

# RESTORE clinical trial

## PARTICIPANT INFORMATION SHEET

<b>HREC Project Number</b>	<b><u>HRE2018-0062</u></b>
<b>Project Title</b>	'RESTORE - Individualised movement rehabilitation for chronic, disabling low back pain'
<b>Principal Investigator</b>	Associate Professor Peter Kent, PhD peter.kent@curtin.edu.au, ph (08) 9266 4382
<b>Version Number</b>	Version 6
<b>Version Date</b>	23 March 2019

*Curtin University Human Research Ethics Committee (HREC) has approved this study (HREC number HRE2018-0062). Should you wish to discuss the study with someone not directly involved, in particular, any matters concerning the conduct of the study or your rights as a participant, or you wish to make a confidential complaint, you may contact the Ethics Officer on (08) 9266 9223 or the Manager, Research Integrity on (08) 9266 7093 or email [hrec@curtin.edu.au](mailto:hrec@curtin.edu.au)*

### **What is this project about?**

- In this study, we compare three different ways of treating low back pain. We want to find out which is best and what the associated costs of each are.
- Currently, it is uncertain which treatment approach is best for persistent low back pain and benefits of treatment are often short-term.
- New studies suggest that it may be better to look at each person individually and teach them to think about their pain and the way they move in a different way.
- So, the current project will test this more thoroughly in a group of 492 adults.
- This project will help inform health care practitioners and policy makers about better care of individuals with this quite common condition.

### **Who is doing the research?**

The project is being conducted by team of experts, including Associate Professor Peter Kent PhD, Professor Peter O'Sullivan PhD, Professor Anne Smith PhD, Dr Amity Campbell PhD, Mr Joao Paulo Caneiro FACP and Dr Rob Schütze PhD (Curtin University), Associate Professor Mark Hancock (Macquarie University), Professor Terry Haines PhD and Mr Rob Laird FACP (Monash University), Professor Alison McGregor PhD (Imperial College, UK), Dr Kieran O'Sullivan PhD (Aspetar Orthopaedic and Sports Medicine Hospital, Qatar), Professor Jan Hartvigsen PhD (University of Southern Denmark, Denmark) and Associate Professor Alistair Vickery FRACGP (University of Western Australia).

### **Is there a cost involved?**

- No, there is no cost involved. If you are randomised to a group in which we provide treatment, you will not pay for that treatment and you will not be paid to participate in the research. If you are randomised to a group in which we do not provide treatment, you will be paid some money as a token of appreciation, if you complete the follow-up questionnaires.
- The project is funded by the Australian National Health and Medical Research Council.
- If you were referred to the study by a clinician, they will be compensated for their time.

### **Why am I being asked and what do I have to do?**

- You are being asked to take part because you have the health condition we are interested in studying and helping (persistent low back pain).

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- For each participant, the study will take 12 months overall and your participation will involve the following:
  - Have a phone conversation with a research team member and sign a consent form. We will ask you to also provide permission for us to access your Medicare and Pharmaceutical Benefits Scheme items for the 12 months you are in the study, as that information will allow us to compare costs across the treatments. Providing permission for this access to your Medicare and Pharmaceutical Benefits Scheme information is not essential to your participation in the study.
  - Allow us to speak to your GP if you tell us that your GP has advised you not to exercise. This is so we can be sure the treatment options are appropriate for you.
  - If you are receiving third-party compensation due to your low back pain, allow us to speak to your case manager to clarify whether participating in this project will be appropriate for you.
  - Complete a baseline questionnaire (approx. 20 minutes) online or over the phone.
  - You will then be randomly allocated (like the flip of a coin) to one of three treatment approaches (to usual care or one of two types of individualised rehabilitation). You will have a 33% chance of being allocated to each approach. You will not be able to choose the treatment group you are allocated to. The study is conducted this way to ensure that the information obtained is reliable. Below we provide more detail of what each approach will include.
  - Complete some online or hard copy questionnaires at various times over the 12-month period (more detail below).
- If you are allocated to the usual care group, your treatment options can be any of those offered by the healthcare professionals you would normally choose to see in the community. In other words, you will choose your treatment but it is not determined by the study or funded by it. *The role of being in this group is very important to the study because the outcomes gained by this group set the bar to know whether the new individualised movement rehabilitation treatment is any better or not.* You will be asked to complete two types of questionnaires; a short one (approximately 5 minutes) at weeks 3 and 6 and a longer one (approximately 20mins) at 3, 6, 9 and 12 months. We will email you a \$30 e-Gift card if you fully complete the 3-month questionnaire, another \$30 card for completing the 12-month questionnaire and an additional \$50 card if you completed every follow-up questionnaire (3 and 6 week, 3, 6, 9, 12 month). These e-Gift cards (Prezsee.com.au) can be spent at a wide range of retailers.
- If you are allocated to one of the two individualised movement rehabilitation groups, you will be asked to attend up to 7 sessions (the first being 90 minutes and the remainder 45 to 60 minutes each) with a physiotherapist over a 3-month period and a follow up at 6 months. The treatment will be at a physiotherapy clinic in one of three locations that is most convenient for you, and at times convenient to you. The treatment in both groups is similar but one group will emphasise some elements of the treatment more than the other. Both groups will include:
  - **Education** – the physiotherapist will listen to your story and give you information about pain and all factors that can contribute to it, and help you make sense of it to better manage your problem.
  - **Specific movement training** – the physiotherapist will look at your movements and postures, and train you to adopt a new way of moving that aims to reduce pain.
  - **Lifestyle and physical activity training** – you will be assisted to increase your physical

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- activity levels as part of your management plan.
- **Measurements of movement** – Measures of your movement will be collected at each treatment session using small wearable wireless sensors (slightly smaller than a matchbox and half the thickness). We will also ask you to leave the sensors on your back the remainder of the day after each treatment session, and then post them back to us the following day in a prepaid envelope. Most people say they hardly notice the sensors throughout their day.
  - **Video** – There is a random 1 in 7 chance that you *may* also be asked if it would be OK if three of your treatment sessions were videoed. The purpose of these videos is for two of the research team members to ensure that your physiotherapist is delivering the individualised rehabilitation in the ideal way. The videos will not be used for any other purpose and will be destroyed after that use. If you are not comfortable with participating in this way, you can just decline the invitation and it will not affect your treatment in any way nor your relationship with your physiotherapist or any of the research team.

### How much time is required for participation in the study?

**For participants in the usual care group:** Initial phone call and completion of all questionnaires at all time points = approximately 2 hours. So, the *total time commitment*: approximately **2 hours over 12 months**.

**For those allocated to the two types of individualised rehabilitation:** Initial phone call and completion of all questionnaires at all time points = approximately 3 hours. Physiotherapy treatment sessions = up to 7.5 hours. So, the *total time commitment*: **up to 10.5 hours over 12 months**.

### Are there any benefits to being in the research project?

- If randomised to the usual care group, you will be greatly helping the study by your experience setting the benchmark by which we will know whether the individualised rehabilitation being studied is any better or not. *Without this, our study would not be possible.*
- If randomised to the 2 individualised rehabilitation groups, you will receive physiotherapy treatment from qualified physiotherapists who have taken the extra training required for them to be part of this study.
- We anticipate the results of this research will allow us to:
  - Improve the knowledge we have about this health condition.
  - Inform health care practitioners about better ways of managing people with the same health condition as you.
  - Inform future research in persistent low back pain.
- After your 12-month participation in the study, if you wish to have access to the individualised rehabilitation treatment at your own cost, this can be arranged.

### Are there any risks, discomforts or inconveniences from being in the research project?

- Participation will require some time commitment depending on your group allocation to attend physiotherapy and complete the questionnaires as described above.
- Participants in the individualised rehabilitation groups will undergo a clinical examination and be prescribed movements to do in the clinic and at home. It is possible these may exacerbate your pain, especially in the short term. If you do experience any increase in pain, please bring this to the attention of your treating physiotherapist.
- The movement sensors are applied to your back using hypoallergenic adhesive pads, and while it is rare, this may cause some minor skin irritation.

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- It is possible that completing the questionnaires may cause you some distress, but this is rare. If the questions cause you any concerns or upset you, please stop answering the questions and contact Dr Rob Schutze (0401 809 827) immediately for advice, who is a clinical psychologist on the research team, or your GP.

### Who will have access to my information?

- The information collected in this research will be re-identifiable (coded). This means that we will remove all personally identifying information on all data and replace it with a code. Only the research team will have access to the code to match your name, if it is necessary to do so. Any information we collect will be treated as confidential and used only in this project. The only people who will have access to your information are the research team and the Ethics Committees at Macquarie University and Curtin University.
- *How will information be stored?* Electronic data will be password-protected and hard copy data (including audio tapes) will be kept in locked storage on campus either in the office of Associate Professor Mark Hancock at Macquarie University, Macquarie Park, NSW or in the office of Associate Professor Peter Kent at Curtin University, Bentley, WA.
- *How long will the information be stored and what happens at the end of the storage period?* The information we collect in this study will be consolidated and kept under secure conditions at Curtin University for 25 years after the research has ended and then it will be destroyed.
- You have the right to access, and request correction of, your information in accordance with relevant privacy laws.
- The results of this research may be presented at conferences or published in professional journals but you will not be identified in any results that are published or presented.
- The de-identified data may be made publicly available, as there is a growing call for such information to be available to allow anyone to check the results and for the data to be used in other ethically-approved research projects. You will not be identifiable in that data.

### Will you tell me the results of the research?

- Yes. We will write to you at the end of the research and inform you of the publication of the main results of the research. This is likely to be in 2021.

### Do I have to take part in the research project?

Taking part in a research project is voluntary. It is your choice to take part or not. You do not have to agree to participate if you do not want to. If you decide to take part and then change your mind, that is okay, you can withdraw from the project and it will not affect your relationship with the researchers. You do not have to give us a reason; just tell us that you want to stop. Please let us know you want to stop, so we can make sure you are aware of anything that needs to be done so you can withdraw safely. If you chose to leave the study, we will use any information already collected, unless you tell us not to. If data has already been de-identified it will not be possible to not use it.

### What happens next and who can I contact about the research?

- If you have any questions about the research:
  - in Sydney please contact the trial manager, Associate Prof Mark Hancock on 02 9850 6622 or via email: [mark.hancock@mq.edu.au](mailto:mark.hancock@mq.edu.au) for more information or ask questions.
  - if you are in Perth please contact the trial manager, Dr Rob Schütze on 0401 809 827 or via email: [r.schutze@curtin.edu.au](mailto:r.schutze@curtin.edu.au).

- If you decide to take part in this research we will ask you to provide consent using an on-line (or paper) consent form. By consent, you are telling us that you understand what you have read and what has been discussed. Consenting indicates that you agree to be in the research project and have your health information used as described. Please take your time and ask any questions you have before you decide what to do. You will be given a copy of the consent form to keep.