

**Participant Information Sheet**

|  |  |
| --- | --- |
| **Title** | The Efficacy of a Pragmatic Slow Eye BlinkingTreatment for Insomnia Blinking Treatment for Insomnia |
| **Chief Investigator/Senior Supervisor** | Professor Gerard A. Kennedy Chief InvestigatorProfessor of Clinical Psychology RMIT University Ph: 03 9925 7457 Email: Gerard.kennedy@rmit.edu.au  |
| **Associate Investigator(s)/Associate Supervisor(s)** | N/A |
| **Principal Research Student(s)** | Daniel ArmstrongPrincipal ResearcherMaster of Clinical Psychology CandidateRMIT University Ph: 03 9925 7457 Email: s3060595@student.rmit.edu.au |

**What does my participation involve?**

**1 Introduction**

Dear Participant,

You are invited to take part in this research project, which is called *The Efficacy of a Pragmatic Slow Eye Blinking Treatment for Insomnia*. You have been invited because of you interest in promoting sleep technology. Your contact details were obtained Facebook and Qualtrics.

This Participant Information Sheet tells you about the research project. It explains the processes involved with taking part. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative or friend.

Participation in this research is voluntary. If you don’t wish to take part, you don’t have to.

If you decide you want to take part in the research project, you are telling us that you:

• Understand what you have read

• Consent to take part in the research project

You will be given a copy of this Participant Information and Consent Form to keep.

**2 What is the purpose of this research?**

This study aims to measure the degree to which a pragmatic slow eye blinking procedure reduces sleep onset latency in people with sleep difficulties. Specifically, in a sample of approximately 50 participants aged 18 to 50 years old, this study aims to reduce sleep latency in both a normal and clinical sample of sleep-onset and sleep-maintenance participants with mild to severe sleep problems utilising a slow eye blinking procedure.

The results of this research will be used by the researcher Daniel Armstrong to obtain a Master of Clinical Psychology degree.

**3 What does participation in this research involve?**

You must be aged between 18-50, have sleep difficulties and have the capacity to give consent to the study and follow instructions and procedures.

Participation will involve completing online questionnaires. These are estimated to take up to 30 minutes and will assess the following areas:

* Demographic information
* Insomnia severity
* Mental health
* Overall wellness

Participants whose results show greater difficulty getting to or staying asleep will be invited to complete the treatment procedure. This will involve slow eye blinking to a metronome for a period of 15 minutes, 10 nights in a row.

**4 Other relevant information about the research project**

Approximately 50 people will take part in the overall project. Participants will be randomly allocated to intervention or control groups.

**5 Do I have to take part in this research project?**

Participation in any research project 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 project at any stage.

If you do decide to take part, you will be given a copy of the Participant Information form to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your relationship with the researchers or with RMIT University.

Submitting your completed questionnaire is an indication of your consent to participate in the study. You can withdraw your responses any time if you change your mind about having them included in the study before we have analysed and published the results.

**6 What are the possible benefits of taking part?**

We cannot guarantee or promise that you will receive any benefits from this research; however, you may appreciate contributing to knowledge. Possible benefits may include the potential to reduce the amount of time it takes to get to sleep. However, in the event the treatment is not effective, your participation in this study may improve knowledge about sleep hygiene.

**7 What are the risks and disadvantages of taking part?**

You may feel that some of the questions we ask are stressful or upsetting. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately. If you become upset or distressed as a result of your participation in the research project, members of the research team will be able to discuss appropriate support for you.

In the event of significant distress, please contact Lifeline on 13 11 14 to discuss your concerns.

This project will use an external site to create, collect and analyse data collected in a survey format. The site we are using is Qualtrics. If you agree to participate in this survey, the responses you provide will be stored on their host server. No personal information will be collected in the survey so none will be stored as data. Once we have completed our data collection and analysis, we will import the data to the RMIT server where it will be stored securely for seven years. The data on the host server will then be deleted and expunged.

**8 What if I withdraw from this research project?**

If you do consent to participate, you may withdraw at any time. If you decide to withdraw from the project, please notify a member of the research team.

You have the right to have any unprocessed data withdrawn and destroyed, providing it can be reliably identified.

**9 What happens when the research project ends?**

The proposed research will be completed December 2018. Results of this proposed research will be published via the Project Page Facebook page, and can be requested by participants from the researchers. The participant may request a copy of their personal data collected in the course of the research.

**How is the research project being conducted?**

**10 What will happen to information about me?**

By completing the online Qualtrics survey you consent to the research team collecting and using information from you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential.

Results from this study will be transferred to a data analysis program and secured on a password protected computer. Researches will analyse the information you provide to see the degree to which the procedure was effective. Once transferred, questionnaires will be de-identified by replacing names with numbers. Data will only be accessible by investigators of this study.

Information collected will be used to write a master’s research thesis. It is anticipated that the results of this research project 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, except with your express permission.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to the information about you that is collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please inform the research team member named at the end of this document if you would like to access your information.

Any information that you provide can be disclosed only if (1) it is to protect you or others from harm, (2) if specifically required or allowed by law, or (3) you provide the researchers with written permission.

*Security of the website*

Users should be aware that the World Wide Web (WWW) is an insecure public network that gives rise to the potential risk that a user’s transactions are being viewed, intercepted or modified by third parties or that data which the user downloads may contain computer viruses or other defects.

*Security of the data*

This project will use an external site to create, collect and analyse data collected in a survey format. The site we are using is Qualtrics. If you agree to participate in this study, the responses you provide will be stored on a host server that is used by Qualtrics. Once we have completed our data collection and analysis, we will import the data we collect to the RMIT server where it will be stored securely for seven (7) years. The data on the Qualtrics host server will then be deleted and expunged.

**11 Who is organising and funding the research?**

This research project is being conducted by Daniel Armstrong, Master of Clinical Psychology candidate at RMIT University.

**12 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). This research project has been approved by the RMIT University HREC.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research* (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.

**13 Further information and who to contact**

If you want any further information concerning this project, you can contact the researcher on 03 9925 7457 or any of the following people:

 **Research contact person**

|  |  |
| --- | --- |
| Name | Professor Gerard A. Kennedy  |
| Position | Chief investigator, Professor of Clinical Psychology   |
| Telephone | 03 9925 7457  |
| Email | Gerard.kennedy@rmit.edu.au  |

**14 Complaints**

|  |  |
| --- | --- |
| Reviewing HREC name | RMIT University |
| HREC Secretary | Peter Burke |
| Telephone | 03 9925 2251 |
| Email | human.ethics@rmit.edu.au |
| Mailing address | Research Ethics Co-ordinatorResearch Integrity Governance and SystemsRMIT UniversityGPO Box 2476MELBOURNE VIC 3001 |

 Should you have any concerns or questions about this research project, which you do not wish to discuss with the researchers listed in this document, then you may contact: