Participant Information Statement

Research Study: Sleep Disturbance in MCI: A Pilot Study of a Cognitive Behavioural Therapy Digital Intervention (SUCCEED)

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1. What is this study about?

We are conducting a research study to find out if digital Cognitive Behavioural Therapy for Insomnia (CBT-I) improves sleep, cognitive performance, mood, and daytime functioning in older adults with mild cognitive impairment (MCI). In addition, since CBT-I is a clinically proven therapy for insomnia, digital CBT-I could allow people to engage with the therapy without the need for a Sleep Psychologist. Thus, we are interested in assessing the feasibility of digital CBT-I as treatment for insomnia in older adults with MC. We also want to get some feedback on using the program and whether participants have any difficulties during the study. This may help in further development of the program for future studies.

You have been invited to take part in this study because you have insomnia which you have not received treatment for within the last 4 weeks and you may have MCI. In this study, we aim to assess the effect of digital Cognitive Behavioural Therapy for insomnia, on sleep, daytime symptoms and on thinking and memory skills.

Participation in this research study is voluntary

By giving your consent to take part in this study you are telling us that you:

- ✓ Understand what you have read.
- ✓ Agree to take part in the research study as outlined below.
- ✓ Agree to the use of your personal information as described.

Please read this sheet carefully and ask questions about anything that you don't understand or want to know more about.

2. Who is running the study?

The study is being carried out by the following researchers:

Chief Investigators:

- Professor Sharon Naismith, Leonard P. Ullman Chair in Psychology, NHMRC Dementia Leadership Fellow, School of Psychology of the University of Sydney and the Brain & Mind Centre.

- Dr. Camilla Hoyos, Senior Research Fellow, School of Psychology, Brain and Mind Centre, University of Sydney and Woolcock Institute of Medical Research.
- Associate Professor Christopher Gordon, Woolcock Institute of Medical Research, University of Sydney.
- Professor Ron Grunstein, Professor of Sleep Medicine and NHMRC Senior Principal Research Fellow, Senior Specialist Physician; Woolcock Institute of Medical Research, University of Sydney.
- Dr Haley LaMonica, Brain and Mind Centre, University of Sydney.
- Associate Professor Nathaniel Marshall, Sydney Nursing School, University of Sydney.

Associated Investigator:

- Associate Professor Stephanie Rainey-Smith, Murdoch University, Australian Alzheimer's Research Foundation.

This project is funded by a seed funding award allocated from the NHMRC Centre of Research Excellence (CRE) to Optimise Sleep in Brain Ageing and Neurodegeneration (CogSleep) (1152945). As the study sponsor, the University of Sydney will provide non-financial support as it will not charge the study for this service.

3. Who can take part in the study?

We are seeking adults aged between 50-80 years with a diagnosis of MCI and insomnia symptoms and who own a computer, tablet, or laptop with internet access.

You will not be able to participate in this study if you:

– have major neurological problems (e.g. Parkinson's, multiple sclerosis, epilepsy);
– had a major head injury, cerebrovascular events (stroke, TIA), or loss of consciousness for more than 30 minutes over the past three years.
– have an alcohol or substance use disorder.
– have a severe mental health disorder (e.g. schizophrenia, bipolar disorder);
– have a current diagnosis of major depression;
– have a major sleep disorder (e.g. narcolepsy, REM sleep behaviour, severe restless legs syndrome);
– have commenced with continuous positive airway pressure therapy, dental snoring device (e.g. MAS), antidepressants, melatonin or engaged in CBT or psychological interventions within the prior 4 weeks;
– are taking any medication to assist sleep for three or more nights per week (e.g. benzodiazepines, sedative hypnotics, opioids);
– are a shift worker.
– have travelled across more than 2- time-zones in the last 7 days and currently experiencing jetlag syndrome.
– have a risk of an increase in daytime sleepiness and decreased alertness (e.g. professional drivers or those who operate heavy machinery).
– have a contraindication to sleep deprivation therapy.

4. What will the study involve for me?

If you agree to participate in this study, you will first be assessed for your suitability (screened) and if suitable you will be randomised (assigned by chance) to either an intervention group or a control group. You will be in the study for 12 weeks. You will be asked to complete online questionnaires to explore modifications in sleep, cognition, mood, and well-being outcomes at the following time points: at the start of the study, and after 12 weeks.

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

Screening Visit
You will first be assessed for your suitability by a video-conference interview with a study team member.

If you have been recruited through the Healthy Brain Aging Clinic, this visit will take approximately 45 minutes and we will collect some information about your health and evaluate your insomnia symptoms to assess your eligibility for the study.

If you have been recruited through Facebook advertisement campaign, this visit will take approximately 90 minutes. We will collect some information about your health and assess for mild cognitive impairment and insomnia symptoms to check whether you are eligible to take part in the study.

If you are suitable and agree to participate in the study, you will be asked to provide consent electronically prior to any of the following procedures:

Randomisation
You will be randomised (assigned by chance) to either an intervention group (digital CBT-I) or a control group (sleep hygiene education). The decision about who will receive digital CBT-I immediately is made by an automated computer system. Everyone gets a 50% chance of being assigned to either group. If you are assigned to the control group, you will have access to the digital CBT-I program after 12 weeks.

Questionnaires
At the beginning of the study and then after 12 weeks, you will be asked to complete various online questionnaires regarding changes in your sleep, daytime functioning, mood, and your experience with digital CBT-I. These should take about 30 minutes to complete.

Cognitive tests
You will be asked to complete three computerised tests (selected from the Cambridge Neuropsychological Test Automated Battery) at baseline and then again at 12 weeks. This cognitive battery will be sent via email link to you and will take approximately 22 minutes to complete.

You will also be invited to an optional (~45-minute) video-conference interview with a neuropsychologist, who will administer some additional neuropsychological tests and ask for your feedback regarding your experience with our cognitive tests.

Randomised Groups

Wait-listed control group:
If you are randomised to the wait-listed control group, you will have access to 3 modules of an online Sleep Health Education package delivered fortnightly. You will receive an email which will take you to an online platform where you will login and receive the material (e.g. the impact of sleep on health, creating a sleep-conducive bedroom, sleep and mood).

At trial completion (week 12), you will be offered the opportunity to engage with digital CBT-I.

Intervention group:
If you are randomised to the intervention group, you will be sent a code to enter a separate website that provides the digital CBT-I. The research team coordinator will contact you to provide instructions of how to access the digital CBT-I website and download the app, as well how to use the program.

Once you have access to digital CBT-I program known as Sleepio (Big Health, Inc.) on your phone or computer, 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 program for 6 weeks. An animated "virtual therapist" (The Prof) will guide you through automated web and e-mail support, and also you will have access to a video library of session content/articles and to a supportive social network/community of end-users. Each of the 6 sessions lasts approximately 30 minutes and will incorporate an initial progress review in relation to individualised goals, and exploration of self-reported diary data relating to your current sleep status and pattern. However, it is up to you how much you use the program on a daily basis. It will only take approximately 5 minutes each day to complete the sleep diary entries in the digital CBT-I app, needed to check your progress.

Check-in call
A brief (10-minute) check-in call at two and six weeks will be conducted by a member of the study team to record any adverse events and assess adherence and engagement.

5. Can I withdraw once I've started?

Being in this study is completely voluntary and you do not have to take part.

If you do take part, you may withdraw at any time without having to give a reason. Your decision will not affect your current or future relationship with the researchers or anyone else at The University of Sydney.

Further, 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.

If you decide to withdraw, you should notify on the study coordinator on 0406 896 567 or email to nicole.espinosa@sydney.edu.au. 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 information that we have already collected however will be kept in our study records and may be included in the study results.

6. Are there any risks or costs?

Participation in this study will not cost you anything.

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.

7. What if injury or complications happen?

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.

8. What happens when the study ends?

At trial completion (week 12), wait-listed control participants will be offered the opportunity to engage with digital CBT-I.

If you had access to the digital CBT-I program and, after the 12 weeks you still feel that you need help with any sleep problems, you might consider the following:

- Visit your GP or other health professional
- Find a sleep service near you on the Australasian Sleep Association service directory.

For further information about sleep, visit the Sleep Health Foundation website.

Additionally, participants who were given a new diagnosis of MCI will be invited to have a face to face or telehealth appointment at the Healthy Brain Aging Clinic (HBA) or we will provide them with details of their local memory clinic via the ADNeT locator map (https://www.australiandementianetwork.org.au/initiatives/memory-clinics-network/find-a-clinic-or-service/)

In case of any questions, please contact the study coordinator on 0406 896 567 or email to nicole.espinosa@sydney.edu.au.

9. Are there any benefits?

We cannot guarantee that you will receive any immediate benefits from this study. However, the study offers comprehensive neuropsychological assessment free of charge, which some people may consider beneficial. However, this study may help us to understand better the effects of digital CBT-I on insomnia and MCI. The information from this research might benefit others in the future.

10. Reimbursement

You will be offered a $20 gift card at completion of week 12.

11. What will happen to information that is collected?

By indicating your consent on the next page, you will agree to the SUCCEED research team collecting and using personal information for the research study. Any information obtained in connection with this research study is coded 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 online in a password protected manner 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. 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. Your data may be published in an open access data repository or also be made available to a third party in the future in which case further ethical approval would be sought from both yourself and the Ethics Review Committee.

You should note that the digital CBT-I program is a separate company with its own terms and conditions regarding how they use the data you provide. The company is committed to protecting the confidentiality of personal information in any form, complying with best practice in relation to obtaining, recording, holding, using, and disclosing information and

conforming to statute law. Once we send you the link to the digital CBT-I program, you are encouraged to read the 'terms and conditions' and 'privacy policy' pages before registering for the program. However, your consent can be withdrawn at any time.

The digital CBT-I program uses personal data (e.g. names, emails, phone, age, gender, and health information), health information (e.g. time spend asleep, number of interruptions during sleep, self-reported sleep quality) and electronic identifies (e.g. IP address, IMEI numbers, browser type) to personalise and support the delivery of your program, as well as tailor the user experience of the System. The data may be included in aggregated data sets shared with their research partners. Personal information is not disclosed to third parties for any purpose significantly different from the original purpose for which it was collected, and your data will not be personally identifiable. Lastly, whilst the digital CBT-I program is separate to the SUCCEED research team, all data that you provide to the CBT-I program may be shared with the SUCCEED research team, but not the other way around.

Any intended future use of data will be limited to the aims of this project and that ethical approval will be sought if intended use is outside the scope of the current project.

12. 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.

13. Will I be told the results of the study?

You have a right to receive feedback about the overall results of this study. You can tell us that you wish to receive feedback by ticking the relevant box on the consent form. This feedback will be in the form of a one-page summary of the trial's key findings. You will receive this feedback after the study is finished. You will not receive individualised feedback about your performance on the online assessments.

14. What if I would like further information?

When you have read this information, the Study Coordinator will be available to discuss it with you further and answer any questions you may have:

- 0406 896 567 or email to nicole.espinosa@sydney.edu.au

15. What if I have a complaint or any concerns?

The ethical aspects of this study have been approved by the Human Research Ethics Committee (HREC) of The University of Sydney [2021/761] according to the *National Statement on Ethical Conduct in Human Research (2007).*

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the University:

Human Ethics Manager
human.ethics@sydney.edu.au