



PARTICIPANT INFORMATION SHEET (BELOW)- Feasibility study (patient)

Title of project: *Behaviour change to rEduce LOW back pain: a feasibility study (BELOW)*

Name of researcher: Stephen Preece

Why am I being invited to take part?

We would like to invite you to take part in a research study. The study is being run by the Centre for Human Movement and Rehabilitation, University of Salford. You are being invited to take part in a research study to help us understand potential new treatments for people who experience long term (chronic) low back pain. You have been invited as you have been diagnosed with low back pain and have had minimal benefit from physiotherapy or other forms of management.

Before you decide, it is important for you to understand why the research is being done and what it will involve. This document gives you important information about the purpose, risks, and benefits of participating in the study. Please take time to read the following information carefully. If you have any questions, then feel free to contact the researcher whose details are given at the end of the document. Take time to decide whether or not you wish to take part. Your decision whether to take part in the study or not will have no bearing on your medical care.

What is the purpose of the study?

The aim of this study is to compare two physiotherapy treatments for people who experience persistent low back pain. Many people with back pain have tried standard physiotherapy on the NHS and not experienced meaningful improvements in their pain. However, current approaches tend to focus on strength exercises and often don't include psychological techniques, which teach patients to think differently and to change the way they react to pain. The two treatments which we will test as part of this study both combine physical re-education with psychological techniques and have either been shown to be effective for treating other chronic pain conditions or have some degree of proven benefit for low back pain. We aim to measure the change in pain and function after receiving treatment.

Do I have to take part?

No, taking part is completely voluntary. If you are interested, contact the researcher (details at the end of this information sheet). If you are not interested, then just disregard this letter.

What will happen to me if I participate in this study?

If you agree to take part in the study, it is important that you don't receive any other physical treatment for your low back pain. This means that if you are offered NHS or private treatment, such as physiotherapy, we need you to postpone this treatment until you have completed the treatment sessions. However, if you do want to receive other physical treatment, then you will need to withdraw from the study.

You will first need to complete three questionnaires:

1. Back pain questionnaires: Understand symptoms, daily life impact, and emotional aspects of back pain.
2. Healthcare Access questionnaires: Asks question about your healthcare service use, such as GP visits or use of medications.
3. Demographic Information: Ask information on age, ethnicity, socio-economic status, gender, disability, and religion.

After you have completed the questionnaires, you will be randomly assigned to one of two treatments.

If you are in treatment group 1:

You will receive the treatment over seven face-to-face physiotherapy sessions. The physiotherapist will first complete a physical assessment using muscle sensors. They will then explain how reacting and thinking differently about your condition has the potential to reduce pain. You will be taught how to consciously relax your back muscles and stomach muscles and will learn how to maintain this relaxation in sitting, standing and during everyday movements. To help with the learning of new muscle patterns, the physiotherapist will use small sensors which visualise your muscle patterns on a screen. Instructional videos are used to explain different parts of the treatment which are watched on a tablet or laptop computer. If you don't have a tablet computer, we will loan you one. If you are unable to use a tablet computer, we will provide you with written materials.

If you are in treatment group 2:

You will receive five face-to-face physiotherapy sessions and two online sessions. The physiotherapist will first assess your movement and strength and then teach you gentle stretches for your neck, back, arms and legs. You will then be taught about pain and how lifestyle factors, such as sleep, diet and stress, may contribute to pain. Building on these ideas, you will be taught relaxation and mindfulness techniques and then provided with exercises designed to improve flexibility, strength, and balance. You will also be taught about the use of pacing to remain active and manage your pain and how to manage flare ups. Again, videos are used to explain the ideas behind the treatment which are watched on a tablet or laptop computer. If you don't have a tablet computer, we will loan you one. If you are unable to use a tablet computer, we will provide you with written materials.

What happens after I have received the treatment?

You will be required to complete the back pain questionnaires and healthcare use questionnaires at two points following treatment. These questionnaires will need to be completed at 14 weeks and 8 months after the date you were enrolled on the study. You will be supported through this process by the research team.

Following the completion of your 14-week questionnaires, you will be able to access other physical treatment options for your low back pain without needing to withdraw from the study. You will be asked to report the treatments you have in the healthcare access questionnaire.

Additional measurements and interviews

As part of our research, we would like to understand the physiological effect of the two treatments. We are therefore offering participants the opportunity to undergo a 30-minute biomechanical assessment before the first treatment session and a follow-up 30-minute assessment after the final treatment session. During each assessment, we will use a 3D measurement system to measure your posture and a small probe to measure the stiffness of your low back muscles. We will also place electrodes on your lower back and measure muscle activity during walking and other simple task, such as bending forwards. In addition, we will use a chest-worn heart rate monitor to measure your heart rate variability and time you as you perform simple tasks, such as standing up from a chair and walking. Note that participation in these assessments is voluntary. However, we will pay you £10 for each assessment if you do agree to this.

We will also offer participants from both groups the opportunity to be interviewed so that we can understand experiences of being involved in the study what you thought about the treatment. These interviews will be carried out over the phone or via video conference and will be an informal way of you expressing your opinions. We will record these interviews, but the data will not be linked to identifiable information such as your name and only the research team (not the physiotherapist) will have access to your opinions. The interview recordings will be stored in a secure folder on the University of Salford network. The interviews will be transcribed (typed onto a computer) by the research team. After this transcription, the recording will be permanently deleted, this will typically be within two weeks of the recording.

What are the possible disadvantages and risks of taking part?

This is a very simple, straight forward study with negligible risks. The physiotherapists involved in the study are experienced in managing patients with low back pain. The physiotherapist delivering the treatment 1 will be using techniques which are used in routine clinical practice, and these will be complemented with the muscle sensors which do not carry any risk. The physiotherapist delivering treatment 2 will ensure that the exercises are individualized to the patient's capabilities. There is a small risk of muscular aches and pains when completing new exercises. This will be monitored by the physiotherapist and appropriate advice/action taken such as reducing the number of exercises or altering the difficulty of exercises.

What are the possible benefits of taking part?

Both groups will receive seven sessions of treatment which may reduce pain and help you to manage disability associated with low back pain. However, we can't promise that everyone will experience clear benefits. Regardless of whether of which group you are in, the results of the study will help us to understand the potential effectiveness of new treatments for people with low back pain. You will receive a payment of £10 once you complete your final set of questionnaires, 8 months after the date you were enrolled on the study. You will also receive £20 if you agree to the attend the biomechanical assessments. This payment will be paid after the second assessment.

Who is organizing and funding the research?

This study is being led by the University of Salford and has been funded by the National Institute of Health Research. Other Universities will also be involved including Keele and Manchester.

How will we use information about you?

We will need to use information from you for the research. This information will include your name and contact details. The research team will use this information to do the research or to check the physiotherapists notes to make sure that the research is being done properly. Those who do not need to know who you are will not be able to see your name or contact details. Your information 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 the information 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.

We are happy to send each participant in the study a summary of the results. Please indicate on the consent form if you would like to receive this summary and confirm that you are happy for us to retain your contact information for 3 years to allow us to send this information to you. No identifiable data will be kept after the end of the study (apart from contact details if you would like a summary of the results).

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 change the data we hold about you. If you do decide to withdraw, this will have no effect on your medical care before participating in the study. If you want to withdraw, please notify the study representative listed in the "Contact Information" section below.

Where can you find out more about how your information is used?

You can find out more about how we use your information at <https://www.salford.ac.uk/privacy> or by asking one of the research team.

What if there is a problem?

The university has insurance to cover against any harm to you which may occur whilst you are taking part in these tests. However, if you decide to take legal action, you may have to pay for this. If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, you can contact the Chief Investigator Dr Stephen Preece on 07498 006 755, email s.preece@salford.ac.uk and if you are not happy you may then contact Katy Sczepura, Ethics Chair, Mary Seacole Building, University of Salford, M5 4WT on 0161 295 5000 or email: K.Sczepura@salford.ac.uk. If you have concerns with regards to how your data is collected and stored then contact Andrew Hartley, Data Protection Officer, Legal and Governance Directorate, Maxwell 6th floor, University of Salford, M5 4WT on 0161 295 6428 or email: a.hartley2@salford.ac.uk. Alternatively, if you have any concerns that you feel should be dealt with by the NHS, then you can talk to the local Patient Advice and Liaison Service (PALS).

Further information and contact details:

If you require more information about the study, want to participate, or if you are already participating and want to withdraw, please contact

Email: health-bepko@salford.ac.uk

Website: <https://hub.salford.ac.uk/volunteer-for-health-research/2024/11/11/below/>

Phone: Dr Jennifer Parker 0161 295 2181

Thank you very much for taking time to read this document!

We appreciate your interest in this study and hope to welcome you at the School of Health and Society, University of Salford, Brian Blatchford Building, Salford, M6 6PU.

Follow the link below to access the study website:

