Participant Information Sheet

Improving quantitative measurement of napping and overnight sleep in healthy older adults: a validation study

Principal Investigator:
Dr Sarah Buchanan, Consultant Neurologist/Senior Lecturer, Department of Medicine

Introduction

Thank you for showing an interest in this project. Please read this information sheet carefully. Take time to consider and, if you wish, talk with relatives or friends, before deciding whether or not to participate. If you decide to participate we thank you. If you decide not to take part there will be no disadvantage to you and we thank you for considering our request.

What is the aim of this research project?

Sleep is important in maintaining health, particularly brain health. Day-time sleep (napping) is an important element of overall sleep, and may have separate health effects from overnight sleep. However, methods traditionally used to assess napping can be inaccurate and limit our ability to determine the health effects of day-time sleep.

While newer methods such as wearable monitoring devices have improved the measurement of overnight sleep, the ability of these devices to detect naps, particularly in older adults, is poor.

This study aims to investigate how newer technologies can be used to improve the measurement of napping, and explore links between napping and overnight sleep. We will ask participants to wear, and have in their homes, a number of sleep monitoring devices for three days.

Who is funding this project?

This study is funded by a Health Research South Academic Start-up Grant.

Who are we seeking to participate in the project?

You are invited to take part in this study if you are aged 60-85 years, live in the community in Dunedin and take day-time naps one or more days per week.

Individuals are not eligible to participate if they have cognitive impairment or doctor diagnosed major neurological or other health conditions likely to influence sleep (e.g., sleep apnoea), use hypnotic medication regularly or live in rest-home or hospital level care.

If you participate, what will you be asked to do?

If you choose to take part in the study, a researcher will visit you at your home to explain the study, obtain your consent, and provide the equipment you will need. Over a period of three days, several devices will monitor your day-time and night-time sleep; the researcher will show you how to use the equipment at the first visit. You will be asked to:

- Wear two watch-like devices for three full days and nights (actigraphy and heart rate monitoring).
- While you are in your home environment, wear a wireless, lightweight Dreem™ headband each afternoon and overnight (polysomnography).
- Set up a video camera to film during each afternoon and early evening in the **non-bedroom** area where you usually nap.
- Have a Withings sleep tracking mat placed under your bed mattress.
- Complete two questionnaires about sleep, a sleep diary and a feedback form.

You will be asked to re-charge the Dreem™ headband each morning. Both the video camera and Withings sleep tracking mat will need to be plugged into a power socket. We will send you text messages each day to remind you to carry out these tasks.

Once you have completed the study, a researcher will visit you at your home to collect the equipment. You will be offered a $40 koha (supermarket voucher) upon completion of the study, and if you choose, a summary of your sleep will be sent to you once your sleep information has been processed.

Is there any risk of discomfort or harm from participation?

The wrist-worn devices can cause minor skin irritation or discomfort in a small number of people, but may be removed if this occurs. The Dreem™ headband is comfortable and does not disturb sleep or activity for most people, however a small number of people might be disturbed by the sensation of the device. If this occurs, it can be removed at any time. Overall, participation in this study is not expected to cause inconvenience or interference with your daily activities.

What information will be collected, and how will they be used?

You will be asked to complete a short questionnaire to collect information about you, such as your age, ethnicity and medical conditions. This information will be stored securely and in a de-identified format to maintain your privacy and confidentiality.

The sleep information collected by the watch-like devices, Dreem™ headband and Withings sleep mat are held securely within the devices. When the devices are returned to the researchers the data will be downloaded and stored securely. Anonymised sleep information from the Dreem™ device will be transferred securely to Beacon Biosignals, the company who manufacturers this equipment.

You will also be provided with a brief diary to record the approximate times of your naps, and asked to complete two questionnaires about sleep and a feedback form. As one of the questionnaires is a clinical screening tool, researchers will be required to notify your GP of any result indicating a potentially significant sleep disorder. This allows appropriate follow-up to be arranged.

The purpose of the video camera is to record any naps that you take, and this will be compared against the sleep information collected by the other devices. The camera may be turned off to stop it recording at any time for any reason, or you may request the deletion of any video footage, without having to explain why. You will be asked to obtain permission from other household members and/or visitors regarding the use of a video camera within the household.

All data will be stored securely, in locked facilities and password protected databases at the University of Otago for at least 10 years, then securely destroyed. Electronic records, including video camera footage, will be accessed by approved researchers only.

What about anonymity and confidentiality?

Video footage

At the second study visit, you will be given an opportunity to request the deletion of any video footage that you do not want researchers to view or have. If you choose to delete any video footage, the researcher will provide you with a laptop computer and instructions to allow you to delete video footage in private.

Identifiable Information

Identifiable information is any data that could identify you (e.g., your name, date of birth or address). The Principal Investigator and small team of approved researchers will have access to your identifiable information to allow researchers to contact you and conduct study visits. Identifiable information will be stored securely in locked facilities and password protected databases at the University of Otago.

De-identified (Coded) Information

To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated by the research team. Instead, you will be identified by a code. The Principal Investigator will keep a secure list linking your code with your name, so that you can be identified by your coded data if needed.

The results of the study may be published in scientific journals or presented at conferences, but not in a form that would reasonably be expected to identify you.

Future Research Using Your Information

If you agree, your coded information may be used for future related and unrelated scientific research. You will not be told when future research is undertaken using your information. Your anonymised sleep information will be sent overseas.

Risks

Although every effort will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with de-identified (coded) information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information is currently very small, but may increase in the future as people find new ways of tracing information.

Rights to Access Your Information
You have the right to access a summary of information about you collected as part of this project. You also have the right to request that any information you disagree with is corrected.

Māori Data Sovereignty
Māori data sovereignty is about protecting information or knowledge that is about (or comes from) Māori people. We recognise the taonga of the data collected for this study. To help protect this taonga we allow Māori organisations to access de-identified study data, for uses that may benefit Māori.

If you agree to participate, can you withdraw later?

Your participation is voluntary. You may withdraw from participation in the project at any time without having to explain why. If you decide to withdraw from the research, your data will be securely destroyed but it may not be possible to withdraw data that has already been used.

Any questions?

If you have any questions now or in the future, please feel free to contact either:

Investigator:	Alice Cox
Phone:	021 279 0054
Email:	neurology.trials@otago.ac.nz

OR

Investigator:	Dr Sarah Buchanan
Email:	sarah.buchanan@otago.ac.nz

This study has been approved by the University of Otago Human Ethics Committee (Health). If you have any concerns about the ethical conduct of the research you may contact the Committee through the Human Ethics Committee Administrator (phone +64 3 479 8256 or email humanethics@otago.ac.nz). Any issues you raise will be treated in confidence and investigated and you will be informed of the outcome.