Curtin University

INTEGRATE clinical trial

PARTICIPANT INFORMATION SHEET

HREC Project Number	HRE2020-0470
Project Title	INTEGRATE - A feasibility trial of stratified Cognitive Functional Therapy for high-risk compensable spinal pain
Principal Investigator	Dr Rob Schütze, PhD
Other Investigators	Peter O'Sullivan PhD, Professor Anne Smith PhD, Associate Professor Peter Kent PhD, Dr Joao Paulo Caneiro PhD (Curtin University), Professor Michele Sterling PhD (University of Queensland), Professor Michael Nicholas PhD (University of Sydney)

What is this project about?

- In this study, we compare two different ways of treating compensable neck or back pain. This is pain associated with a road traffic crash or workplace injury. We want to find out which might be best and what the associated costs of each are.
- Currently, it is uncertain which treatment approach is best for neck and back pain and the benefits of treatment are often short-term.
- New studies suggest that it may be useful to integrate treatment from various health care professionals to address all aspects of a person's pain experience.
- The current project will test this integrated approach compared to usual care in a pilot study of 60 people.
- This project will help inform health care practitioners, funders, and policy makers about better care for individuals with these quite common injuries.

Who is doing the research?

- The project is being conducted by team of experts, including Professor Peter O'Sullivan PhD, Professor Anne Smith PhD, Associate Professor Peter Kent PhD, Dr Joao Paulo Caneiro PhD and Dr Rob Schütze PhD (Curtin University), Professor Michele Sterling (University of Queensland) and Professor Michael Nicholas (University of Sydney).
- The Insurance Commission of Western Australia (ICWA) is funding this research. However, they are not involved in the research design or data analysis. Your decision to participate in this trial or not participate will not prejudice your compensation claim in any way.

Is there a cost involved?

- No, there is no cost involved. If your motor vehicle or workplace injury claim has been accepted by the Insurance Commission of Western Australia (ICWA), then all of your accepted treatment costs will be paid for according to their usual policies.
- The project is funded by the Insurance Commission of Western Australia (ICWA) through a grant administered by the Australian Physiotherapy Association (APA).
- The health professionals involved in your care will be paid by ICWA for their services.

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 that we are interested in studying and helping (neck or back pain related to a road traffic crash or workplace injury).
- For each participant, the study will take 6 months overall and your participation will involve the following:
  - Have a phone conversation with a research team member and sign a consent form online.
  - Complete a baseline questionnaire (approx. 15 minutes) online or over the phone.
  - You will then be randomly allocated (like the flip of a coin) to one of two treatment approaches (to usual care or integrated rehabilitation). You will have a 50% 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 follow-up online questionnaires at 3 months and 6 months.

- If you are allocated to the **usual care group**, your treatment will involve whatever you, your General Practitioner (GP) and any other health professionals decide on, and ICWA agrees to fund. This is the type of treatment pathway currently used for motor vehicle and workplace injury claims and your ICWA claims officer can explain more about this. This is the current best practice care and usually involves seeing whichever health care practitioners your GP thinks are needed to treat your condition. If you are allocated to this usual care group, we will not be involved in your treatment. However, if you score highly on measures of depression or anxiety during the baseline questionnaire, we will contact you and suggest you discuss this with your GP. Aside from your usual care, you will also be asked to complete two more online questionnaire, one at 3 months and one at 6 months.

- If you are allocated to the **integrated rehabilitation group**, you will be asked to attend up to 10 sessions (the first being 60minutes and the remainder up to 30-60 minutes each) with a physiotherapist over a 6-month period. 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. This 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 activity levels as part of your management plan.
  - If you are experiencing significant psychological symptoms (e.g. increased stress, anxiety, trouble with sleep, low mood, problems driving etc.), your physiotherapist may recommend that you also work with a clinical psychologist to tackle these challenges. The psychologist and physiotherapist would work together to make these two aspects of your treatment complementary and align with your goals. The psychological aspect of the treatment might include: education to help you make sense of pain, relaxation training, help with problem solving, developing skills to get you thinking in a helpful way, goal-setting, and specific exercises to deal with any anxiety related to the crash itself. This would involve up to 10 sessions. You would be free to decide whether you engage with this psychological treatment or not.
  - You will continue to see your GP as needed. Your GP will also be contacted by the physiotherapist and psychologist involved in your care so that they can all communicate throughout the trial and integrate their care to align with your goals and needs.
  - If you are already receiving treatment from a physiotherapist and/or psychologist, we may recommend you transfer your care to the trial physiotherapist/psychologist for the duration of the trial because it is generally better to only see one health professional from the same discipline at a time. However, we will discuss this with you, and you will make the final decision.
  - In addition to whatever GP care you need, this integrated rehabilitation approach involves up to 10 sessions of physiotherapy plus up to 10 sessions of clinical psychology support (if recommended and you agree to it). This dose of treatment is what we expect will be sufficient to help you to rehabilitate. If you and your GP believe further physiotherapy/psychology treatment is needed after this, we will seek approval from ICWA to fund more sessions. However, this will follow ICWA's normal approval process and we cannot guarantee that they will agree to further sessions.
- We may also ask you whether you are interested in providing some verbal feedback about your experience of this treatment. This would take the form of an interview that is recorded and transcribed for analysis. If you are approached about this, we will give you another information sheet and consent form to consider before agreeing to participating.

- Video – In the Participant Consent Form, we will ask you whether your clinician can video record some of your treatment sessions. The purpose of these videos is for the research team to give your clinician feedback on their treatment to help optimise the intervention you receive. The videos will only be viewed by the trial researchers and clinicians and will not be used for any other purpose. If you are not comfortable with this, you can just decline the invitation on the consent form, and it will not affect your treatment in any way nor your relationship with your clinicians or any of the research team. You can also verbally decline consent for video at any time by telling your clinician to not record.
- Since there is ongoing uncertainty surrounding the future impact of COVID-19 in Western Australia, there is a chance that face-to-face healthcare appointments may be restricted by the WA government if there are new virus outbreaks. We will follow the directives and recommendations of relevant government authorities to best protect participants and public health. Therefore, if required, we may deliver some appointments for those in the integrated rehabilitation group via telehealth rather than in person. Our health practitioners have experience with this and would guide participants through the process.
- Regardless of which group you are allocated to, with your consent we will request information from ICWA about which treatments you receive in the 6 months you are involved in the trial and how much they cost.

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 1 hour. So, the *total time commitment:* approximately **1 hours over 6 months**.

For those allocated to the integrated rehabilitation group: Initial phone call and completion of all questionnaires at all time points = approximately 1 hour; physiotherapy treatment (up to 10 hours) and psychologist sessions (up to 10 hours). So, the *total time commitment:* **up to 21 hours over 6 months**. This is in addition to time spent seeing your GP and any other health professionals they recommend.

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 integrated rehabilitation being studied is any better or not. *Without this, our study would not be possible.* Since this usual care pathway involves treatment from well-qualified health professionals, you are also likely to experience the benefits of high-quality health care.
- If randomised to integrated rehabilitation groups, you are also likely to experience the benefits of high-quality health care from well qualified clinicians. We do not currently know if this treatment is any better than usual care treatment.
- We anticipate the results of this research will allow us to:
  - Improve the knowledge we have about this health condition.
  - Inform ICWA and health care practitioners about better ways of managing people with the same health condition as you.
  - Inform future research in compensable neck and back pain.
- After your 6-month participation in the study, if you wish to have access to the individualised rehabilitation treatment at your own cost (or paid for by ICWA if your claim is still open and they agree to fund it), this can be arranged. If your claim has been finalised, subsidised access to this treatment may be available through Medicare rebates. This would require a referral from your GP and the research team can explain more about this.

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 +/- psychology sessions 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.
- If you receive psychological treatment for emotional distress associated with the injury, you may experience a short-term exacerbation of symptoms as you start to address the problem. This is likely to be temporary and is part of the rehabilitation process.

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 trial manager will have access to the code to match your name. Once all data is collected, the coding key will be destroyed to make the data anonymous.
- In addition to information you supply in the online questionnaires, information collected by ICWA about the treatments you access and their costs will be shared with the research team and stored confidentially.
- *How will information be stored?* Electronic data will be password-protected and stored on a secure Curtin University server.
- *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 7 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.
- Your stored anonymous data may be used in future ethically-approved research projects. The anonymous 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 2023. We will contact you by email using the details you provide when enrolling in the project. As noted above, your email details will be password-protected and stored on a secure Curtin University server.

Do I have to take part in the research project?

Taking part in a research project is voluntary. It is your choice whether to take part or not. You do not have to agree to participate if you do not want to and it will have no impact on your motor vehicle injury claim with ICWA. 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 or ICWA. 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 please contact the trial manager, Dr Rob Schütze on 9266 3176 or via email: r.schutze@curtin.edu.au.
- If you decide to take part in this research, we will ask you to provide consent using an online 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. We encourage you to discuss this with someone who is able to support you in your decision to participate or not, such as trusted family, friends or health professionals. You will be given a copy of the consent form to keep.

Curtin University Human Research Ethics Committee (HREC) has approved this study (HREC number HRE2020-0470*). 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*

CONSENT FORM

HREC Project Number	HRE2020-0470
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- I have read the Participant Information Sheet and I understand its contents
- I believe I understand the purpose, extent and possible risks of my involvement in this project.
- I voluntarily consent to take part in this research project, and I know I can refuse or withdraw at anytime.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I understand that this project has been approved by Curtin University Human Research Ethics Committee and will be carried out in line with the National Statement on Ethical Conduct in HumanResearch (2007) – updated July 2018.
- I consent to the storage and use of my information in future ethically-approved research projects.
- I consent to the Insurance Commission of Western Australia (ICWA) providing the researchers withmy medical records including information about the treatments I have accessed and their costs during the trial period.
- If I am allocated to the integrated rehabilitation group, I consent to my health providers (GP, physiotherapist, and psychologist) communicating with each other about my care in order tointegrate their treatments.
- I understand that I will receive a copy of this Consent Form and the Participant Information Sheet.
- I do / do not give permission (please tick the preferred answer) for some of my treatment sessions tobe videoed so that the research team can give my physiotherapist and psychologist feedback on theirtreatment. This is to help optimise the intervention. I understand that if I don't want this to occur, I can decline and still participate in the trial regardless of the way I answer this:
  - Yes, I give permission ☐ No, I do not give permission ☐

Participant Name	
Participant Signature	
Date	

Declaration by researcher: I have supplied a Participant Information Sheet and Consent Form to the participant who has signed above, and believe they understand the purpose, extent and possible risksof their involvement in this project.

Researcher Name	
Researcher Signature	
Date	

WITHDRAWAL OF PARTICIPATION FORM

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Declaration by Participant

I wish to withdraw from taking part in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me, or myrelationship with the Insurance Commission of Western Australia.

Participant Name	
Participant Signature	
Date	

In the event that the participant's decision to withdraw is communicated verbally, the Senior Researcher must describe the circumstances.

Declaration by Senior Researcher

I have given a verbal explanation of the implications of withdrawal from the research project, and I believe that the participant has understood that explanation.

Researcher Name	
Researcher Signature	
Date	