



**Chief Investigator: Dr Amelia Scott**

## **PARTICIPANT INFORMATION AND CONSENT FORM**

*The Sleep Course: an online transdiagnostic sleep intervention*

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

This research is being conducted by:

- Dr Amelia Scott, Clinical Psychologist / Research Fellow, Macquarie University
- Dr Madelyne Bisby, Clinical Psychologist / Research Fellow, Macquarie University
- Dr Joanne Dudeny, Clinical Psychologist / Research Fellow, Macquarie University.
- Dr Alana Fisher / Research Fellow, Macquarie University
- Dr Milena Gandy, Clinical Psychologist / Research Fellow, Macquarie University.
- Dr Andreea Heriseanu, Clinical Psychologist / Research Fellow, Macquarie University
- Dr Eyal Karin, Senior Research Assistant, Macquarie University.
- Ms Taylor Hathway, Clinical Psychology Registrar / Research Assistant, Macquarie University
- Professor Nick Titov, Professor and Director MindSpot Clinic, Macquarie University.
- Professor Blake Dear, Director eCentreClinic and Clinical Psychologist, Macquarie University.

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](mailto: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 acceptability, feasibility and efficacy of the Sleep Course, and to gather feedback from participants to inform further improvements to the program.

Research tells us that there are lots of good strategies that people can use to improve their sleep health. However, research also indicates that most Australians cannot access the kinds of self-management programs that provide this information and teach these skills. There are a number of barriers that commonly prevent access to these treatments, such as availability, cost, distance and waitlists. Also, a lot of research is only conducted in people with clinically-diagnosed insomnia disorder.

Lots of the existing research that examines sleep treatment also excludes people who have problems with anxiety or mood, or medical conditions, alongside their sleep difficulty. We know that a lot of people with sleep problems may also struggle with their emotional wellbeing or have medical conditions, so we are interested to understand whether these people may also benefit from the Sleep Course.



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

You are eligible to participate in this trial if: (1) you feel you have difficulties with sleep (either falling asleep, staying asleep or waking too many times in the night). (2) these difficulties are causing you distress, or affecting you socially, at work, or in another important way (3) you are 18 years or older; (3) you are living within Australia. Currently, we cannot include experiencing very severe depression or who have any intention or plan to harm themselves. Or, anyone who has harmed themselves in the previous 12 months. 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. Importantly, you can also choose to withdraw from the research at any time without any consequence.

## **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](http://www.ecentreclinic.org)). This application process takes about 10 to 15 minutes and involves completing some questionnaires via the eCentreClinic website. These questionnaires assist us in understanding your symptoms and difficulties as well as 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 brief telephone interview, discuss the course and answer your questions. You will be provided a start date for the course and create a login name and password for accessing the course.

The *Sleep Course* consists of 4 lessons. You will be asked to complete these lessons over 6 weeks and to complete some worksheets that will help you to remember the material you have learned. Each lesson provides important information about techniques for managing sleep difficulty and associated problems (e.g. worry about sleep, fatigue). 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. 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 sleep improvement programs. You will also receive brief weekly contact (e.g., 5 to 15 minutes) 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).
- 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)
- 3 months after the course (time needed: 10 to 15 minutes).

These questionnaires will help 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 should you participate in the research.

**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 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 sleep duration, satisfaction with sleep and also their daytime functioning (e.g. alertness, irritability). Also, based on previous research from our other courses, we know that more than 90% of participants find our courses worth their time and that they would recommend them 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. Few adverse effects have been reported in similar studies reported in similar research. Sometimes, when people try to change their sleeping habits, they experience a short-term increase in tiredness and sleep loss. Importantly, if you become distressed or concerned, you are invited to contact Dr Amelia Scott (02 9850 8602) or any of your other health professionals to discuss this distress. 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.

**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:

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](mailto: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](mailto: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](mailto: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.