Research study: Sleep Consolidation Therapy for Insomnia Study

INFORMATION FOR PARTICIPANTS

You are invited to take part in a research study for people with insomnia. In this study, we aim to treat people with insomnia through sleep consolidation therapy delivered via SleepFix, a smartphone application. The study aims to improve sleep and wellbeing and will help inform the further development of the smartphone application.

Everyone who participants in this study will be given access to SleepFix on their smartphone. You will use the program for 3 weeks, with or without a Fitbit (depending on which group you are assigned) and have another 3 weeks access to the app if you feel that you want to engage in the therapy for longer. We will ask you to complete online questionnaires at start of the study, weekly (for 3 weeks), after 6 weeks and 12 weeks.

Why have I been invited to participate in this study?

This study may be suitable for you because you have insomnia which could benefit from this intervention. The SleepFix app has been designed to personalise the sleep therapy for individuals to improve sleep using sleep consolidation therapy.

What are the aims of this study?

We would like to find out if SleepFix improves sleep, daytime functioning and mood. Sleep consolidation therapy is a clinically-proven therapy for insomnia. The SleepFix app allows people to engage with the therapy without the need for a Sleep Psychologist. SleepFix will ask participants to limit their time in bed to how much sleep time they are currently achieving. You will be prescribed a new bedtime and rising time for the duration of the treatment component (3 weeks).

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 Woolcock.sleepfix@sydney.edu.au (Email).

What does this study involve?

This study will be delivered completely online, there are no face-to-face visits required. 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 approximately 20 minutes). You will also be

randomly selected to receive a Fitbit wearable device to track your sleep. If you already have a Fitbit device you will need to tell us and you can use it during the study.

ii. Getting started

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. 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 5 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 (only if selected to randomly receive the device). You can continue using SleepFix following the 3 weeks of the treatment.

iv. Completing questionnaires during the study

Throughout the study, you will be reminded to complete weekly online questionnaires. The questionnaires will ask about your sleep, daytime functioning, mood and your experience with SleepFix. We will ask you to complete these online at the following timepoints:

- Each week for the first 3 weeks (5 minutes each time)
- At week 6 (20 minutes)
- Final questionnaires at week 12 (20 minutes)

Activities	Screen	Weeks					
		BL	1	2	3	6	12
Online screen for eligibility	X						
Randomisation (Fitbit devices)	X						
General Self-Efficacy Scale		X					
Autonomy and competence in Technology Adoption		X					
Insomnia Severity Index (ISI)		X	X	X	X	X	X
Sleep Quality		X	X	X	X	X	X
Depression (PHQ-9)		X				X	X
Anxiety (GAD-7)		X				X	X
Fatigue		X	X	X	X	X	X
Epworth Sleepiness Scale		X				X	X
Health and Work Performance Questionnaire (HPQ)		X				X	X
Mini Technology-based Experience of Need Satisfaction (TENS) -task and -interface			X	X	X		
Basic Psychological Needs Scale		X					X
SleepFix therapy delivery			X	X	X	X	
Adherence (sleep diary)			X	X	X	X	X
Adherence (Fitbit wristband *if included*)			X	X	X	X	X

Legend: X – optional use of SleepFix therapy.

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 13 weeks.

How many other participants are there in the study?

It is anticipated that 120 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 Woolcock.Sleepfix@sydney.edu.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 therapy. This has been reported previously but improves after 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.

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. You will also be providing valuable information regarding the use of a smartphone application to help with sleep loss and daytime dysfunction in insomnia. If you are provided with a Fitbit wristband to monitor your sleep as part of therapy you do not need to return the device at the end of the study.

Study costs and compensation

Participation in this study will not cost you anything.

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 re-identifiable and confidential. Data from individuals who have completed the initial screening questionnaires but were ineligible will be deleted.

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. 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. As this study is part of the Cooperative Research Centre for Alertness, Safety and Productivity, re-identifiable data (i.e. study results from which identifiers have been removed and replaced by a code, but it remains possible to re-identify a specific individual) may be shared with research collaborators of the Cooperative Research Centre for Alertness, Safety and Productivity (www.alertnesscrc.com). Data will not be shared without permission of Principal Investigators of the current project. All data available for sharing will be stored on a web-based database located in Australia. Re-identifiable data may be retained indefinitely by the Cooperative Research Centre for Alertness, Safety and Productivity. Your data may also be made available to a third party in the future other than the Cooperative Research Centre for Alertness, Safety and Productivity, in which case further ethical approval would be sought from both yourself and the Ethics Review Committee.

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:

<u>Principal Investigators:</u>
Professor Ron Grunstein (Medical)
Associate Professor Christopher Gordon
Associate Professor Nathaniel Marshall
Associate Professor Delwyn Bartlett (Psychological)
Professor Rafael Calvo
Professor Nick Glozier (Psychiatrist)
Ms Melissa Aji (PhD Candidate)

This project is funded by the Cooperative Research Centre (CRC) for Alertness, Safety and Productivity. This is an Australian Government Initiative that brings together industry, government, and university sectors in a coordinated program. The major aim of the CRC is to reduce the burden of impaired alertness on the safety, productivity and health of Australians. The Alertness CRC will develop and deploy the next generation of shift scheduling and workplace design techniques; alertness assessment devices; individualised programs for better sleep health; and, a range of innovative strategies to

reduce fatigue. As the study sponsor, the Woolcock Institute of Medical Research will provide non-financial support as it will not charge the study for this service.

Further Information

You can contact the research team 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 Bellberry Human Research Ethics Committees 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 Operations Manager, Bellberry Limited on 08 8361 3222.

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: jelliot@woolcock.org.au and quote project number 2018-06-419.