Physiotherapist Attitudes and Experiences of Digital Health Interventions for Treating Sleep Disturbance in People with Chronic Low Back Pain

INTERVIEW/FOCUS GROUP

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Introduction

The following study is designed by researchers at the Woolcock Institute of Medical Research and University of Sydney to explore current attitudes and experiences of physiotherapists towards the use of digital health interventions (DHI) for treating sleep disturbance in people with chronic lower back pain (LBP). Research over the previous decades reveals that people with chronic LBP often experience unsatisfactory sleep which suggests a possible prevalence of undiagnosed conditions of sleep disturbance, such as insomnia. As sleep therapies are costly and can be difficult to access, we are researching the attitudes and experiences of physiotherapists and people with chronic LBP towards DHIs which have the capacity to make sleep therapies more affordable and accessible. Partaking in an interview or focus group will help us to identify the obstacles that would impair clinical integration of DHIs for sleep disturbance.

You have been invited to participate in this study because you are a physiotherapist who has some level of clinical experience treating patients with chronic LBP. This Participant Information Statement (PIS) tells you about the research study. Knowing what this study involves will help you to decide if you want to take part in the research. Please read this PIS carefully and ask questions about anything you don't understand or want to know more about.

Participation in this research is voluntary. If you do not wish to take part, you do not have to and without consequence. If you wish to withdraw from the study before or during the interview/focus group, then you may do so without any prior notice or reason give.

What is the purpose of this research?

The purpose of this research is to explore the attitudes and experiences of physiotherapists towards digital sleep health interventions for people with chronic LBP. SleepFix, a smartphone application, is one such digital intervention that we have developed to treat insomnia. However, this app has not yet been tested or optimised for a population with chronic LBP. This study will help us to assess the readiness and willingness of physiotherapists to integrate DHIs for sleep disturbance with their usual practice.

The study is sponsored by the Woolcock Institute of Medical Research, supported by a grant from the Cooperative Research Centre (CRC) for Alertness Safety and Productivity.

Who can take part in the study?

Physiotherapists currently living in Australia with some level of clinical experience treating people with chronic LBP. Physiotherapists must have completed the online survey related to this study before partaking in an interview or focus group.

What does participation in this research involve?

This study is a semi-structured interview/focus group. If you agree to participate, you are required to read this participant information sheet and give your consent by digitally ticking the "I consent to taking part in the study" checkbox. Participants will then be contacted by study researchers to arrange a date and time will then be arranged with to complete a 30-40-minute interview or focus group via telephone or Zoom. The interview/focus group consists of questions exploring experiences treating patients with chronic low back pain and sleep disturbance, the interaction of low back pain and sleep, familiarity with digital health interventions, and self-perceived readiness and willingness to integrate digital health interventions for sleep in the workplace. The questions are designed to be almost entirely open-ended.

Can I withdraw from the study once I've started?

Participation in this study is entirely voluntary. You do not have to take part in it. Your decision whether to participate will not affect your current or future relationship with the researchers or anyone else at The University of Sydney or Woolcock Institute of Medical Research.

Participants will be informed immediately before commencing the interview/focus group that they have the right to withdraw from the study at any time without prejudice and are not obligated to state their reasons. Information already collected from earlier in the interview or focus group will be retained to ensure that the results of the study can be measured properly and to comply with clinical trial data storage requirements.

What are the side-effects and/or risks associated with this study?

Aside from giving up your time, we do not expect that there will be any risks or costs associated with taking part in this study.

What are the benefits associated with being in the study?

It is hoped that by taking part in this research, you will be providing valuable information which will assist with the development and clinical integration of DHIs which will assist the treatment of sleep disturbance in people with chronic low back pain. Furthermore, it is hoped that the DHIs which may be

developed from findings made through this study will one day become a part of the sleep resources which physiotherapists can provide to applicable patients with chronic LBP and sleep disturbance.

Each participant who completes an interview/focus group will receive an eGift card valued at $50**.**

How do I access the results of the study?

You have the right to receive feedback about the overall results of this study. You can tell us that you wish to receive feedback when asked by your interviewer at the end of interview/focus group. This feedback will be in the form of a summary of the project's findings. You will receive this feedback once the study is complete.

What will happen to the answers I provide?

All information obtained during this study will be made anonymous and your information will be linked to a unique identifier code number, or name, during data handling and at the time of publication. By providing consent, you are agreeing to these conditions and understand that any data published in scientific journals will not identify you.

All study interview/focus group transcripts will be identified by a coded identification number to maintain patient confidentiality. All records that contain names or other personal identifiers, such as locator forms and informed consent forms, will be stored separately from study records identified by code number. The study database will be secured with password-protected access systems. Databases are stored by the Woolcock Institute of Medical Research for 15 years after the completion of the study or as required by the NHMRC.

Contact Information

If you still have questions or require more information after reading this document, please contact James Puterflam (PhD student) at james.puterflam@sydney.edu.au

Ethics approval and complaints

The ethical aspects of this research project have been approved by the University of Sydney Health Research Ethics Committee (HREC) - **insert project number here**. This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007, updated 2018)*. This statement has been developed to protect the interests of people who agree to participate in human research studies. Should you wish to discuss the study or view a copy of the Complaint procedure with someone not directly involved, particularly in relation to matters concerning policies, information or complaints about the conduct of the study or your rights as a participant, you may contact the Ethics Office, University of Sydney, on 02 9036 9161 or email human.ethics@sydney.edu.au

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In giving my consent, I state that:

I have read and understood the **Interview Participant Information Sheet Version 1.1 (September, 2022)** for the above named research study.

- I am aware that there is minimal risk with the procedures involved in this study.
- The researchers have answered any questions that I had about the study, and I am happy with the answers.
- I freely choose to participate in this study and understand that I can withdraw at any time during the interview.
- I am aware that a researcher will contact the email address or mobile number I provided at the end of the survey to arrange a time and date for the interview or focus group
- I understand that the interview/focus is strictly confidential, and my answers will be made anonymous at the time of interview transcription and publication.