ABN 15 211 513 464

Associate Professor Chris Gordon
The University of Sydney
Faculty of Medicine and Health
Susan Wakil School of Nursing and Midwifery
Woolcock Institute of Medical Research
CIRUS Centre for Sleep and Chronobiology

Woolcock Institute of Medical Research
The University of Sydney
NSW 2006 AUSTRALIA
Telephone: +61 2 9114 0040
Facsimile: +61 2 9114 0014
Email: christopher.gordon@sydney.edu.au
Web: http://www.sydney.edu.au
http://www.woolcock.org.au

The feasibility of a mobile application (SleepFix) delivering behavioural therapy for Insomnia in primary care

PRIMARY CARE PARTICIPANT INFORMATION SHEET

(1) What is this study about?

Part A

In this part of the study, we aim to explore the perspectives and experiences of primary care professionals in implementing digital sleep health interventions.

Part B

In this part of the study, we aim to assess the feasibility of a novel mobile application called SleepFix in primary care. SleepFix delivers sleep retraining therapy to people with insomnia. This therapy involves shortening the amount of time spent in bed in order to consolidate sleep.

(2) Who is running the study?

The study is being carried out by the following researchers:

- Associate Professor Christopher Gordon from the Woolcock Institute of Medical Research, The University of Sydney
- Professor Ronald R Grunstein, head of Sleep and Circadian Group, Woolcock Institute of Medical Research
- Associate Professor Delwyn Bartlett from the Woolcock Institute of Medical Research, The University of Sydney
- Professor Nick Glozier from Brain and Mind Centre, The University of Sydney.
- Associate Professor Keith Wong from the Woolcock Institute of Medical Research, The University of Sydney
- Dr Janet Cheung from School of Pharmacy, University of Sydney

This study is being funded by the Department of Health (Federal), Sydney Health Partners Medical Research Future Fund. This study is sponsored by the Woolcock

Institute of Medical Research. The SleepFix app is supplied by Alertness CRC who do not have financial interests in this study.

(3) What will the study involve for me?

There are two parts to the study. You can participate in either part A or part A and B.

Part A

1. Complete a short online survey

You will be invited to complete a short online survey on a secure online platform. The survey will take up to 10 minutes to complete. The survey will collect information on your demographics, years of practice, practice size and your experience with digital health interventions and sleep management.

2. Take part in a semi-structured interview

After completion of the online survey you will be invited to take part in a semi-structured interview to be conducted remotely over the phone, through Zoom or Skype. The interview will explore your perceptions and experiences with digital therapies and sleep health. The interview will take approximately 40 minutes and will be recorded, transcribed and analysed. .

Part B

You will be asked to recruit insomnia patients for the researchers. Following your assessment of the patient's insomnia, we ask you to:

- Complete a short checklist (3 questions) about the patients sleep (this will be collected by the research team following the study)
- Provide the patient with the provided handout detailing instructions for getting started
- Complete a short survey at the end of the study

Patients in this study will be given access to the SleepFix app on their smartphone free of charge. The therapy program is instituted over 3 weeks with a Fitbit (provided by the research team) and another optional 3 weeks of usage. We will ask them complete a short online questionnaire at start of the study and after 6 weeks.

(4) How much of my time will the study take?

Part A

Complete a short online survey – up to 10 minutes

Take part in a semi-structured interview – approximately 30-40 minutes

Part B

Completing the checklist with the patient should take a few minutes. The follow-up survey regarding your experience with prescribing SleepFix will take a maximum of 10-15 minutes each.

(5) Who can take part in the study?

To be eligible to participate in this project, you must:

- Be a registered General Practitioner, Nurse or Pharmacist (Part A and B)
- Attempt to recruit insomnia patients *(Part B only)*
- Agree to assessing the patient using the checklist *(Part B only)*

(6) Do I have to be in the study? Can I withdraw from the study once I've started?

Being in this study is completely voluntary and you do not have to take part. Your decision whether to participate will not affect your current or future relationship with the researchers or anyone else at the Woolcock Institute of Medical Research and The University of Sydney.

If you decide to take part in the study and then change your mind later, you are free to withdraw at any time. You can do this by contacting study coordinator Melissa Aji on 02 9114 0481 or Woolcock.sleepfix@sydney.edu.au.

(7) Are there any risks or costs associated with being in the study?

Aside from giving up your time, we do not expect that there will be any risks or costs associated with taking part in this study.

(8) Are there any benefits associated with being in the study?

The value of being involved in the research and perhaps improved care of your insomnia patient. In addition to this:

Part A

(1) Following completion of the survey, you will be given the option to go into the draw for a $200 Visa gift card (1 gift card to be given per health care professional group). If you wish to take part in the draw, you will need to provide a mobile number or email at the end of the survey. When recruitment is complete, a random draw of supplied contact details will be undertaken by a researcher who is not involved in the study. The successful participant will be notified. Please note, participation in the prize draw is voluntary.
(2) If you choose to take part in the semi-structured interview, you will be reimbursed for your time by way of a $50 gift card.

Part B

(3) You will receive financial remuneration ($50) for each patient referred who downloads and activates the app.

(9) What will happen to data collected during the study?

Interviews in Part A will be conducted over the phone, Zoom or Skype and recorded as audio and/or visual recordings and stored electronically on a password protected database, on a secure server (Research Data Storage maintained by the University of Sydney) until transcribed. Only the investigators and study coordinators will have access to the recordings. All recordings will be transcribed and checked for accuracy, and the original recording will be erased. Transcripts will be de-identified and stored on a secure server located at the Woolcock Institute and maintained for a minimum of 5 years after the completion of the study.

For Part A and B, all patient information will be stored securely and his/her identity/information will be kept strictly confidential, except as required by law. Your name/personal information will not appear in any of the study results. Study findings may be published in a peer-reviewed journal, but you will not be individually identifiable in these publications.

(10) Will I be told the results of the study?

You have a right to receive feedback about the overall results of the study. You can tell us that you wish to receive feedback by providing your contact details in the survey or directly to the research coordinators. This feedback will be in the form of a summary of the project's findings. You will receive this feedback after the study is finished.

(11) What if I would like further information about the study?

When you have read this information, Melissa Aji will be available to discuss it with you further and answer any questions you may have. If you would like to know more at any stage during the study, please feel free to contact:

- Melissa Aji at the Woolcock Institute of Medical Research, The University of Sydney on (02) 9114 0481.
- Paula Ordonez at the Woolcock Institute of Medical Research, The University of Sydney on (02) 9114 0495.

(12) What if I have a complaint or any concerns about the study?

The Sydney Local Health District Research Ethics Committee has reviewed and approved this study in accordance with the National Statement on Ethical Conduct in Human Research (2007) incorporating all updates. This Statement has been developed to protect the interests of people who agree to participate in human research studies. Should you wish to discuss the study or view a copy of the Complaint procedure with someone not directly involved, particularly in relation to matters concerning policies, information or complaints about the conduct of the study or your rights as a participant, you may contact the Executive Officer on 02 9515 6766 and quote protocol number *X19-0418.*

The conduct of this study has been authorised by the Woolcock Institute of Medical Research, any person with concerns or complaints about the conduct of this study may

also contact the Research Governance Officer on (02) 9114 0412, email: jelliot@woolcock.org.au and quote project number *X19-0418.*

This information sheet is for you to keep.