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Participant Information Sheet

1. Study title

Play-Back: motivating core-muscle exercises with wearable sensors, haptics and interactive gaming

Principal Investigator: Dr Paul Bentley

Collaborators: Dr Ravi Vaidyanathan, Professor Alison McGregor, Dr Paul Strutton, Ms Reneira Seeamber, Dr Saksham Dhawan and Dr Zhenhua Yu.

2. Invitation paragraph

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and decide whether you wish to take part. Talk to others about the study if you wish. Ask us if there is anything that is not clear or if you would like more information.

Thank you for reading this.

3. What is the purpose of the study?

We are developing a practical method that will help prevent lower back pain, and/or treat back pain in those who suffer with it. The method works by motivating exercises of the lower back, buttocks and abdomen ("core muscles") which are known to be important for preventing lower back pain. The system may also encourage healthier postures during everyday life.

The method involves wearing a simple belt that contains several sensors touching the front and back of your trunk. The sensors will detect when, and how long the wearer contracts (i.e. squeezes) their core muscles. This information will be fed wirelessly into a person's phone to feedback how often and how successfully they have performed core muscle exercises. This can motivate people to perform these exercises more often, and also tell people whether they are performing exercises correctly. During your session, you may be asked to use the feedback from the muscle sensors visualised on an app to guide your exercise.

In the study you will partake in we shall collect data from the sensor belt while you perform exercises as supervised by a physiotherapist. We shall use this data to train the computer to know when the exercises are performed correctly. As the study progresses, we will build a model that predicts when the trunk muscles are contracting appropriately. This model will be tested on a new set of subjects who perform the same exercises.

4. Why have I been chosen?

Because you are a healthy subject who has or has not previously experienced lower back pain and who can perform a set of simple back exercises under physiotherapy supervision. If you suffer, or have suffered back pain in the past, you can still partake, providing the exercises do not cause you pain.

5. 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 to keep and be asked to sign a consent form. You are free to withdraw at any time and without giving a reason. Please contact Dr Paul Bentley (Tel: 0203 311 7383, Fax: 0203 311 7487) if you would like to withdraw.

6. What will happen to me & what do I need to do if I take part?

We shall ask you to perform a series of exercises over ~1 hour exercises will be taught and supervised by a physiotherapist, Pilates instructor, or a researcher who has been trained by a physiotherapist. The exercises are mostly performed whilst lying or sitting on a floor mat. You will be reimbursed for reasonable travel expenses. In addition, you will receive a £20 Love2shop gift voucher for each laboratory assessment visit you complete. If you attend all three laboratory assessments (baseline, 4 weeks, and 8 weeks), you may receive up to £60 in vouchers in total.

Prior to you performing the exercises we shall fit you with a belt containing the muscle sensors that detect muscle activation. At the same time we shall place a pad on the skin containing a fine wire (electrode) that records electrical activity in the muscle ("EMG"). It is **not** possible that you could be electrocuted or stimulated in any way by this electrode pad. The purpose of this EMG is to see whether the novel wireless sensor belt is detecting the same pattern of muscle activity – as we would expect if the method works well.

The exercises will be performed in three rounds. During two of the rounds, you will not have access to any visual feedback from the muscle sensors on the belt. However, during one of the rounds, you will be asked to use an app displaying real-time feedback from the belt to guide your exercise. We will use the data from the EMG sensors to determine whether you engage your muscles more or less when exposed to the app.

During the exercises, we may also scan your abdomen or back with an ultrasound camera ("probe"). This will allow us to see the core muscles and whether they are contracting. We will be able to measure exactly how much your muscles have contracted. This involves touching the skin with a special type of camera ("probe"), as well as using a gel rubbed on the skin to allow for the ultrasound camera to see properly.

If you have previously had lower back pain over the last year, you will be invited to take part in an optional sub-study. You will be given a belt/sensor system and access to the app to take home for 4-8 weeks. During this period, you will be asked to perform 20-30 minute exercise sessions, 3-5 times a week. Before and after the 4/8-week period, the Biering-Sorenson Test, which is a tool for predicting lower back pain risk, will be performed. This involves you holding a position where your upper body is unsupported for as long as you can. Voluntary spinal muscle force may also be collected using an adapted force/pressure gauge before and after the 4/8-week period. You will also be asked to rate your pain throughout the study duration using a visual analogue scale.

Other wearable measurements that may be taken include data from Empatica smart watches (<https://www.empatica.com/platform/research-studies/>) which captures movement, electrodermal activity, skin temperature changes, and photoplethysmograms. These watches have been CE-marked and FDA-cleared. The data collected from these watches will only remain with the research team and will not be shared with Empatica.

During the home study period, you will have access to the research team for any questions or help. Furthermore, a member of the research team will have a weekly follow-up to provide any further support and assistance as required.

Before and after the 4/8-week home exercise period, you will be invited to complete an assessment using a piece of physiotherapy equipment called a Cybex isokinetic dynamometer. This is a commonly

used rehabilitation machine that measures how much force your muscles produce during controlled movements. For this assessment, you will stand in the machine in a supported position. Your pelvis and upper body will be gently secured using padded straps across the chest and hips. This helps to keep your body stable so that the machine can accurately measure the strength of your back and abdominal muscles.

You will then be asked to bend forward and backward at the waist against a padded support arm of the machine, or in some tests to push as hard as you can while the machine holds you in one position. The movements are controlled and supervised at all times by a researcher. You will be given clear instructions before each test, and you can stop at any time if you feel uncomfortable. During these movements, the belt/sensor system will record muscle activity. The Cybex machine will simultaneously record how much force your muscles are producing. This allows us to understand how the readings from the belt relate to actual muscle force.

In some parts of the assessment, you may be shown real-time feedback from the belt through the app. In other parts, you will not see any feedback. This helps us understand whether seeing your muscle activity changes how you perform or how long you continue the task. You may experience temporary muscle fatigue or mild soreness afterwards, similar to what you might feel after exercise, but the tests will stop immediately if you feel any significant discomfort.

7. Are there any disadvantages of taking part?

It is very unlikely you will come to any harm with the exercises you asked to do. They will be supervised by a trained individual.

If you feel any pain, or feel the exercises are too exhausting you should let us know and we can stop.

The sensors (novel wireless sensors and EMG), belt, ultrasound, and gel are completely harmless.

Please let us know if you have had any allergies to Lycra or medical gel before and we shall exclude you from partaking.

8. What are the benefits of taking part?

There are no direct benefits to you in taking part. However you will be taught exercises by a physiotherapist that have been proven to be beneficial to help prevent back pain.

We can also if you wish, let you know the results and eventual outcome of our study. Please let us know if this is the case.

9. What will happen if I don't want to carry on with the study?

That is no problem. You can withdraw at any time. Please contact Dr Paul Bentley (Tel: 0203 311 7383, Fax: 0203 311 7487) if you would like to withdraw.

10. What if something goes wrong:

Imperial College London holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator (Dr P Bentley, Consultant Neurologist, Charing Cross Hospital, Imperial College Healthcare NHS Trust, Fulham Palace Rd, London W6 8RF. Tel: 0203 311 7383 , Fax: 0203 311 7487). If you are still not

satisfied with the response, you may contact the Imperial College, Research Governance and Integrity Team (RGIT).

11. What will happen to the results of the study?

It can take up to 2 years to collect all the results. Then we will analyse them with statistical techniques. We then plan to present this data to other health-care professionals at conferences and in professional publications. Your data will be completely anonymous so that no-one needs to know that you ever took part.

We can send you a copy of the published results if you wish. You will not be personally identified in any report/publication.

12. Who is organising and funding the research?

Imperial College London is the study sponsor. Imperial College Confidence in Concept Award, EPSRC-funded AI4 Healthcare PhD Centre for Doctoral Training, and the UKRI Zinc Catalyst Award and the UKRI Developmental pathway funding scheme.

13. Who has reviewed the study?

This study was given ethical approval by Imperial College Research Ethics Committee (ICREC).

Transparency notice

14. HOW WILL WE USE INFORMATION ABOUT YOU?

Imperial College London is the sponsor for 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. Imperial College London will keep your personal data for:

- 10 years after the study has finished in relation to data subject consent forms.
- 10 years after the study has completed in relation to primary research data.

We will need to use information from you for this research project.

This information will include your initials/age/gender/weight/height. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

LEGAL BASIS

As a university we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study.

Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research

INTERNATIONAL TRANSFERS

There may be a requirement to transfer information to countries outside the European Economic Area (for example, to a research partner). Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a European Commission (**EC**) adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient organisation that incorporates EC approved standard contractual clauses that safeguard how your personal data is processed.

SHARING YOUR INFORMATION WITH OTHERS

For the purposes referred to in this privacy notice and relying on the bases for processing as set out above, we will share your personal data with certain third parties.

- Other College employees, agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.
- The following Research Collaborators from Imperial College London in the study:
 - Dr Ravi Vaidyanathan (Faculty of Engineering) who is involved in the development of the novel wireless sensors and may evaluate data collected from the sensors.
 - Professor Alison McGregor (Faculty of Medicine) who is a Professor of Musculoskeletal Biodynamics and is involved in aspects of exercise protocol development.
 - Dr Paul Strutton (Faculty of Medicine) who is involved in EMG sensor analysis and may evaluate the data collected from the sensors.

WHAT ARE YOUR CHOICES ABOUT HOW YOUR INFORMATION IS USED?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED

You can find out more about how we use your information

- by asking one of the research team
- by sending an email to p.bentley@imperial.ac.uk, or
- by ringing us on 0203 311 7383.

COMPLAINT

If you wish to raise a complaint on how we have handled your personal data, please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO). The ICO does

recommend that you seek to resolve matters with the data controller (us) first before involving the regulator.

that you seek to resolve matters with the data controller (us) first before involving them.