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 INDividualised EXercise approach for people with chronic low back pain (INDEX study): The development of an enhanced EMG biofeedback app

**Participant Information Sheet (PIS)**

You are being invited to take part in a research study on the design for a mobile application being developed for patients with chronic low back pain. This research project part of a Master's of Science dissertation. Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully before deciding whether to take part and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Thank you for taking the time to read this.

**About the research**

**Who will conduct the research?**

Carolina Costa Lopes, a Postgraduate student from the University of Manchester. Supervised by Dr Alexander Casson from The University of Manchester, and Dr Janet Deane from The University of Manchester.

**What is the purpose of the research?**

The aim of this project is to develop a mobile application for chronic low back patients to visualise electromyography (EMG) data as they conduct exercises. The application will allow patients to visualise the data collected from Delsys EMG sensors applied to their low back. Chronic low back patients are recommended to complete exercises at home to manage their condition. However, it is often difficult for the patients to truly understand what they are trying to achieve through the exercises, leading to less compliance and worse outcomes. The aim of the creation of this application is to help patients better understand their muscle movements during their exercises. This project will also involve understanding what the physiotherapists would want from an application for them to use it within routine chronic low patient care.

You have been chosen because you have experienced low back pain at some point, or because you are a physiotherapist.

**Am I suitable to take part?**

We would love to speak to you if you:

* Are over 18
* Have experienced low back pain before and are happy to discuss it OR you are a physiotherapist
* Have access to a computer, tablet or mobile phone with video and a stable internet connection (for the Teams conversation)

**Will the outcomes of the research be published?**   
The outcomes of the research will be part of a student dissertation and may be published in the future.

**Who has reviewed the research project?**

This research study has been reviewed by the University of Manchester Proportionate Research Ethics Committee, application number 14085.

**What would my involvement be?**

**What would I be asked to do if I took part?**

**Preparation:**  
You will be sent an electronic consent form which you should return to us by email (to [alex.casson@manchester.ac.uk](mailto:alex.casson@manchester.ac.uk)).

There will be two sessions of roughly 1h each. They will be group sessions conducted on Microsoft Teams.

**During the session:**

* You will join a call with a group of other participants.
* You will be given a presentation on the background of the project and more information on the aims of the research.
* You will then be shown multiple designs for different sections of the application.
* You will be a series of questions about your thoughts on each design and which you prefer and why.

In session two, a new presentation will be given with updates on the project, and a similar feedback session will happen but with newer designs based on the answers given in the first session.

**Will I be compensated for taking part?**

No.

**What happens if I do not want to take part or if I change my mind?**

It is up to you to decide whether or not to take part. To take part, please contact the investigators using the details at the end of this information sheet.

If you do decide to take part you will be given this information sheet to keep and will be asked to return an electronic consent form to us. If you decide to take part you are still free to withdraw at any time without giving a reason and without detriment to yourself. However, it will not be possible to remove your data from the project once it has been anonymised as we will not be able to identify your specific data. This does not affect your data protection rights. If you decide not to take part you do not need to do anything further. If you would like for us to delete the data that we have collected up until that point, we will do so. This does not affect your data protection rights. If you do decide not to take part, you do not need to do anything further. Audio recording is essential to the participation in the study. You should be always comfortable with the recording process, if you are not, you are free to leave the meeting and request that your data is not processed further.

**Data Protection and Confidentiality**

**What information will you collect about me?**

In order to participate in this research project, we will need to collect information that could identify you, called “personal identifiable information”. Specifically, we will need to collect:

* Contact details: So that we can arrange follow up sessions for feedback on updated designs for the application. This will be deleted once the second session is complete, and fully transcribed.
* Your age and gender so that we can report the demographics of our dataset in any papers or reports that are published as a result of this study. The data will be anonymised, connected only to your participant number and not to your name or contact details
* Your electronic participation consent form
* Audio and video recordings during the group discussion. You are free to turn off your camera during the meetings, but audio is required.

**Under what legal basis are you collecting this information?**

We are collecting and storing this personal identifiable information in accordance with UK data protection law which protect your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is “a public interest task” and “a process necessary for research purposes”.

**What are my rights in relation to the information you will collect about me?**

You have a number of rights under data protection law regarding your personal information. For example you can request a copy of the information we hold about you, including audio recordings.

If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our [Privacy Notice for Research](http://documents.manchester.ac.uk/display.aspx?DocID=37095).

**Will my participation in the study be confidential and my personal identifiable information be protected?**

In accordance with data protection law, The University of Manchester is the Data Controller for this project. This means that we are responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used. All researchers are trained with this in mind, and your data will be looked after in the following way:

The study team at The University of Manchester will have access to your personal information and they will anonymise it as soon as possible. Your name and any other identifying information will be removed and replaced with a random ID number. The research team will have access to the key that links this ID number to your personal information. Your consent form will be retained for 5 years on UoM servers for audit purposes.

All recorded sessions will be transcribed automatically by Microsoft Teams and checked and corrected by the researcher (Carolina Costa Lopes). Once the transcript has been checked to ensure it is correct, the recording will be deleted within a month, and personal identifiable information will be removed from the transcript and replaced with an assigned ID. Once the second session has been completed and transcribed, all data will be anonymised by deletion of the Key to the Unique ID.

Your participation in this research will be recorded in Teams and your personal data will be processed by Microsoft. This may mean that your personal data is transferred to a country outside of the European Economic Area, some of which have not yet been determined by the United Kingdom to have an adequate level of data protection. Appropriate legal mechanisms to ensure these transfers are compliant with the Data Protection Act 2018 and the UK General Data Protection Regulation are in place. The recordings will be removed from the above third-party platform and stored on the University of Manchester managed file storage as soon as possible following the completion of data collection.

Please also note that individuals from The University of Manchester or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.

**What if I have a complaint?**

**Contact details for complaints**

If you have a complaint that you wish to direct to members of the research team, please contact:

**DR. ALEXANDER CASSON**

**ROOM E44C, SACKVILLE STREET BUILDING, UNIVERSITY OF MANCHESTER, MANCHESTER, M13 9PL**

[**alex.casson@manchester.ac.uk**](mailto:alex.casson@manchester.ac.uk)

**0161 529 3163**

**If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact**

TheResearch Ethics Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: [research.complaints@manchester.ac.uk](mailto:research.complaints@manchester.ac.uk)  or by telephoning 0161 306 8089.

If you wish to contact us about your data protection rights, please email [dataprotection@manchester.ac.uk](mailto:dataprotection@manchester.ac.uk) or write to The Information Governance Office, Christie Building, The University of Manchester, Oxford Road, M13 9PL at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the [Information Commissioner’s Office](https://ico.org.uk/concerns) about complaints relating to your personal identifiable information Tel 0303 123 1113

**Contact Details**

If you have any queries about the study or if you are interested in taking part then please contact the researcher(s)

**DR. ALEXANDER CASSON**

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