Research study: The feasibility of a mobile application (SleepFix) delivering behavioural therapy for Insomnia in primary care

PARTICIPANT INFORMATION SHEET

You are invited to take part in a research study for people with insomnia. In this study, we aim to treat your insomnia using a novel mobile application called SleepFix. The app program uses an evidence-based therapy called sleep retraining therapy which improves your sleep. The therapy works by reducing the time spent in bed awake and improving the total amount of time asleep. We are testing whether this app-based insomnia therapy is feasible in primary care by assessing how many individuals with insomnia download and use the app after being prescribed by their health professional.

Everyone who participates in this study will be given free access to the SleepFix therapy app on their smartphone. You will use the program for 3 weeks and have another 3 weeks access to the app if you feel that you want to engage in the therapy for longer. We will also provide you with a Fitbit to track your sleep. We will ask you to complete a series of online questionnaires at the start of the study and after 6 weeks.

This study is being funded by the Department of Health (Federal), Sydney Health Partners Medical Research Future Fund. This study is sponsored by the Woolcock Institute of Medical Research. The SleepFix app is supplied by Alertness CRC who do not have financial interests in this study.

Why have I been invited to participate in this study?

This study may be suitable for you because you have been diagnosed with insomnia by your GP or registered health practitioner. To treat your insomnia, your health professional will provide you with an invitation letter (like a prescription) for the SleepFix app which has been designed to improve your sleep. We are assessing whether individuals who have insomnia and visit their primary healthcare provider will use the app after being prescribed by the health professional.

What are the aims of this study?

The study aims to determine if a therapy delivered using an app would be suitable to use in primary care.

Do I have to participate?

No, it is entirely up to you whether you wish to participate in the study. If you do take part, you may withdraw at any time without having to give a reason. It is best to discuss the study with friends or family prior to consent. If you decide to terminate your participation in this study, please notify the SleepFix Research Team on 02 9114 0481 (Telephone) or at SleepFix@Woolcock.org.au (Email).

What does this study involve?

This study will be delivered completely online, there are no face-to-face visits required. You have been given access to this website following your appointment with your health professional who has prescribed for you the SleepFix mobile application.

Please read the information below to better understand what the study involves.

i. Providing consent and completing questionnaires

If you agree to participate, you will be asked to provide consent electronically (next page) and complete your first set of questionnaires (which will take approx. 15 minutes). You will also be contacted by the research team to organise the delivery of a Fitbit device to track your sleep. If you already have a Fitbit device that measures sleep, please let the research team know.

ii. Getting started

Once you have completed your questionnaires, you will be assigned a unique access code which will be used at registration once you downloaded the app. Before commencing therapy, we will ask you to watch a number of short instructional videos about SleepFix, how the treatment works and how to use the app. Following this, you will be provided with the instructions of how to download the SleepFix app.

iii. Using SleepFix

Once you have installed SleepFix on your phone, you will need to set up the program. You will need to register an account and enter your SleepFix access code to proceed. This involves a short series of questions about your current sleep pattern and what you think you can achieve during the therapy. You will be asked to use the app for 3 weeks, with a further 3 weeks of optional usage. However, it is up to you how much you use the app on a daily basis. It will only take approximately 2 minutes each day to complete the sleep diary entries in the SleepFix app, needed to check your progress. We will ask you to wear the Fitbit wristband for 3 weeks. You can continue using SleepFix following the 3 weeks of the treatment.

iv. Completing questionnaire at end of the study

You will be reminded to complete your week 6 questionnaire via email and/or text. We will ask you to complete these online at week 6 (approx. 20 minutes).

v. Participating in an interview (following week 6)

You will be invited to participate in a short one-on-one interview over the phone following completion of the study (approx. 10 minutes). You will be asked about your experience with the study and the mobile application.

Activities	Screening	Weeks	
		BL	6
Online screen for eligibility	X		
Baseline demographics questionnaire		X	
Insomnia Severity Index (ISI)		X	**X**
Sleep Difficulty Score		X	**X**
Sleep Quality		X	X
Pittsburgh Sleep Quality Index		X	X
Patient Health Questionnaire (PHQ-9)		X	X
Generalised Anxiety Disorder Questionnaire (GAD-7)		X	X
Flinders Fatigue Scale (FFS)		X	X
Epworth Sleepiness Scale (ESS)		X	X
Treatment Acceptability Questionnaire (TAQ)			X
Internet Evaluation and Utility Questionnaire (IEUQ)			X

How much time will the study take?
The total time you will be enrolled in this study from start until completion will be up to 6 weeks.

How many other participants are there in the study?

It is anticipated that 110 participants will be enrolled into this study.

What are my responsibilities as a participant in this study?

If you decide to participate in this research study, you will be expected to follow the guidelines contained on this page. We will also require you to report any adverse events via email or telephone to the research team. If there are problems with you continuing in the study, please contact the research team on 02 9114 0481 (Telephone) or at SleepFix@Woolcock.org.au (Email).

Are there any side-effects and/or risks associated with this study?

We do not anticipate any risks in taking part in this study. However, it is advised that you do not drive or operate machinery unless you feel sufficiently alert to do so safely during the therapy. You may experience some increased fatigue and sleepiness during the commencement of therapy. This has been reported previously but improves after two weeks and further improves following completion of the therapy.

Contact the SleepFix research team if you would like more information.

Compensation for injuries or complications

If you suffer any injuries or complications as a result of this study please contact the research team as soon as possible who will then assist you in arranging appropriate medical treatment. In addition, you

may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study.

If you suffer any injuries or complications as a result of this study, you should contact the study doctor as soon as possible, who will assist you in arranging appropriate medical treatment. 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 the event of loss or injury, the parties involved in this study agree to be bound by the Medicines Australia Guidelines for Compensation for Injury Resulting from Participation in an Industry-Sponsored Clinical Trial. A copy of these guidelines is available from the Executive Officer of the Ethics Review Committee or electronically at https://medicinesaustralia.com.au/policy/clinical-trials/indemity-and-compensation-guidelines/.

It is the recommendation of the independent ethics committee responsible for the review of this study/investigation that you seek independent legal advice.

Benefits

The direct benefit of participating in this study is the potential improvement in your sleep and insomnia symptoms. You will also be providing valuable information regarding the use of a smartphone application to help with sleep loss in insomnia.

Study costs and compensation

Participation in this study will not cost you anything. You will receive a free Fitbit device that measures sleep. This is yours to keep and you do not have to return it at the end of the study. Primary healthcare providers will be reimbursed for their role in prescribing the app.

Could my study participation be terminated?

If you experience any physical or mental health issues, you may withdraw from the study or if we are concerned about you, your participation may be terminated.

What will happen if I don't want to take part anymore?

You may decide to discontinue your participation at any time. Your decision to stop participating in the study will not affect your current or future medical care, or any benefits to which you may otherwise be entitled. Any study data that are collected before you discontinue from the study will be used in the analysis of the study results.

What will happen to information about me?

By indicating your consent on the next page, you will agree to the SleepFix research team collecting and using personal information for the research study. Any information obtained in connection with this research study is confidential. Data from both the app and the online questionnaires will be collected.

Data will be stored on two platforms, one for the questionnaire data and another for the app-based data. Re-identifiable data on the app will be stored on a separate server to data that contains individually identifiable data from the questionnaire.

The re-identifiable app data will be stored on a database located on Amazon Web Services in Sydney, NSW, Australia (Amazon Web Servers have 2 physical locations in Sydney).

The identifiable questionnaire data will be stored on a cloud-based platform developed and maintained by the Woolcock Institute of Medical Research (Research Tools TM). Data from individuals who have completed the initial screening questionnaires but were ineligible will be deleted.

Following completion of data collection, the non-identifiable data will be moved to the University of Sydney (NSW) Research data storage. The data will be analysed at the Woolcock Institute, Sydney, NSW. Data will not be used for future research purposes.

All data collected will be anonymised using a code number when you consent to participate in the study. The key linking your identity to your participant code will be stored electronically on a password-protected database on a secure server. This ensures your data will remain anonymous. Your data will only be used for the purposes of this study and will not be shared with anyone outside the research team. Access to your data will only be granted to the research personnel and data will be held for a minimum of 15 years, as per policy.

How will the results of the study be shared?

The results will be published in academic journals and presented at conferences. Any data published in scientific journals will not be able to identify you.

Who is running and funding the study?

The study is being conducted within this institution by the following researchers:

Principal Investigators:
Associate Professor Christopher Gordon (Sleep Scientist)
Professor Ron Grunstein (Sleep Medicine Specialist)
Associate Professor Delwyn Bartlett (Psychologist)
Professor Nick Glozier (Psychiatrist)
Associate Professor Keith Wong (Sleep Medical Specialist)

Further Information

You can contact the study coordinator using the contact details below:

- 02 9114 0481
- Woolcock.Sleepfix@sydney.edu.au

The study Psychiatrist Investigator is Professor Nicholas Glozier who is available to answer any inquiries or discuss concerns about the study procedures or the therapy described. Please feel free to contact him on (02) 9515 1596 (Telephone) or at nick.glozier@sydney.edu.au (Email).

The study Psychologist Investigator is Associate Professor Delwyn Bartlett who is available to answer any inquiries or discuss concerns about the study procedures or the therapy described. Please feel free to contact her on (02) 9114 0460 (Telephone) or at delwyn.bartlett@sydney.edu.au (Email).

Ethics Approval and Complaints

The Sydney Local Health District Research Ethics Committee has reviewed and approved this study in accordance with the National Statement on Ethical Conduct in Human Research (2007) incorporating all updates. 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 Executive Officer on 02 9515 6766 and quote protocol number *X19-0418*.

The conduct of this study has been authorised by the Woolcock Institute of Medical Research, any person with concerns or complaints about the conduct of this study may also contact the Research Governance Officer on (02) 9114 0412, email: grigori.kaplan@sydney.edu.au and quote project number *X19-0418.*