Mobile App-delivered Sleep Therapy (SleepFix) for Individuals with Chronic Low Back Pain and Insomnia: a Randomized Controlled Trial with Internal Pilot Study

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Introduction

This study is designed to see if a digital behavioural therapy for insomnia (dBTi) reduces pain-related interferences in people with chronic low back pain (LBP) and insomnia. A current survey we have conducted of people with chronic LBP found that 90% of this population report some kind of sleep problem. In some people it is clear that pain drives poor sleep whilst in others, poor sleep persists in the absence of pain suggesting the possibility of insomnia. Despite the close relationship between chronic LBP and insomnia, many people do not receive effective treatment for their sleep. There are a few challenges to addressing insomnia, in people with chronic LBP: 1) patients and healthcare providers may be unaware of the relationship between insomnia and back pain; 2) an overreliance on interventions for pain-associated insomnia, like painkillers or hypnotic medications, which may address symptoms but not the underlying cause; and 3) the usual means of delivering sleep therapies are expensive and may be difficult to access.

Our research team has developed a smartphone app, *SleepFix*[@], which is effective for reducing the severity of insomnia symptoms in an insomnia population. *SleepFix*[@] delivers Sleep Retraining Therapy (SRT) which reduces the proportion of time spent in bed awake, and increase the proportion of time in bed asleep. How effective it is in a population with chronic low back pain and insomnia is unknown. We are interested to know how people with chronic LBP and insomnia experience SRT delivered through *SleepFix*[@] and whether it improves their health condition.

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.

Medications, drugs and devices have to be approved for use by the Australian Federal Government. *SleepFix*[@] has not yet been approved in Australia. This study will be conducted under the Therapeutic Goods Administration (TGA) Clinical Trials Notification (CTN) Scheme. This allows the investigators to use this product for medical research purposes once the research has been assessed and approved by an authorised Human Research Ethics Committee (HREC).

This Participant Information Statement (PIS) informs you about this 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 wish to learn 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, you will be required to complete a telephone interview and some baseline questionnaires. In the telephone interview, the outline of the study and key requirements for participation will be explained to you and you will have the opportunity to ask anything that you are unsure about.

What is the purpose of this research?

We are interested in determining whether SRT delivered via *SleepFix@* can be used to improve the interference-related pain in a population of people with chronic LBP and insomnia. We are also interested to learn how insomnia symptoms, sleep quality, pain-related beliefs about sleep and quality of life are affected by *SleepFix@* use. We are also interested in exploring the user experience of *SleepFix@* and any changes that result from using *SleepFix@*.

Who can take part in the study?

- People between 18 and 80 years of age.
- Currently experiencing chronic LBP (Lower back pain occurring for three months or more).
- Insomnia symptoms (a score of more than 10 on the insomnia severity index, ISI)
- Access to a smartphone
- English fluency

What does participation in this research involve?

If you would like to participate then you must complete a pre-screening survey (already complete if you are reading this), telephone interview and baseline questionnaire. After reading this Patient Information Statement and signing you consent (ticking the 'I consent' option) a member from the research team will contact you to arrange time for a telephone interview. Following the interview, you will receive a link to complete your baseline questionnaires (~10 minutes to complete). The questionnaires capture information related to demographics; insomnia; sleep quality; beliefs about sleep; depression; anxiety; quality of life; and digital literacy. 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.

Once the baseline questionnaire is complete you will be randomized to one of two study groups – treatment or control. If you are randomized to the treatment group then you will receive the *SleepFix@* App. *SleepFix@* provides a personally-tailored sleep program which takes 3 weeks to complete however, the App may be used longer if desired. If you are randomized to the control group, then you

will receive three sleep health education modules weekly during the 3-week treatment period. After 6 weeks, all participants will be required to complete an end-of-study questionnaire. If you were in the control group, then you will receive access to *SleepFix*[@] once you have completed your end-of-study questionnaire. If you were in the treatment group then you will be invited to complete a 10-minute exit interview at the end of the study. This interview is to learn about your experiences using *SleepFix*[@] and whether it has led to any changes in behaviours related to sleep and pain management.

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 baseline questionnaire and verbal agreement following your telephone screening will constitute your consent to participate in this study. You have the right to withdraw from the study at any time without prejudice and are not obliged to state your reason. The investigators will attempt to follow-up any withdrawals and encourage you to complete a *withdrawal of consent* form online and no further information will be collected from the date the withdrawal of consent form is completed. Personal information already collected will be retained to ensure that the results of the study can be measured properly and to comply with clinical trial data storage requirements.

If you fail to complete *end-of-study questionnaire* or discontinue for personal reasons, attempts will be made to determine whether the reason for dropping out was due to an adverse event. If you have any clinically significant abnormalities which requires your discontinuation from the study, you will be monitored until recovery from the abnormality, if possible. The Coordinating Principal Investigator also may withdraw you from the study if you are unwilling or unable to comply with required study procedures. you may also be withdrawn if the study sponsor or government or regulatory authorities terminate the study prior to its planned end date. All enrolled participants will be contacted accordingly.

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

The questionnaires related to this study are considered to involve minimal psychological risks. Crisis support (Lifeline) and emergency service contacts will be listed on participant ineligibility pages alongside recommendations to contact their GP.

This is a real-world application of an intervention. You will self-report any adverse events via email or telephone to the research team. An adverse event in this trial will be defined as any untoward medical occurrence in a participant without regard to the possibility of a causal relationship. The study website and *SleepFix*[@] App will include information about common symptoms experienced during the therapy.

We have added a cautionary note regarding the driving or operating of heavy machinery if you are feeling sleepy.

You will be provided contact details for reporting of adverse events about these common symptoms as well as any event that may occur during the therapy. At weeks 3 and 6 you will be sent a link to an online questionnaire to report any adverse events to date. Research staff will respond to all reports of adverse events and action accordingly. Additionally, if you who wish to receive a teleconsult at follow-up, you will be asked questions about any adverse events. All adverse events will be collected after you have provided consent and enrolled in the study. If you experience an adverse event after electronic informed consent has been obtained (entry) but you have not yet received the study intervention, the event will be reported as not related to SRT.

All adverse events occurring after entry into the study or until hospital discharge will be recorded by research staff. An adverse event that meets the criteria for a serious adverse event (SAE) between study enrolment and study discharge will be reported to the Woolcock Institute of Medical Research. Adverse events reported spontaneously will be recorded with a medical evaluation of severity and causality and coded using the Medical Dictionary for Regulatory Activities (MEDDRA). Preferred Terms will be reported.

What are the benefits associated with being in the study?

By partaking in this study there are numerous benefits that are possible for yourself and for all people with chronic LBP and insomnia:

- Your insomnia symptoms may be decreased and sleep quality improved.
- Your underlying causes of insomnia (psychological and/or behavioural) may be identified and addressed.
- Your daily pain-related interference and severity of LBP may be reduced.
- You will be part of pioneering research, a first of its kind, for the sleep-pain field which examines the effectiveness of a digitally delivered behavioural therapy for insomnia in a chronic LBP population.
- Your participation will help researchers to further understand the associations and relationship of chronic LBP and insomnia.

How do I access the results of the study?

You will receive an email at the end of the study containing a summary of the research findings.

What will happen to the data I enter?

All information obtained during this study is anonymous as we collect no personal identification. The personal and contact details that you provide will be used solely for the purpose of communication and delivering study materials, weblinks and reminders. By providing consent, you are agreeing to these conditions and understand that any data published in scientific journals will not identify you.

App data storage

All identifiable app data collected during the *SleepFix*[@] program are transferred to the online web server using 256-bit SSL (secure socket layer) encryption, the highest level of encryption widely implemented in web browsers. All app data will be stored on a database separate to the questionnaire data. These separate databases will only be linked using the access code provided to participants after consent. This will ensure that identifiable data in the app will not be linked to the database that contains the questionnaire research data. All app data will be anonymised and reported with a numeric ID. The document that links the study participant ID and access code is only accessible by the research team.

Questionnaire data storage

All data will be captured on a web-based platform connected through to the backend to the public facing study website (https://sfixbackpain.au). Data will be de-identified and stored securely on a password protected, web-based platform on a secure server. The web-based platform is developed and maintained by the Wappsystem Pty Ltd. The secure server is located at Amazon Web Services in Sydney, NSW. (https://docs.aws.amazon.com/whitepapers/latest/aws-overview/security-and-compliance.html).

Complaints and compensation

If you suffer any injuries or complications as result of this study, please contact the research team as soon as possible who will assist you in arranging appropriate next steps. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital. In addition, you may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is sufficiently serious and is caused by unsafe drugs or equipment, or by the negligence of one of the parties involved in the study (for example, the researcher, the hospital, or the treating doctor). You do not give up any legal rights to compensation by participating in this study.

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 if urgent – 0414 818 290.

Ethics approval and complaints

The ethical aspects of this research project have been approved by the Sydney Local Health District (SLHD). 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 Research Ethics and Governance Office on 02 9515 6766 or email SLHD-RPAEthics@health.nsw.gov.au, and quote protocol number X23-0145.

A copy of this patient information statement can be downloadable or saved and kept on your PC or mobile device.

In giving my consent, I state that:

I have read and understood the **PIS and CF for SleepFix LBP, Version 2.0. June, 2023** 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 however in doing so, I will be followed up to complete a study withdrawal form.
- I understand that the research survey is strictly confidential, and my answers are anonymous.

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

☐ I consent to be contacted to take part in the study.

{CONSENT BUTTON IN LIEU OF:

NAME: .....

MOBILE PHONE NO.: .....

EMAIL ADRESS: .....

SIGNATURE: .....

DATE: .....