

***Experiences and Attitudes of People with Chronic Low Back Pain Towards
Digital Sleep Health Interventions***

INTERVIEW

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 people with chronic low back pain towards the use of digital health interventions. Research over the previous decades reveals that people with chronic low back pain often experience unsatisfactory sleep which possibly suggests 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 people with chronic low back pain towards the use of digital health interventions.

You have been invited to participate in this study because you have told us that you currently have chronic low back pain. 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 decide you want to take part in the research study and continue to the survey, it is assumed you consent to the details in this document.

What is the purpose of this research?

We are interested in learning about your experiences of chronic low back pain and how you managed it. We are also interested in whether you have used or would be willing to use a digital health intervention. A digital health intervention are health services delivered electronically through formal or informal care. We are also interested in understanding the interaction between low back pain and sleep and what your attitudes are towards using digital health for managing sleep problems.

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?

People who are 18 years of age or older experiencing chronic low back pain which has been occurring for a duration of three months or more. Participants must have completed the online survey related to this study before partaking in an interview.

What does participation in this research involve?

This study is a semi-structured interview. 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 to complete a 20-30-minute interview via telephone or Zoom. The interview consists of questions exploring the experience of living with chronic low back pain and sleep disturbance, the interaction of low back pain and sleep, experiences and attitudes towards digital health interventions, and opinions regarding how pain and sleep could be addressed through a shared model. 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 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 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 regarding your experiences of chronic low back pain, digital health use and sleep. This information will be important for the future development and integration of digital health interventions for sleep which we hope will improve the sleep resources accessible to people with chronic low back pain.

Each participant who completes an interview 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 by providing your contact details at the end of the survey. 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 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 or on +61 414 818 290

Ethics approval and complaints

The ethical aspects of this research project have been approved by the University of Sydney Health Research Ethics Committee (HREC). 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 90369161 or email human.ethics@sydney.edu.au

In giving my consent, I state that:

I have read and understood the **Participant Information Sheet for Interview of People with Chronic Low Back Pain Version 1.0 (December, 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 is strictly confidential, and my answers will be made anonymous at the time of interview transcription and publication.

By ticking this box, I hereby agree to participate in all aspects of this research study.

☐ I consent to taking part in the study.

{CONSENT BUTTON IN LIEU OF:

NAME:

SIGNATURE:

DATE: