Digital Sleep Therapy for Older Adults with Cognitive Impairment (ExCEED Study)

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Introduction

You are invited to take part in a research study for people with insomnia symptoms who report subjective cognitive impairment. In this study, we aim to treat your insomnia using a mobile phone application called SleepFix which has been developed by researchers from the Woolcock Institute of Medical Research and The University of Sydney who will be conducting this study. The purpose of this study is to assess the efficacy of SleepFix mobile phone application in reducing insomnia symptoms in older adults with cognitive impairment from the community aged 60 years or over. SleepFix delivers digital Brief Behavioural Therapy for insomnia (dBBTi) by reducing excess time spent in bed. dBBTi is a component of the gold standard Cognitive Behavioural Therapy for insomnia that is typically administered to treat insomnia in a clinical context. Everyone who participates in this study will be given access to the SleepFix therapy mobile phone application to download onto their smartphone, either during the course of the study or afterwards, depending on the randomised group to which you are allocated.

You have been invited to participate in this study because you have reported both insomnia symptoms and subjective cognitive impairment. This Participant Information Statement (PIS) tells you about the research study. The information provided in this PIS will help you decide if you want to take part in the research. Please read this carefully and ask questions about anything that 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.

The study is sponsored by the Woolcock Institute of Medical Research, supported by a grant from The National Health and Medical Research Council (NHMRC) Centre of Excellence Seed Funding and Brain and Mind Centre (BMC) Development Grant, University of Sydney.

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).

What is the purpose of this research?

The aim of this study is to determine the efficacy of digital Brief Behavioural Therapy for Insomnia (dBBTi) compared to digital sleep health education (Control group) at reducing insomnia symptom severity (Insomnia Severity Index: ISI) in older adults (60+ years) with subjective cognitive impairment from baseline compared to week 8.

The study also aims to evaluate changes in subjective and objective cognition in the therapy and control groups as well as assessing sleep wake metrics, subjective sleep quality, fatigue, sleepiness, anxiety, depressive symptoms and quality of life in both Therapy and Control group.

In addition, the relationship between therapeutic outcomes (change in ISI) and cognitive performance and whether there is a relationship between therapy adherence and therapeutic outcome based on sleep diary will be examined.

Who can take part in the study?

You can complete the survey if you are aged 60 years and over and report insomnia symptoms, poor sleep and subjective cognitive impairment. There are no costs to you during the study.

What does participation in this research involve?

This study will be conducted entirely remotely through a secure online platform, the SleepFix mobile phone application and telephone calls; there are no face-to-face visits required.

After the confirmation of your eligibility, you will be supplied with this Participant Information Sheet and Consent Form. Consent will be obtained digitally using text input fields and filling out your first and last name, email address and mobile number for a member of the research team to contact you during the study. Next, you will be asked to complete a series of baseline questionnaires, which will take approximately 20-25 minutes. Throughout the study you will be asked to repeat these questionnaires as per the study schedule (see Table 1 below):

Study Activity	Baseline (Wk 0)	Wk 3	Wk 8	Wk 16
Demographics	x			
Self-reported Subjective Cognitive impairment	x			
eHealth Literacy Scale	x			
Insomnia Severity Index	x		x	x
British Columbia Cognitive Complaints Inventory	x		x	x
Objective cognition	x		x	x
Generalised Anxiety Disorder	x		x	x
The Geriatric Depression Scale (GDS)				
Flinders Fatigue Scale	x		x	x
Euro Quality of Life – 5 dimensional	x		x	x
Epworth Sleepiness Scale	x		x	x
Pittsburgh Sleep Quality Index	x			
Adverse Events Check-in		x	x	

Randomisation

You will be randomised either to the Treatment group, who have immediate access to the SleepFix mobile phone application or the Control group who will have access to an online Sleep Health Education Package for the duration of the study and will receive access to the SleepFix mobile phone application upon completion of the study.

Control Group:

The Control group will receive free access to an online Sleep Health Education Package containing 3 modules about the importance of sleep, how poor sleep occurs as well as information to help improve sleep hygiene. These will be distributed bi-weekly but once available, access to modules will be unlimited to control participants. Upon completion of the final follow-up questionnaires (16 weeks) you will be invited to trial the SleepFix mobile phone application free of charge.

Treatment Group*:*

The Treatment group participants will be given continuous access to the SleepFix app. After the initial recruitment and randomisation, participants will learn about SleepFix, how the treatment works and how to use the mobile phone application. Instructions to download the SleepFix mobile phone application as well as a unique access code will be used at registration once you download the mobile phone application.

Using SleepFix

Once you have installed SleepFix mobile phone application on your phone, you will need to register an account and enter your access code to proceed. To set up the program you will complete a short series of questions about your current sleep. Once started, it will only take approximately 2 minutes each day to complete the sleep diary entries in the SleepFix mobile phone application, which are required for the therapy to progress.

What do I have to do?

All participants will be required to complete four questionnaire batteries over the course of 16 weeks. In addition, the control arm will be required to read and refer to an online sleep health module every two weeks and will require no more than 10 minutes. On the other hand, the Treatment group will be required to use the SleepFix mobile phone application involving daily diary entries for three weeks requiring no more than five minutes per day.

While completing the study, you are also responsible for:

- following guidelines and directions from this information sheet and study staff
- completing requirements of the study honestly and to your best ability
- telling the study staff about any changes to your health during the study (see adverse events below)
- not be part of any other sleep research study while participating in this study without first talking to the study staff.

Adverse Events

Throughout the study you are welcome to contact the research team if any new medical events or other occur while you are involved in the study. At weeks three and eight, you will be asked how you are feeling including questions about how your health may have changed since starting the study.

Additional Costs

There are no financial costs associated with participating in this research project other than your time.

Reimbursement

To encourage questionnaire completion and the time taken to complete, all participants will be offered a $15 gift card for completion at week eight, and a $35 gift card at completion of week 16.

What are the possible benefits of taking part?

For those in the treatment group, your symptoms associated with your insomnia and cognitive function may improve while you take part in this study. It is possible that there will be no direct benefit to you from taking part, however, this study may help us to better understand the efficacy of the SleepFix mobile phone application in older adults with cognitive impairment. The information from this research might also benefit others in the future.

What are the possible risks and disadvantages of taking part?

The most common side effect of this treatment is increased daytime fatigue and sleepiness, especially during the onset of the treatment. This has been reported to improve after two weeks and further improves following completion of the therapy. Therefore, it is advised that you do not drive or operate machinery unless you feel sufficiently alert to do so safely during the therapy. Please contact a member of the SleepFix team if you would like more information. DETAILS HERE

What if I withdraw from this research project?

You also have the right to withdraw from the study at any time and for any reason. If you wish to withdraw from the study, please advise a member of the research study team. You may be asked to complete a withdrawal of consent form to formalise your withdrawal. Any health risks or special requirements linked to withdrawing will be discussed with you.

If you do withdraw your consent during the study, there will be no additional information collected from you, although 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.

Can I have other treatments during this research project?

You may continue to take your regular medications or treatments you have been taking for any medical condition or for other reasons. It is important to inform the research staff about any treatments or medications for sleep you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments and any ongoing changes during the trial.

What will happen to information about me?

By indicating your consent, you will agree to the SleepFix research team collecting and using information for the research study. Any information obtained in connection with this research study is confidential and will be anonymised using a code number which will be stored electronically on a password-protected database on a secure server.

Data from the SleepFix mobile phone application will be stored separately to online questionnaires data. All data collected at the start of the SleepFix application (called onboarding) and survey data will be collected using a web-based SPARDAC database (Single Page Application - Research Data Capture) developed by Wappsystem Pty Ltd and hosted on Amazon Web Services (AWS) in Sydney, NSW, connected through the backend of the public-facing study website. Within this database, your study data will be anonymised and

stored separately to your identifiable personal information such as contact details. These are only linked using a unique access code that is only available to certain staff who may be required to contact you.

The SleepFix application-based data is encrypted onto a mobile application web server hosted on Amazon Web Services in Sydney, NSW, using the highest level of encryption available for web browsers (256-bit Secure-Socket Layer). Your SleepFix mobile phone application data is only accessible to authorised staff who may need to make contact with you to assist with app usage.

These databases can only be linked using an access code after initial recruitment, informed consent and randomisation. The participant access code database is only accessible by authorised personnel. This ensures that your identifiable data cannot be linked to therapy data.

Your records may be reviewed by:

- Woolcock Institute of Medical Research - the study sponsor
- People who work with the sponsor on the study
- The University of Sydney
- Government agencies, such as the Australian Therapeutic Goods Administration (TGA)
- Sydney Local Health District HREC – the Ethics Committee which reviews and approves research studies.

These people may look at study records to ensure the study has been conduct in the correct way or for other reasons that are allowed under the Australian law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

Permission to use your data for future research projects

Your anonymised data may be shared with other research collaborators who provide a methodologically sound proposal and sign a data access agreement. Your de-identified data may be shared with other local or international collaborators and used for future research purposes; however, Human Research Ethics Committee (HREC) approval will be sought prior to any future use of the data. You can indicate your agreement to this on the Consent Form.

After the study is complete

A report of this study may be submitted for publication, but individual participants will not be identifiable. Upon completion of the study, the study data will be permanently removed from study databases and transferred to password-protected secure servers at the University of Sydney and stored for 15 years, as per NHMRC Clinical Trial policy. All data will be de-identified, i.e. no personal details are stored.

Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the Sydney Local Health District (SLHD) 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.

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.

Further information and who to contact

Every reasonable precaution will be taken to ensure your safety during the course of the study. If you require any further information concerning this project or if, at any point, you have any issues or medical problems which may be related to your involvement in the project (for example, any side effects), you can contact:

Name	Matthew Rahimi
Position	Project Officer
Telephone	0401615177
Email	matthew.rahimi@sydney.edu.au
Location	Woolcock Institute of Medical Research

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact the reviewing HREC approving this research and HREC Executive:

Reviewing HREC name	Sydney Local Health District (RPAH Zone)
HREC Executive Officer	Merela Ghazal
Telephone	9515 7176
Email	SLHD-RPAEthics@health.nsw.gov.au
Protocol No.	X21-0434

For matters relating to the conduct of research at the site at which you are participating, the details of the local HREC Office contact/site complaints person are:

Name	Gregory Kaplan
Position	Research Governance Officer
Telephone	(02) 9114 01412
Email	Gregory Kaplain@sydney.edu.au

This information sheet is for you to keep

Digital Sleep Therapy for Older Adults with Cognitive Impairment (ExCEED Study)

ONLINE CONSENT FORM

I have read and understood the **Participant Information Sheet Version 1.0 (July 2021)** for the above named study and agree to the following terms:

- I am older than 60 years.
- I confirm that I have read and understand the Participant Information Sheet for the *Digital Sleep Therapy for Older Adults with Cognitive Impairment* study.
- I understand that if I have any questions or require further information, I can contact the research team. If I have had questions, I confirm that these have been answered to my satisfaction.
- I freely agree to participate in this research project according to the conditions in the Information sheet which I confirm has been digitally provided to me.
- I understand that my involvement in this study may not be of any direct benefit to me.
- I understand that being in this study is completely voluntary and I can withdraw from the study at any stage without penalty by advising the research team. If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw will be stored and analysed.
- I understand how my data will be stored, who will have access to it and what will happen to the data after the end of the study. I understand that my de-identified data may be used for future research, and I agree to this.
- I understand the Coordinating Principal Investigator, Associate Professor Christopher Gordon, will manage the e-consent database and have access to the Consent Forms, which will be stored at the Woolcock Institute of Medical Research.
- I understand I can download a copy of this signed consent form for me to keep.

[Digital consent and option to download/print signed copy]

I hereby agree to participate in all aspects of this research study YES □ NO □

NAME: .....

EMAIL ADDRESS: .....

PHONE NUMBER: .....

I prefer to be contacted by: Email □ Text □ Both □