THE UNIVERSITY OF AUCKLAND
NEW ZEALAND
MEDICAL AND HEALTH SCIENCES

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PARTICIPANT INFORMATION SHEET

Can open-label placebos augment an existing online treatment for insomnia?

Principal Investigator: Professor Keith Petrie
Student Researcher: Sasha Finlay
Co-Investigator: Professor Lee Ritterband and Professor Borge Siversten

Purpose of the study and invitation:

You are invited to take part in a study examining whether different ways of presenting existing online treatments for insomnia improves sleep. This study is aiming to recruit 90 participants. This information document contains an overview of the study to help you make an informed decision as to whether you would like to take part in this research.

This study is being carried out by Sasha Finlay, a Masters student from the Department of Psychological Medicine, and Professors Keith Petrie (Psychological Medicine, University of Auckland), Lee Ritterband (Norwegian Institute of Public Health) and Borge Sivertsen (University of Virginia) who are supervising this project.

It is important that you read this document carefully so that you can make an informed decision about whether you would like to participate.

Who is eligible to take part in this study?

To take part in this research you must be 18 years of age or older, be able to read, speak and write in English, have a reported Insomnia Severity Index (ISI) score of ≥7 and have access to the internet, a computer and an active email address. You must be able to attend one approximate 30-minute session at the Clinical Research Centre (Grafton Campus).

You will not be eligible for this research if you are currently receiving psychological treatment for insomnia or have irregular sleep schedules that prevent the ability to follow intervention recommendations (e.g. night shift work). If you are currently taking any medications that interfere with sleep, currently receiving chemotherapy or treatment for hyperthyroidism, chemotherapy, chronic pain or epilepsy you will not be able to participate in this study. Furthermore, if you have any untreated sleep disorders other than insomnia you will not be able to take part in this research.

What does the study involve?

If you are eligible and choose to participate in this study, the researcher will arrange a time for you to complete one in-person session at the Clinical Research Centre, University of Auckland Grafton Campus. At this session, you will be asked to complete a baseline questionnaire that will ask about your sleep, health and various other measures. Following this, you will then be randomly assigned into one of three treatment groups.

The first group will be given access to the SHUTi (Sleep Healthy Using the Internet) online treatment program. SHUT-i is an interactive and tailored web-based program that requires participants to complete one module per week for six weeks. Participants in this group will also receive a 20mL plastic bottle labelled 'Placebos' containing 84 placebo tablets, with instructions to take two tablets every night before sleep. A placebo tablet is an inert or inactive tablet that does not contain any active drug ingredient.

The second group will be given access to the SHUTi (Sleep Healthy Using the Internet) online treatment program only. SHUT-i is an interactive and tailored web-based program that requires participants to complete one module per week for six weeks.

The third group is the waitlist control group will receive online sleep health patient education (PE). The PE program will include fixed material about the effect, prevalence, and causes of insomnia. The waitlist control group will be given full access to SHUT-i at the end of the study.

After you have completed your programme, the researcher will email you to ask you to complete a post-assessment questionnaire. In an additional three months time, you will be contacted again to complete the final questionnaire.

Benefits and risks

There are no expected risks or discomforts associated with this study. By taking part in this study, you can help us understand ways to improve existing treatments for insomnia.

This study will follow all COVID-19 guidelines and precautions set by the Clinical Research Centre.

Who pays for the study?

You will not incur any financial costs due to participation in this study. However, you will be required to arrange your own transportation to the in-person session at the Clinical Research Centre, University of Auckland Grafton Campus. If you choose to drive to the in-person session, we will provide free parking at the Grafton Clinical Centre.

To thank participants for their contribution to the research, you will receive a $50 shopping voucher. This research is funded by the Department of Psychological Medicine at the University of Auckland as part of a Masters in Health Psychology.

Your rights as a participant

Participation in the study is entirely voluntary. If you are a student of the researchers, your participation or non-participation in this study will have no effect on your grades or relationship with the University and you may contact my Head of Department should you feel that this assurance has not been met.

You can withdraw from the study at any time without giving a reason and withdraw any data traceable to you up until one week following your completion of the study. You will be given a copy of this document to keep. If you withdraw you will still receive a gift card.

All personal information will remain strictly confidential and no material that could personally identify you will be used in any report on this study. Participant names will only appear on the consent form, which will be coded with a participant identification number so that your identity is kept confidential on all questionnaires. After completion of the study, all confidential data, including computer data files, recordings and transcriptions, will be stored for a minimum period of six years to allow for publication and re-analysis, after which time it will be securely and confidentially disposed of. Research publications and presentations from the study will not contain any information that could identify you.

What will happen after the study?

Consent forms (which have participant names and contact details) will be kept in a separate folder from the questionnaires (which will be de-identified). Consent forms and de-identified questionnaires will be stored will be stored by the researcher in electronic format: in a password protected data file on a University of Auckland computer. Data and consent forms will be kept for a period of six years. Only the student researcher and research team will have access to this information.

You will be given the option of requesting a summary of the results of this study. If you select on the Consent Form that you would like to receive a summary, it will be sent to you via email once the study has been completed. As it takes some time to analyse the results of studies, it may be more than a year after your participation that you receive this information.

We appreciate the time you have taken to read this information. If you have any questions please contact:

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AHREC Chair contact details:
For concerns of an ethical nature, you can contact the Chair of the Auckland Health Research Ethics Committee at ahrec@auckland.ac.nz or at 373 7599 ext 83711, or at Auckland Health Research Ethics Committee, The University of Auckland, Private Bag 92019, Auckland 1142.

Support Services:
If participants experience any feelings of distress or discomfort through out the course of this study, there are free support services that you can contact 24/7 including Lifeline at 0800 543 354, or Healthline at 0800 611 116.

If you are a student at The University of Auckland, The University Health and Counselling provide short-term counselling support for students. You can contact the University Health and Counselling on 0800 698 427.

This study has been approved by the Auckland Health Research Ethics Committee (AHREC) on XXX for three years (ref: XXX).