



Chief Investigator: Dr Amelia Scott

PARTICIPANT INFORMATION AND CONSENT FORM

The Sleep Course: a randomized controlled trial of online cognitive behavioural therapy for insomnia

You are invited to participate in a research trial of a self-management course, the *Sleep Course*, for adults with insomnia. The Sleep Course is designed to provide good information and skills to help people improve their insomnia symptoms.

This research is being conducted by:

- Dr Amelia Scott, Macquarie University Research Fellow and Clinical Psychologist
- Ms Taylor Hathway, Senior Research Assistant and Clinical Psychology Registrar
- Dr Madelyne Bisby, Macquarie University Research Fellow and Clinical Psychologist
- Prof Chris Gordon, Research Leader of Insomnia and Chronobiology, Sleep and Circadian Research Group, Woolcock Institute of Medical Research
- Professor Blake Dear, Director of the eCentreClinic at Macquarie University and Clinical Psychologist

Before you decide to participate in this research trial it is important for you to understand why the research is being done and what participation will involve. Please take the time to read the following information carefully and discuss with others, including your GP or specialist, as needed.

PLEASE NOTE: You are also welcome to contact the eCentreClinic via email contact@ecentreclinic.org with any questions regarding this research or your participation at any point. You can contact Dr Amelia Scott directly on 02 9850 8602.

1. What is the purpose of this research trial?

The purpose of this research is to investigate the efficacy of the Sleep Course, and to gather feedback from participants to inform further improvements to the program. Research tells us that cognitive behavioural therapy (CBTi) is an effective treatment for insomnia for many people. However, research also indicates that most Australians cannot access CBTi. There are a number of barriers that commonly prevent access to these treatments, such as availability, cost, distance and waitlists. We also don't know how people's symptoms improve while they are taking part in CBTi, and which parts of treatment are most helpful.

2. Who is eligible to participate in this research trial?

You are eligible to participate in this trial if: (1) you are experiencing at least mild symptoms of insomnia (either falling asleep, staying asleep or waking too many times in the night), (2) you have been experiencing these difficulties for at least one month, (3) these difficulties are causing you distress, or affecting you socially, at work, or in another important way (4) you are 18 years or older; (5) you are living within Australia. Currently, we cannot include experiencing very severe mental health or substance use issues, or severe health problems that need to be treated first. You will also need access to the internet to participate in this research.

3. What if I do not want to participate or I want to withdraw later?



Participation in this research trial is entirely voluntary. It is up to you whether or not you decide to participate and your decision will not impact your relationship with the research investigators or their respective institutions. You can also choose to withdraw from the research at any time without any consequence. Importantly, consistent with best practice for health research, any information and data you provide up until your withdrawal cannot be deleted or withdrawn

4. What does this research trial involve?

Once you have read this information sheet and decide you wish to participate, you can submit an application to participate in the research trial via the eCentreClinic website (www.ecentreclinic.org). This application process takes about 20 minutes and involves completing some questionnaires via the eCentreClinic website. These questionnaires help us to measure your symptoms and understand whether the course is likely to be helpful for you. Eligible applicants will be contacted by a member of the eCentreClinic team to conduct a telephone interview, discuss the course and answer your questions. Upon enrolment, you will be randomly allocated to a group who starts treatment immediately, or a group who starts treatment after an 8-week delay.

The *Sleep Course* consists of 4 lessons. You will be asked to complete these lessons over 8 weeks. Each lesson provides important information about techniques for managing insomnia and associated problems. Each lesson has illustrated examples of how people learn these techniques. Each lesson takes about 30 minutes to complete and the home-based tasks will take a further 4 hours each week. While you are enrolled in the course, you are free to seek and continue any psychological, medical, or other treatments for your sleep issues and emotional wellbeing. Participation in this study does not limit or interfere with your access to any other support or treatment options.

You will also be asked to **complete a sleep diary** before you start the course, and once you finish – this is a very common and helpful part of insomnia treatment. You will also receive optional weekly contact from an experienced Psychologist who will provide support and answer your questions as you work through the course.

We will ask you to complete online questionnaires:

- Before the course starts (time needed: 10 to 15 minutes, and then 2 minutes each morning to complete a sleep diary for a one-week period).
- Weekly while you are completing the course (time needed: 5 to 10 minutes)
- At the end of the course (time needed: 10 to 15 minutes, and then 2 minutes each morning to complete a sleep diary one-week period)

These questionnaires will help us determine whether the course has been helpful. We will also ask you for feedback about your experience of the course and things you believe we can improve for future participants. Once you have completed the course, a clinician from the eCentreClinic will contact you regarding your results and answer any questions you might have. You will have access to the Sleep Course for approximately 6 months after you finish the course.

5. How is this research being paid for?

There are no costs for participants in this research trial and participants cannot be paid for their participation. This research is funded via a Macquarie University Research Fellowship and the eCentreClinic, Macquarie University.

6. Will I benefit from participating in this research trial?

Based on existing research, we expect that you will find this course interesting and helpful. The strategies in this course have been shown in other research studies to help people improve their insomnia symptoms, sleep patterns (e.g., time taken to fall asleep, and time awake in the middle of the night), and also their daytime functioning (e.g. mood and energy). We have already evaluated the Sleep Course in 74 participants, and 91% said they would recommend the course to others. However, we cannot guarantee or promise that you will receive any benefit from participating.

7. Are there risks to participating in this research trial?

There are no known discomforts or risks associated with participating in this kind of course. It is very unlikely that the present study will result in physical harm. Sometimes, when people are taking part in treatment like the current course, they experience a short-term increase in tiredness and sleep loss. This relates to specific CBTi treatment strategies, which you will be made aware of in the relevant course lesson. Importantly, if you become distressed or concerned, you are welcome to contact Dr Amelia Scott (02 9850 8602) or any of your other health professionals. You are also welcome to withdraw from this research at any time and we are available during business hours to discuss your symptoms and further treatment options with you.

8. How will my confidentiality be protected?

Any identifiable information that is collected about you will remain entirely confidential and will not be disclosed without your express permission - unless we are required to do so by law. Importantly, where we hold significant concerns about your personal safety or the safety of others, particularly children, we are legally required to notify emergency and other governmental services. We will publish the results of this research and discuss these results at national and international scientific conferences; however, in any publication, information will be presented in such a way that you cannot be identified. Moreover, only key researchers at the eCentreClinic will have access to your personal details or information. Your anonymised data may be used in future research to further scientific knowledge. We will take strict measures to protect your privacy, ensuring that your identity remains confidential.

9. Can I see a copy of the published research?

We will ask all participants whether they would like to receive a copy of any published manuscripts resulting from this research. So, you are welcome to request a copy of any research manuscripts that are published. You are also welcome to contact Dr Amelia Scott or the eCentreClinic to discuss this research and ask any questions you may have at any time.



PARTICIPANT CONSENT FORM

The Sleep Course: a pilot trial of an online transdiagnostic sleep intervention

Once you have read this Participant Information and Consent form, you can click the ‘consent’ button to start your application to participate in this research trial.

Importantly, by submitting an application, you consent to the points below, you acknowledge that:

1. You would like to participate in the Sleep Course
2. You have read the Participant Information Statement, which explains the aims of the study and nature of your participation.
3. You have the opportunity to raise any questions or concerns with us, regarding this research, at any time.
4. You can withdraw from the research trial at any time without prejudicing your relationship with the researchers or Macquarie University, Sydney Australia.
5. The eCentreClinic may contact crisis or emergency services, as required by law, if there are significant concerns about my safety or someone else’s safety during the course.
6. Research data gathered from the present research may be published in a de-identified format; that is, in an entirely anonymous format where individuals cannot be identified.
7. Research data gathered from the present research may be used in future studies not described in the Participant Information Statement. All data would be in a de-identified format and the research would be subject to approval from a Human Research Ethics Committee.
8. You can raise any questions or concerns about this research project with Dr Amelia Scott (02 9850 8602) or any staff (contact@ecentreclinic.org) at the eCentreClinic at any time.

If you have any complaints or reservations about any ethical aspect of your participation in this research, you may contact the Ethics Review Committee through the Director, Research Ethics and Integrity (telephone 9850 7854; email ethics@mq.edu.au). Any complaint you make will be treated in confidence and investigated, and you will be informed of the outcome.

REVOCATION OF CONSENT FORM

If at any time you wish to withdraw from this study, please contact Dr Amelia Scott at any time or **email the below text to contact@ecentreclinic.org.**

I hereby wish to **WITHDRAW** my consent to participate in the research proposal described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with Macquarie University.