App-delivered Sleep ThERapy for Older IndiviDuals with insomnia (ASTEROID Study)

PART A – FOCUS GROUP

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Introduction

You are invited to take part in a survey and/or focus group for people with insomnia. In this study, we aim to assess acceptability and determine the user experience needs in relation to a mobile phone application named SleepFix in older adults with insomnia. The app has been developed by researchers from the Woolcock Institute of Medical Research and The University of Sydney who will be running this study. The researchers have contracted software company *Saje Mind pty ltd* for ongoing SleepFix app maintenance. This company has no influence on the writing of the study protocol or other study related material. They will have access to overall study data and app usage data for the purpose of app maintenance and SleepFix development as required by the research teams at the Woolcock Institute and The University of Sydney.

This Participant Information Sheet and Consent Form tells you about the research study. It explains what the study is about and what will happen. It also tells you about the risks and benefits of the study. Knowing what is involved will help you decide if you want to take part in the study. Before you decide if you want to take part, it is important that you read this information. Please ask the study doctors or staff to explain any words or procedures that you do not clearly understand. You can take as much time as you need to make this decision.

What is the purpose of this research?

Insomnia disorder is a major health problem which commonly affects older adults frequently characterized by subjectively reported difficulty falling or maintaining sleep, or nonrestorative sleep resulting in significant daytime symptoms such as difficulty concentrating, mood disturbances amongst a range of other symptoms.

The purpose of this research is to determine the behaviours and User Experience (UX), and the acceptability of the new mobile application, SleepFix, in older adults from the community aged 60 years or over. SleepFix has been developed by the Woolcock Institute of Medical Research as a digital tool to deliver digital brief behavioural therapy for insomnia (dBBTi) in adults. The app delivers Sleep Retraining Therapy (SRT), a major component of dBBTi that the aims to reduce excess time spent in bed and reset sleep by matching the time you spend in bed to your total sleep time. The app will be distributed amongst the focus group to review current SleepFix UX. Following 2 weeks use of SleepFix, you will be able to provide feedback on the app's features.

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.

What does participation in this research involve?

If you agree to participate in this focus group you will first be assessed for your suitability (screened). Eligibility is determined on results from the Insomnia Severity Scale and the Pittsburgh Sleep Quality Index upon registration. If eligible, you will be presented with this Participant Information Sheet to be read and understood thoroughly, and then invited to consent to the study. Consent will be in the

form of a digitalised signature if a physical signature is not possible. If you consent you will be asked to register your first name, date of birth, gender, email address and mobile number. The focus group will be held at the Woolcock Institute of Medical Research in Glebe, NSW or, where this is not possible, held via Zoom depending on COVID-19 government requirements. A member of the research team will contact you to organise your participation in the focus group in conjunction with a text message with the link to download the SleepFix app, your unique access code and a link to the onboarding instructions if this is not possible in person. The focus group will involve approximately 10 participants and run for approximately 60-90 minutes. It will be audio recorded for analysis.

Your responsibilities during this study are limited to attendance at two virtual or in-person 60-90 minute focus group sessions as well as mobile application usage each day for 2 weeks, which should require no longer than a weekly total of 15 mins.

First Focus Group

Once all other participants are in attendance, the focus group will begin by exploring your views to better understand your mobile health app preferences, usage, and goals.

During this initial group, the research team will ensure that you have successfully downloaded and onboarded on to the SleepFix app. The research team member will then seek your immediate feedback on the usability and features of the SleepFix app.

Second Focus Group

After trialling SleepFix for a minimum of 2 weeks, a second focus group will be organised in the same method as the first. The research team member will seek your feedback again, on the usability and features of the SleepFix app.

All participants will be invited to trial the SleepFix app for an additional 4-6 weeks (from the start or continuing from where they had progressed to).

Additional Costs

There are no additional costs associated with participating in this research project.

Reimbursement

You will be offered a $50 gift card for each focus group you attend as reimbursement for your time.

What are the possible benefits of taking part?

Your symptoms associated with your insomnia 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 understand better the efficacy of SleepFix in older adults. The information from this research might benefit others in the future and these findings may be used to further develop and optimise the SleepFix app.

What are the possible risks and disadvantages of taking part?

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. Please contact the SleepFix team using contact details below if you would like more information.

Can I have other treatments during this research project?

Whilst you are participating in this research study, you may continue to take your regular medications or treatments you have been taking for your condition or for other reasons. It is important to tell the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture, or other alternative treatments. You should also tell the study staff about any changes to these during your participation in the research study.

Do I have to take part in this research project?

Participation in any research study is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the study at any stage and you do not have to give a reason.

If you do decide to take part, once you have consented you will be given a digitalised copy of this Participant Information Sheet and signed Consent Form for your own records.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with the Woolcock Institute of Medical Research.

What if I withdraw from this research project?

If you wish to withdraw from the study, please advise a member of the 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, the study doctor and relevant study staff will not collect additional personal information from you from the date your withdrawal of consent form is submitted. 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.

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.

Focus group interviews will be conducted either in person or over Zoom and recorded as audio and/or visual recordings and will stored electronically on a password protected database, on a secure server until transcribed. Only the investigators and study coordinators will have access to the recordings. All recordings will be transcribed and checked for accuracy, and the original recording will be permanently erased. De-identified transcripts will be stored on a restricted, password-protected secure server located at the Woolcock Institute of Medical Research in Glebe, NSW and maintained for up to 15 years after the completion of the study.

Data from the SleepFix app will be stored on an online web server with the highest level of encryption and is only accessible by authorised personnel who may need to contact you throughout the study. Following completion of data collection, app data will be aggregated to ensure no personal identification is possible and used for analysis.

The data will be analysed at the Woolcock Institute, Sydney, NSW and upon completion of the study, the app data will be removed from the app server permanently and a copy of the aggregated dataset will be stored on a password-restricted secure data storage servers at the University of Sydney and may be held for 15 years.

It is anticipated that the results of this study will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified.

In accordance with relevant Australian and/or New South Wales privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team.

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 that reviews and approves research studies,

These people may look at your records to make sure the study has been done the right way. They also want to make sure that your health information has been collected the right way, or for other reasons that are allowed under the 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 data may be shared with other 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 Participant Consent Form.

Complaints and compensation

If you suffer any injuries or complications as result of this study please contact the research team listed below as soon as possible who will then 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.

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.

Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or you still have questions or wish to get into contact during the study, please contact the project coordinator:

Name	Helena Salomon
Position	Project Coordinator
Telephone	02 9114 0481
Email	Helena.Salomon@sydney.edu.au

If you have any complaints about any aspect of the project, the way it is being conducted, any questions about being a research participant in general or wish to talk with someone not directly involved in the study then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	Sydney Local Health Health District (RPAH Zone)
HREC Executive Officer	Merela Ghazal
Telephone	02 9515 7176
Email	SLHD-RPAEthics@health.nsw.gov.au
Protocol No.	X21-0265

For matters relating to the conduct of research at the site at which you are participating, you can contact the following:

Local HREC Office contact (Single Site - Research Governance Officer)

Name	Greg Kaplan
Position	Chief Operating Officer
Telephone	(02) 9114 0412
Email	Grigori.Kaplan@sydney.edu.au

This information is for you to keep.

I have read and understood the Participant Information Sheet Version 1.0 (July 2021) for the above *App-delivered Sleep ThERapy for Older IndiviDuals with insomnia (ASTEROID) PART A – Focus Group* 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 above study.
- I understand that my interview will be audio and/or video recorded.
- I understand that only the research team will have access to this recording.
- I understand that the recording will be deleted following transcription.
- 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 page 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 that my de-identified data may be used for future research and I agree to this
- 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 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.

I hereby agree to participate in all aspects of this focus group research study

YES ☐ **NO** ☐

NAME: .....

SIGNATURE: .....

DATE: .....

(Copy of digitalised signature will be obtained where physical signature is not possible)