



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

ONLINE SURVEY

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Introduction

The following study is designed 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.

<u>Participation in this research is voluntary.</u> 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 have previously 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 serves 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.

What does participation in this research involve?

This study is entirely online and anonymous. If you agree to participate you will provide your consent by digitally ticking the "I consent to taking part in the study" checkbox. This will allow you to progress to the online survey (~10 minutes). The survey consists of 24 questions about your experiences regarding the care you have previously received for your low back pain, sleep, and your attitudes and willingness towards digital health intervention for treating sleep disturbance. The questions will be a mix of multi-part questions, rating scales, yes-no and 'select all that apply' questions as well as some open-ended questions.

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.

Submitting your completed questionnaire is an indication of your consent to participate in the study. You can withdraw your responses any time before you have submitted the questionnaire. Once you have submitted it, your responses cannot be withdrawn because they are anonymous and therefore, we will not be able to tell which data is yours.

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.

We are offering participants who complete the survey, the opportunity to take part in a prize draw for 1 of 2 eGift Cards worth \$200. If you wish to take part in the prize draw, you will be required to provide a mobile number and email address following completion of the survey (on the last page). Your mobile number will then go into a draw with the other participants who complete the survey. When the survey completion time closes, a random draw of provided mobile numbers will be undertaken by a researcher





who is not involved in the study. The successful participant will be notified by a telephone call to the mobile number. Please note, participation in the prize draw is voluntary. The contact details provided as part of the prize draw will not be linked to answers collected from the survey which means your answers will remain unidentifiable from the contact details you provide.

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 data I enter?

All information obtained during this study is anonymous as we collect no personal identification. Contact details provided for purpose of the prize draw will not be linked to the information provided in the survey. By providing consent, you are agreeing to these conditions and understand that any data published in scientific journals will not identify you.

All questionnaire and survey data will be captured on an encrypted web-based database connected through the backend of the public-facing study website (www.backpainsleep.com.au) via a securely encrypted link. The database is stored securely using password protection that only authorised research members have access to.

Any contact details you enter for either the prize draw, or to receive study outcome information will be collated in a separate file on the database that will not be attached to your survey responses. These files will be permanently deleted once their purpose has been fulfilled.

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). 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 **Online Survey Participant Information Sheet for People with Chronic Low Back Pain Version 1.0 (July, 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 up until I submit the completed survey.
- I understand that the research survey is strictly confidential, and my answers are anonymous.