a physically active lifestyle, which includes exercising regularly.

During this study, we will investigate the effect of two different interventions on basic health outcomes. Participants in the 'online resources intervention' group will be given access to online exercise resources, designed by physiologists from the School of Sport and Exercise Sciences at LJMU, which aim to encourage regular exercise. Participants in the 'mHealth intervention' group will work with an exercise physiologist to design an exercise programme. To compliment this programme participants will use a fitness watch and mobile phone application to provide feedback during exercise and enable the exercise physiologist to provide personalised support.

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

- Male or female
- Aged 18-75.

- No known cardiovascular or metabolic disorder (e.g. heart failure, diabetes, previous myocardial infarction etc.).
- Not currently meeting the recommended exercise guidelines (this will be determined during a screening appointment with a member of the research team).

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

- Aged <18 or >75.
- Pregnancy or planning to become pregnant in the next 3 months.
- <6 months postpartum or stopped breastfeeding <1 month before recruitment.
- Not owning a smartphone with a data plan or access to WiFi.

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

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 have access to exercise materials developed by physiologists from the School of Sport and Exercise Sciences at LJMU. If randomised to the mHealth intervention group, you will receive a 12-week personalised exercise programme designed with you by an exercise physiologist. As part of the programme, you will receive regular support and encouragement from your exercise physiologist. To compliment this support, you will be provided with a wrist worn fitness watch (Polar Ignite) and access to an online training app (Polar Flow) for the duration of the study. 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 physiologist to follow your progression and provide personalised feedback.

You will also complete three basic health assessments, and the research team can communicate these to you.

Will you be in the mHealth intervention or the Online Resources intervention?
You have a 50/50 chance of being in the mHealth intervention or online resources intervention. All participants will have the same health assessments and access to online resources designed to encourage regular exercise. Groups will be allocated randomly using a computer programme, the same as tossing a coin, so that it is as fair as possible. Once you have consented to taking part in the study we will randomly allocate you to a group before you begin the trial.

If you are randomly assigned to the mHealth intervention, what does the exercise programme involve?

With support from an exercise physiologist, the aim of the programme will be to slowly increase your exercise levels. You will be able to choose different types of exercise including continuous exercise, time efficient interval exercise and weight training. You will also be able to choose different modes of exercise: outdoor or home-based. You will not need any equipment for this exercise programme.

Exercise counselling. You will be offered four exercise counselling sessions during the 12-week programme. These sessions will be performed using an app and will help build your motivation and confidence to train regularly and progress your training with guidance from your exercise physiologist

Mobile health technology. To help you achieve your training goals you will be given a fitness watch and access to an online training App. The fitness watch will act as a personal trainer on your wrist, giving you feedback during exercise sessions on how to complete the planned exercise. The training App will allow you to plan your training programme (with the help of your exercise physiologist) and monitor your progress towards the goals you set.

Support messages. You will receive weekly personalised feedback on your exercise sessions. This will allow for extra communication between yourself and your exercise physiologist.

If you are randomly assigned to the Online Resources intervention, what does the exercise programme involve?

You will be given access to online resources produced by the School of Sport and Exercise Sciences at LJMU. The resources will guide you through a 12-week exercise programme with the aim of increasing the amount of exercise you do each week. You will be able to choose different types of exercise including continuous exercise, time efficient interval exercise and weight training. You will also be able to choose different modes of exercise: outdoor or home-based. You will not need any equipment for this exercise programme.

What do I have to do?

Due to COVID-19, **ALL** aspects of the study will be remote. Therefore, you will not have any physical contact with researchers and can do everything from the comfort of your own home. If you agree to taking part in the study we will ask you to do three health assessments (each taking approximately 30 minutes). One will be performed before the start of the exercise programme (week 0, Pre), one mid-way through the intervention (week 6, Mid), and one on completion of the programme (week 12, Post). Details of what you can expect during the health assessments are explained below. We will provide you with detailed 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.

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 physical activity readiness questionnaire, and some basic screening questions. 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 in Microsoft Word.

Health assessment

Pre, mid and post exercise programme health assessments will be identical, unless stated below. Prior to the health assessments a member of the study team will call/video-call you to go over the protocol and techniques for each measure. You will also be given written and video resources to help you with the measures.

You will be asked to complete the health assessments in the morning having completed an overnight fast, without caffeine, alcohol or vigorous exercise the day before testing. Before completing the assessment, we will ask you to drink a glass of water. The assessment should take approximately 30 minutes.

Body characteristics

We will ask you to measure your height, weight and waist circumference. We will provide you with a tape measure, and scales if you do not have any.

Blood Pressure

We will ask you to measure your blood pressure with a home use blood pressure monitor (similar to what is used at GP surgeries). You will be asked to wrap the blood pressure cuff around your upper arm and record your blood pressure three times.

Blood sample

You will be asked to provide a blood sample pre and post the training period. Using a commercially available home testing kit (www.MonitorMyHealth.org.uk) we will ask you to collect a small blood sample from your finger. Using a lancet, you will be asked to make a small cut on your finger (you will feel a small scratch). You will then be asked to fill a very small tube with 500ul of blood (equivalent to 4-5 drops of blood).
From these samples we will assess your HbA1c, total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides. Your blood samples will be sent by you to be tested in an NHS laboratory (via a prepaid envelope provided with the testing kit). Your identify will not be available to the laboratory analysing the sample. The only information provided to the laboratory will be your study ID. Only the direct research team will have access to your personal information. Once your sample has been analysed it will be disposed of in line with the Human Tissue Act. Blood samples will only be taken Pre and Post the intervention.

Wearables

We will ask you to wear two devices to track your physical activity and blood sugar levels for 7 days after the health assessment.

1. You will be asked to wear a physical activity monitor on your wrist (similar to a watch).
2. You will also be asked to 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 7-day period. To start the sensor we will ask you to scan it with a reader device. After the 7-day recording period we will ask you to scan the sensor again before removing it. Flash glucose monitoring will only be done pre and post the programme.

Following the 7 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) stamped addressed envelope and placing in the post.

Questionnaires

As part of the health assessment, you will be asked to complete three online questionnaires. You can decide not to complete a questionnaire or any specific questions. The questionnaires will ask about: 1) your typical exercise levels over the past week; 2) the impact of your health status on your everyday life (e.g. limitations in physical activities because of any health problems, perceived pain, and vitality); and 3) your motivation for regular exercise.

We will also ask you to complete two surveys during this study. The first survey will be after the initial baseline testing and will ask you about your experiences of the testing. The second survey will be after the 12-week intervention and will ask you about your perceptions of the intervention and resources. We will also ask you for any recommendations to improve the study.

Monitoring

You will be asked to complete an online questionnaire about the amount of exercise you completed over the last week. You will complete this questionnaire after 4, 8 and 12 weeks of the programme.

If you are randomised to the online resources intervention, you will be provided with a heart rate sensor for the duration of the study that we will ask you to wear on your forearm during any exercise sessions you perform during the 12 weeks. The device uses a simple elastic strap to keep a plastic sensor in contact with your skin. The device will not give you any feedback during exercise and the data will only be available to the research team.

Interview

You **may** be asked to take part in one or two phone/video (as preferred) interviews during this research study. If invited to the first interview (after completing baseline testing) you will be asked about your experiences of collecting your own health measures. If invited to the second interview at the end of the 12-week programme you will be asked about your experiences of the intervention and resources.

If you are interviewed the audio recording will be recorded on a password protected device. This recording will then be transcribed and anonymised so the typed discussion will not be identifiable to you. You are free to decline the interview or to be audio-recorded. You should be comfortable with the recording process and you are free to stop the recording at any time. If you are offered to participate in an interview, a member of the research team will explain the process and give you an opportunity to ask any questions before making a decision on whether to participate.

Mobile Apps

Participants in the mHealth intervention group will be asked to download the training App (Polar Flow) and a video calling App (Zoom). No personal information or sign-up is required for the Zoom App to work. 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 mobile applications used in this study require 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.

Are There Any Risks?

- Blood Sampling: You will collect a finger prick blood sample at two different time points during the 12-week programme (week 0 and 12). You may experience some sensitivity where the blood sample is taken and perhaps a small bruise, but this will be short-lived and normally only last ~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. As you are a healthy participant there is an extremely small risk of a cardiac event or complication which ranges from 1 in 400,000 – 800,000 hours of exercise in adults without existing heart disease.

At any stage throughout the experiment you are free to withdraw from a test and/or the study as a whole and therefore can stop the testing immediately at any time.

Will I be recorded and how will the recorded media be used?

If you are randomised to the mHealth intervention group, we will ask if we can audio-record your exercise counselling meetings with the exercise physiologist. This is so we can observe the progression of discussions that occur over the 12-week intervention. You may also be invited to an interview to discuss your experiences of the intervention and study process. A member of the research team will explain the audio-recording process and you will have a chance to ask questions before deciding whether you are happy or not for the exercise counselling meetings to be recorded, and whether to participate in an interview. You are free to decline to be audio-recorded. Your decision will not affect your participation in the study.

Audio-recordings will be made on a password protected device. This recording will then be transcribed and anonymised so the typed discussion will not be identifiable to you. 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?

You will be asked to provide a blood sample pre and post the training period. From these samples we will assess your HbA1c, total cholesterol, HDL cholesterol and triglycerides. Your blood samples will be sent by you to be tested in an NHS laboratory (via a prepaid envelope provided with the testing kit). Your identify will not be available to the laboratory analysing the sample. The only information provided to the laboratory will be your study ID. Only the direct research team will have access to your personal information. Once your sample has been analysed it will be disposed of in line with the Human Tissue Act.

Will my General Practitioner/family doctor (GP) be informed of my participation?
No. We will not contact or send any information of yours to your GP. However, if any measures are identified outside of 'normal' ranges, you will be informed and encouraged to contact your GP.

What will happen to the data provided and how will my taking part in this project be kept confidential?
During the study we will collect personal data from you (name, date of birth, phone number and email address). This data will be collected so we can keep in touch with you while you are on the study. The data will be stored on password protected files on password protected computers, accessed only by the direct research team. Once you have completed the study, we will destroy this information, unless you would like a copy of the final study results. If you would like a copy of the final results, we will retain your name, phone number and email address (stored as above) so we can contact you later. The results should be available 1 year after you complete the study. Your personal data will then be deleted.

As well as personal data we will collect study data. All data will be labelled with a specific study ID code, not with your name. This will mean your data will not be identifiable to you. This data will be destroyed 5 years following completion of the study.

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 disclosed.

What if we find something unexpected?
We will not contact or send any information of yours to your GP. However, if any measures are identified outside of 'normal' ranges, you will be informed and encouraged to contact your GP.

Who is organising and funding the study?
This study is organised and funded by Liverpool John Moores University.

Who has reviewed this study?
This study (project ID: XXX) has been reviewed by Liverpool John Moores University ethics committee and received ethics clearance (XXX).

What if something goes wrong?
All procedures have been included within Liverpool John Moores University Liability Insurances and if you are harmed in any way by taking part in this research project your normal rights apply and you may have grounds for legal action.

If you have any concerns regarding your involvement in this research, please discuss these with the researcher in the first instance. 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.

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 until you complete the study, unless you would like a copy of the final study results. If you would like a copy of the final results we will retain your name, phone number and email address (stored as above) so we can contact you later. The results should be available approximately 1 year after you complete the study. Your identifiable information will then be deleted.

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 Researchers:

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