Participant Information Sheet

Interventional Study - *Adult providing own consent*

Woolcock Institute of Medical Research

TITLE	Sleep Companion Phase 2 – Results and Sensor Validation Trial
SHORT TITLE	Sleep Companion and Sensor Trial
PROTOCOL NUMBER	Southern Adelaide Clinical Research Ethics Committee EC00188 Protocol Number 295.17
COORDINATING PRINCIPAL INVESTIGATOR/PRINCIPAL INVESTIGATOR	Prof Doug McEvoy (Principal Investigator); Dr Andrew Vakulin (Coordinating Principal Investigator) A/Prof Christopher Gordon (Project Leader)
ASSOCIATE INVESTIGATOR(S)	Prof Ron Grunstein (Woolcock Institute of Medical Research) Associate Professor Peter Catcheside, Dr Ching Li Chai-Coetzer
LOCATION	Adelaide Institute for Sleep Health: A Flinders Centre of Research Excellence Flinders Medical Centre

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project. This is because you feel that you are suffering from a sleeping problem. The research project is evaluating the accuracy of an online assessment tool for identifying sleep problems.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. 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, friend or your local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:
• Understand what you have read
• Consent to take part in the research project
• Consent to have the tests and treatments that are described
• Consent to the use of your personal and health information as described.

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

2 What is the purpose of this research?

The aim of this project is to assess the accuracy of an online assessment tool for identifying sleep problems when compared to a diagnosis given by a sleep specialist.

The aim of the Alertness Cooperative Research Centre (CRC) is to reduce the burden of impaired alertness on the safety, productivity and health of Australians. The broad CRC program aims to develop and deploy the next generation of shift scheduling and workplace design techniques; alertness assessment devices; individualised programs for better sleep health; and a range of innovative strategies to reduce fatigue.

These new products and services have the potential to reduce direct and indirect health and economic costs of sleep disorders in the community.

This research is being conducted by The Adelaide Institute for Sleep Health: A Flinders Research Centre of Excellence and Woolcock Institute of Medical Research (NSW).

3 What does participation in this research involve?

A member of the research team will contact you by phone and the consent process will occur completely outside of the medical care. For community consumers, the consent process will happen online and over the phone. You will be informed that your participation is entirely voluntary and that you can choose not to participate or to withdraw from the study at any time without affecting your medical care in any way and that no study assessments will be completed until the consent form has been signed.

Optional

You will also be asked to complete a sleep diary, wear a FitBit, and sleep with the EarlySense device underneath their mattress in their own home for one night or one week prior to their physician appointment. The FitBit is a wrist-worn device, like a watch, that records activity. This activity can be used to provide an indication of when the individual is asleep versus awake. The sleep diary asks you to keep a record of your sleep timing and perceived quality of sleep each night. The EarlySense device is non-invasive; simply placed underneath the mattress where it collects information about sleep duration and quality. The information collected by EarlySense is transmitted to a mobile device kept next to the bed. You will be asked to return the EarlySense device with them to their appointment with the physician.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way. The researchers aim to compare the results of the FitBit and EarlySense devices to the diagnosis provided by the physician. consultation There are no additional costs associated with participating in this research project, however you may be reimbursed for your time using the recording devices and any travel costs incurred. All tests and medical care required as part of the research project will be provided to you free of charge.

It is desirable that your local doctor be advised of your decision to participate in this research project. If you have a local doctor, we strongly recommend that you inform them of your participation in this research project.

4 What do I have to do?

You will be asked to commit to and complete all aspects of the study in accordance with the instructions provided. All aspects of the study are described and shown in the Figure below. The duration of the project is no longer than 4-weeks.

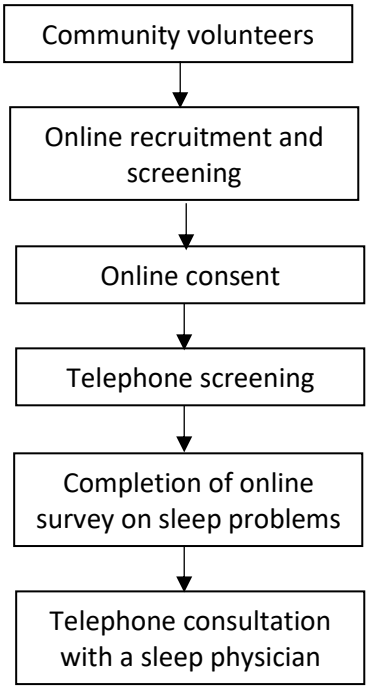

Figure 1 – Participation pathways through the study.

Community volunteers:
- Complete an on-line survey on sleep problems.
- Complete a single 20 minute telephone assessment with one or multiple sleep physicians

5 Other relevant information about the research project

There will be an expected number of 45 people taking part in the study with 45 recruited from the Woolcock Institute of Medical Research using online social media advertisements (e.g. Facebook). Both clinical patients and community volunteers will be recruited for this study.

This study follows on from an initial study which used existing and newly developed sleep health questionnaires designed to evaluate the likelihood of potential common sleep problems including, snoring/sleep apnoea, insomnia, delayed sleep phase disorder, shift work and chronic sleep restriction.

The aim of this project is to refine the risk assessment of common sleep problems as derived by the previous study when compared to sleep specialist assessment. You will follow the standard clinical procedures regarding consultation and treatment options for any sleep problem at your physician appointment.

You are participating in research that includes the Philips SmartSleep Analyzer. You will be providing responses related to your demographics, health, and/or a medical condition. Philips does not track who you are, nor collect any information that would identify you. Your

responses are not stored long term and will only be used by Philips for the purposes outlined in your research consent document, under the direction of the research sponsor.

6 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 this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with your medical practitioner.

7 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at this hospital. Other options are available; these include consultation with a sleep physician, sleep psychologist, or other relevant medical practitioner. Your study doctor will discuss these options with you before you decide whether or not the take part in this research project. You can also discuss the options with your local doctor.

8 What are the possible benefits of taking part?

There is no immediate benefit to you. Volunteers will have the opportunity to contribute to important research to help development of better online tools to help with sleep problem screening that can lead to online self-help sleep therapies that are accessible to wider community ahead of clinical investigation.

You will be provided with survey results and have a consult with a sleep physician and in doing so will be provided with a clinician review and further clinical investigation and sleep problem treatment if applicable.

9 What are the possible risks and disadvantages of taking part?

Project risks are low. You have a negligible risk of minor discomfort, or inconvenience, when completing the online questionnaires.

The decision tree algorithm tested in this project will provide feedback to you regarding their answers to the survey and their objective data. You will be followed up by a sleep specialist at which time they will consult with the clinician regarding the feedback and potential sleep problems, at which time they will be advised regarding pathways into normal clinical care when appropriate.

10 What will happen to my test samples?

No test samples will be collected.

11 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue.

If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, he/ she will explain the reasons and arrange for your regular health care to continue.

12 Can I have other treatments during this research project?

Whilst you are participating in this research project, it is important to tell your study doctor and the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your study doctor about any changes to these during your participation in the research project.

13 What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing. If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the sponsor up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

Please be aware that there are no implications of withdrawing from this participation, your decision to withdraw from this research will not affect your routine treatment, your relationship with those treating you or your relationship with your medical practitioner

14 Could this research project be stopped unexpectedly?

This research project is very unlikely to be stopped unexpectedly due to the low risks involved as well as the type of funding arrangement. In the event that the project does terminate early, you will still have continued access to normal clinical care.

15 What happens when the research project ends?

You will be presented with a report at the end of the survey providing them with information on sleep problems and a range of potential solutions for their sleep problem in a form of devices, on-line self-management tools and information on their sleep problem.

Part 2 How is the research project being conducted?

16 What will happen to information about me?

You will be allocated a unique study identifier (ID) and the research data will be stored identified by the unique ID alone on a secure database. Only your de-identified data will be used in research reports, presentations and scientific publications. Your data will be stored on a secure on-line database for a period of 15 years followed by standard confidential waste destruction procedures.

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential.

Local identifiable hardcopy records will be maintained at each study site in a locked filing cabinet in an office kept locked when unattended by a member of the research team. Identifiable electronic records will be maintained on secure local network facilities with login/password protected access restricted to personnel involved in the project. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project.

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 permission.

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

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

17 Complaints and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

18 Who is organising and funding the research?

This research project is being conducted by A/Prof Andrew Vakulin and funded by the Cooperative Research Centre (CRC), an Australian Government initiative.

You will not benefit financially from your involvement in this research project even if, for example, your data (or knowledge acquired from analysis of your data) prove to be of commercial value to The Cooperative Research Centre. In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to the Cooperative Research Centre, the study doctors or their institutions, there will be no financial benefit to you or your family from these discoveries.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

19 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). The ethical aspects of this research project have been approved by the Southern Adelaide Clinical 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.

20 Further information and who to contact

If you have any concerns which may be related to your involvement in the project (for example, any side effects), any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact any of the following people:

General contact person/s

Name	Christopher Gordon
Position	Project Leader
Telephone	(02) 9351 0586
Email	Christopher.Gordon@sydney.edu.au

Name	Helena Salomon
Position	Project Coordinator
Telephone	(02) 9114 0181
Email	Helena.Salomon@sydney.edu.au

Name	Matthew Rahimi
Position	Project Coordinator
Telephone	(02) 9114 0495
Email	Matthew.Rahimi@sydney.edu.au

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC)
HREC Executive Officer	Executive Officer
Telephone	(08) 8204 6453
Email	research.ethics@health.sa.gov.au

Local HREC Office contact (Single Site -Research Governance Officer)

Name	Alexandra Mudd
Position	Ethics Officer
Telephone	(08) 8204 6285
Email	Alexandra.mudd@sa.gov.au