

Professor Lisa Lampe
College of Health, Medicine and Wellbeing
School of Medicine and Public Health
University of Newcastle
Callaghan 2308, Australia
Tel: (02) 4033 9631
Email: lisa.lampe@newcastle.edu.au

Information Statement for the Research Project
**Feasibility of at-home virtual reality delivered
mindfulness in the treatment of insomnia**

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You are invited to participate in the research project identified above which is being conducted by A/Prof. Lisa Lampe, Prof. Rohan Walker, Dr. Murielle Kluge, and Ms. Rita Hitching from the School of Medicine and Public Health and School of Biomedical Sciences and Pharmacy at the University of Newcastle and A/Prof. Christopher Gordon from the School of Medicine at Macquarie University.

The information below provides more detail about the study and how you can participate if you choose to. This project is part of Ms. Rita Hitching's Ph.D. studies at the University of Newcastle. A/Prof. Lampe, Prof. Walker, Dr. Kluge, and A/Prof. Gordon supervise Ms. Hitching's research. The University of Newcastle has partly funded this project.

What is the research study activity about?

This is an optional data collection activity for the 4-week at-home mindfulness insomnia treatment study you are already enrolled in. We are comparing a person's physiological responses: breathing, heart rate, skin conductance, and brain activity during mindfulness. The results may increase our understanding of the pathophysiology of insomnia, the neurological impact of mindfulness, and how VR may enhance it.

Who can participate in the research?

You were selected as a participant in this study because you are already enrolled in the 4-week at-home mindfulness insomnia treatment study. For this optional study activity only, if you have a history of seizures, you will not be eligible to participate.

Why is the research being done?

There is limited understanding of the effect of mindfulness as a treatment for insomnia when delivered using VR rather than a 2D device such as a computer, phone, or tablet. The purpose of this optional study activity is to compare how the body responds to the same mindfulness content delivered using VR or a computer.

What does the research involve?

You will be asked to wear headphones, a biometric belt underneath your clothes, and finger electrodes on your non-dominant hand, to measure your breathing, heart rate, and skin conductance while you complete your first mindfulness session. The mindfulness content is part of Week 1 of the at-home mindfulness study and will take approximately 15 minutes to complete.

What would you be asked to do?

You will be fitted with the EquiVital life monitor belt underneath your clothes and finger electrodes on your non-dominant hand. The EquiVital life monitor is a non-invasive belt that sits on your skin and collects heart rate and respiratory data, sent via Bluetooth to a computer. The finger electrodes are similarly non-invasive and stick to the hand using adhesive tape. The electrodes are wired to the EquiVital belt to collect and transmit data on skin conductance (sweating).

You will be fitted with an ADInstruments electroencephalogram (EEG) cap that sits over your hair. The ADInstruments cap uses clip-on electrodes to record your brain's electrical activity. Your upper body will be video and audio recorded as you practice your mindfulness session. Before and after you complete your mindfulness session you will fill out two questionnaires regarding your level of relaxation and alertness.

What choice do you have?

Participation in this optional study activity is entirely your choice. If you do not want to take part, you do not have to. Whether you agree to participate or not, your decision will not disadvantage you in any way. You can continue with the 4-week insomnia treatment study without having to participate in this optional study activity.

How much time will it take?

The optional study activity will take approximately 1 hour to complete, in a single session.

What are the risks and benefits of participating?

By participating in this research, you will help us better understand what the physiological impacts of mindfulness are. After completion of the activity, you are welcome to view your biometric readouts (heart rate, respiratory rate, and skin conductance) and brain activity collected. A research team member will talk you through your responses if you wish to see them. This can be done immediately after your test session or by appointment (there is an option on the consent form to indicate your interest).

Will the study cost you anything?

Participation in this study will not cost you anything. You will receive an additional \$20 in the form of a Flexi electronic gift card for participating in this additional study. Your gift card will be sent via email at the end of the baseline study visit. You can get more information about redeeming your gift card at <https://www.giftpay.com.au/>.

How will your privacy be protected?

All data and information collected as part of the study including consent forms, will be kept in a locked office inside a locked file cabinet at the University of Newcastle. Electronic copies of the data will be stored using a University approved cloud storage server. Questionnaire responses and any identifiable or personal information will be de-identified using a participant ID number and treated confidentially. Access to any identifiable data will be restricted to members of the research team unless you have consented otherwise.

To protect your privacy the audio/video recording will be captured and recorded using Zoom, an enterprise-grade platform that provides secure and encrypted recordings. Additional information on Zoom's privacy statement can be found at <https://explore.zoom.us/docs/en-us/privacy.html>.

The Zoom recording will be stored electronically on a secure, cloud-based platform, a password-protected folder managed by the University of Newcastle. Access to cloud data storage requires single sign-on (SSO) credentials and double authentication. Data will only be accessible to the research team. Data will be retained securely for a minimum of fifteen years from the completion of the research project. Information will be managed and stored in accordance with the University's Research Data and Materials Management Guideline. More details are available at <https://policies.newcastle.edu.au/document/view-current.php?id=72> or any successor Guideline as well as any other applicable University of Newcastle policy provisions.

How will the information collected be used?

The data will be used to assess the difference between mindfulness delivered using VR or a computer screen. Findings will be published in scientific publications and reports, and presented at scientific conferences, and other meetings. It will also contribute to Ms. Rita Hitching's Ph.D. thesis. No information that identifies you will ever be used in any of the outputs generated from the research project, but individual anonymous responses may be quoted. Non-identifiable data may also be shared with other parties to further research and public knowledge and encourage scientific scrutiny as part of a peer-review process to verify the robustness and integrity of the study.

What do you need to do to participate?

Read this Information Statement in its entirety and be sure you understand all the information provided before agreeing to participate. If there is anything you do not understand, or if you have questions, contact Ms Rita Hitching to get further information about the project. If you decide to participate, please complete, and sign the Consent Form provided and return it to the Chief Investigator A/Prof Lisa Lampe noted on this form.

Thank you for your time and consideration.

Rita Hitching
PhD Student Researcher
University of Newcastle

A/Prof Lisa Lampe
Chief Investigator
University of Newcastle

Concerns or complaints about this research

The University of Newcastle's Human Research Ethics Committee has approved this project, one of the University's College-based human ethics advisory panels. Approval No. H-[TBC]. If you have concerns about your rights as a participant in this research, or if you have a complaint about the manner in which the research is conducted, please contact the Chief Investigator A/Prof Lisa Lampe via email at lisa.lampe@newcastle.edu.au or by phone.

If you prefer to contact someone independent of the research project, you can forward your concerns to:

Human Research Ethics Officer
Research and Innovation Services
University of Newcastle
University Drive
Callaghan NSW 2308, Australia Phone:
(02) 4921 6333
Email: Human-Ethics@newcastle.edu.au