PARTICIPANT INFORMATION SHEET– PATIENT

Metro North Hospital and Health Service

Title	The effect of simulating functional tasks during an immersive virtual reality environment on pain and fear of movement in people with chronic non-specific low back pain
Protocol Number	HREC/2021/QRBW/73003
Project Sponsor	RBWH and RBWH Foundation
Principal Investigators	• Dr Peter Window, Research Coordinator, RBWH • Ms Michelle McGrath, Senior Medical Engineer/Research Coordinator, Queensland Motion Analysis Centre, RBWH Dr Esther Smits, Adjunct Fellow, RECOVER Injury Research Centre • Dr Daniel Harvie, Early Career Research Fellow, Griffith University • Dr Esther Smits, Adjunct Fellow, RECOVER Injury Research Centre • Dr Venerina Johnston, Honorary A/Professor, School of Health and Rehabilitation Sciences, The University of Queensland • Professor Trevor Russell, Professor and Director of RECOVER Injury Research Centre, University of Queensland, Surgical Treatment and Rehabilitation Service
Associate Investigators	• Grahame Milne, Specialist Physiotherapist, RBWH • Megan Murdoch, Physiotherapist, RBWH & Tess Cramond Pain and Research Centre, Surgical Treatment and Rehabilitation Service

Introduction: You are invited to take part in this research project evaluating the effect of pain education and Virtual Reality gameplay on people with Chronic Low Back Pain. This Participant Information Sheet and Consent Form will tell you about the research project. It explains what is involved to help you decide if you want to take part in this study. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you do not understand or want to know more about. Before deciding whether to take part, you might want to talk about it with a relative, friend or local health worker.

Participation in this research is completely voluntary. If you do not wish to take part, you do not have to. Your decision on whether to take part in this research project will in no way affect the management of your condition at the Royal Brisbane and Women's Hospital.

If you choose to participate in this study, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project and the intervention that is described
- Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

What is the purpose of this research? The main aim of this research project is to evaluate the effect of pain education with virtual reality gameplay on pain levels and fear of movement in individuals with chronic low back pain. The project is also looking at whether pain education with virtual reality gameplay improves trunk movement during functional tasks, and physical activity levels. Virtual Reality and pain education are already used separately for chronic low back pain treatment. However, there has been no research to assess the effect of these two techniques used together. This project will address this gap.

What does my participation in this research involve? Participation in this study will not affect your normal management through the Royal Brisbane and Women's Hospital. If you choose to participate, a member of the research team will organise a mutually suitable time for you to attend, where you will

be asked to sign the Consent Form (at the end of this document) prior to commencing. There will be no additional costs associated with participating in this research project. The costs of parking OR public transport will be reimbursed if required. Upon the completion of three sessions you will be provided with a gift card to the value of $40 as recognition for participating in the research trial.

Participation in this research project will involve attending three sessions over three weeks (combined total: 3.75 hours) that will take place at the Education and Research Centre, Level 1 Surgical, Treatment and Rehabilitation Services (STARS) Hospital (296 Herston Road, HERSTON QLD 4029).

In the first session (week 0), you will complete two questionnaires: a rating of your pain, and a measure on your beliefs about how safe it is to move your back. A series of small round markers will then be attached to your trunk and legs to measure movement patterns using 3D motion capture during the following movement tasks: i) comfortable back movements (forward bending, backwards, bending, side bending), ii) lowering a 4kg box from shoulder height to knee height, iii) lifting a 4kg box from floor height to knee height; and iv) self-selected aggravating movement (e.g. leaning over a bench). Each task will be repeated three times, will be undertaken at your own pace and will not exceed your limits of comfort. You will then participate in a pain education session delivered by an experienced physiotherapist where you will learn about how pain is produced, gradually increasing activity and strategies to avoid flare up of your pain symptoms. You will be able to ask questions during this session. You will also be provided with an activity tracker (a small, wireless device attached with a waterproof dressing to your thigh) to monitor your physical activity levels for the next seven days. This session is expected to take 1.5 hours.

During the second session (week 1), you will repeat the assessments and movement tasks performed in the first week. You will then be familiarised with the virtual reality system which includes a wearable headset and two hand controllers. Following this you will undergo 20 minutes of virtual reality gameplay (three, five-minute sessions with breaks). Gameplay will involve moving through a virtual arcade and playing three different games: basketball hoops, puck slides, and ten-pin bowling. Whilst you are using the virtual reality you will be filmed for your own feedback, to see how your lumbar spine is moving. 3D motion capture will also record your trunk movement. At the completion of this session, you will be again provided with an activity tracker to monitor your physical activity levels for the next seven days. This session is expected to take 1.5 hours.

The final (third) session will take place the following week (week 2). You will repeat the assessments and movement tasks performed in the first session. This session is expected to take 45 minutes. This will be the final session and the completion of your participation in the project.

Other relevant information about the research project: As your lower back will need to be easily seen during 3D motion capture, suitable clothing is required (including shorts/tights, and a crop top/sports bra for women).

Do I have to take part in the research project? Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any time.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep. Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your current or future healthcare management.

What are the possible benefits of taking part? We cannot guarantee that you will receive any benefits from this research. However, participation in this project will help to determine if virtual reality gameplay and pain education combined is more effective for people with chronic low back pain on pain and fear of movement than usual care, which will inform of its use to the wider healthcare community.

What are the possible risks and disadvantages of taking part? Participation in this study will incur no financial cost to you, nor will it have any effect on your current relationship and management with any Queensland Health services.

As you will be asked to repeat functional movement tasks as a part of the assessment, there is a small risk that your symptoms may increase temporarily. You will be given the opportunity to become familiar with the task and the weight of the box prior to the start of the assessment to ensure you are comfortable and confident with what is required. There will be many opportunities to rest, or to delay further assessment if the symptoms increase beyond your expectations.

As a result of the pain education session, you may feel more confident to increase your current level of activity, which may increase your symptoms momentarily. To make sure you can do this without an excessive increase in your symptoms, you will be provided with education on gradually increasing activity levels at a suitable rate.

Wireless activity trackers (ActivPAL) will be attached to the thigh and worn for seven days to assess daily physical activity levels. There is a slight risk of skin irritation occurring due to the ActivPAL. To reduce this risk, hypoallergenic skin adhesives (e.g. Fixomull) will be used to attach the tracker. If you experience skin irritation, you will be instructed to alternate the tracker to the other thigh. If the irritation persists, the ActivPAL may be removed and activity monitoring will be ceased. It is important then to notify the research team. In Session 1, you will be shown how to attach the ActivPal to your thigh in case the ActivPal comes off due to exercise, sweating, showering, or any other reason whilst you are at home. You will be provided with additional dressings to take home.

Some people who use virtual reality headsets experience simulation sickness, temporary dizziness and nausea. The gameplay sessions are short (five minutes) to lessen the risk of experiencing this sickness, and for the research team to monitor your symptoms. If you do experience these symptoms, you are able to rest as required during the session, between sessions, or you are able to delay further intervention if symptoms persist. The virtual reality headsets will be cleaned between participants.

This study will be performed only when COVID-19 restrictions allow it. COVID recommendations from the Queensland's Chief Health Officer will be practiced at all time.

What if I withdraw from the research project? If you decide to withdraw from the project, please contact the research team directly via the contact details below or complete the withdrawal form. If you do withdraw your consent during the research project, relevant research staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly. You will be given an option at the time of your withdrawal as to whether you wish your data to be retained and used by the research team or removed from the study. Withdrawal from this research project will in no way affect your current management and relationship with any health service in Queensland. **What happens when the research project ends?** Upon completion of the research project, a manuscript will be submitted to a peer-reviewed journal for publication. If you are interested in the final outcome of this study, by contacting a member of the research team, you can be provided with a summary of the results.

What will happen to information about me? By signing the Consent Form, you consent to the collection and use of personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential at all times. All data collected from this study will be stored securely by the research team, for a minimum of 15 years, as per the recommended National Health and Medical Research Council (NHMRC) guidelines. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission.

It is anticipated that the results of this project will be published and/or be presented in a variety of forums, including publications and conference presentations. In any publication and/or presentation, information will be provided in such a way that you cannot be identified. All audio-visual data will be stored by the strictest of confidentiality guidelines, including password-locked files on a secure network, and will be accessible only to members of the research team. Following the completion of this study, all audio-visual files will be permanently destroyed.

Complaints and Compensation: If you have any complaints or suffer any complications as a result of this research project, you should contact the research team as soon as possible, such that appropriate action may be taken. However, if you wish to make an independent complaint, you can contact the Royal Brisbane and Women's Hospital Human Research Ethics Committee (HREC) via the contact details provided below.

Who is organising and funding the research? This research project is being conducted through the collaboration of the RBWH Physiotherapy, the University of Queensland and the Griffith University. Funding for this project has been awarded through the RBWH and RBWH Foundation Research Project Grant Scheme. No member of the research team will receive a personal financial benefit from your involvement in this research team (other than their ordinary wages). There are no conflicts of interest from either the research team members or health services of Queensland.

Who has reviewed the research project? All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of the Royal Brisbane & Women's Hospital.

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.

Further information and who to contact: The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in this project (for example, any side effects), please feel free to contact:

Site	Royal Brisbane and Women's Hospital
Name	Dr Peter Window
Address	Butterfield St, HERSTON QLD 4006
Telephone	(07) 3646 4214
Email	peter.window@health.qld.gov.au

Site	Surgical, Treatment and Rehabilitation Service
Name	Ms Megan Murdoch
Address	Level 3, Surgical, Treatment and Rehabilitation Service, HERSTON QLD 4029
Telephone	(07) 3646 6141
Email	megan.murdoch@health.qld.gov.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC name	Royal Brisbane & Women's Hospital HREC
HREC Position	Co-ordinator
Telephone	(07) 3647 1007
Email	RBWH-Ethics@health.qld.gov.au

CONSENT FORM – PATIENT

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Associate Investigators	• Grahame Milne, Specialist Physiotherapist, RBWH • Megan Murdoch, Physiotherapist, RBWH & Tess Cramond Pain and Research Centre, Surgical Treatment and Rehabilitation Service

Declaration by Participant

1. I have read the Participant Information Sheet or someone has read it to me in a language that I understand.
2. I understand the purposes, procedures and risks of the research described in the project.
3. I give permission for my healthcare professionals and/or hospital to release information to the research team concerning my condition and treatment for the purposes of this project. I understand that such information will remain confidential.
4. I have had an opportunity to ask questions and I am satisfied with the answers I have received.
5. I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.
6. I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print): _____

Signature: _____ Date: _____

Declaration by Senior Researcher

I have given a verbal explanation of the research project; its procedures and risks and I believe that the participant has understood that explanation.

Name of Senior Researcher (please print): _____

Signature: _____ Date: _____