Study: Management of Sleep Apnoea and Insomnia in Primary Care (MOSIP)
Ethics Committee Approval Number: 2021/HRE00154

Principal Investigator: Professor Robert Adams, Flinders Health and Medical Research Institute (FHMRI): Sleep Health, Flinders University. Please direct all enquiries to Dr Nicole Lovato (nicole.lovato@flinders.edu.au).

Sites: This project will be managed by FHMRI: Sleep Health, Flinders University, SA.

1. INTRODUCTION:

We are contacting you because your GP has referred you to this research study. This study aims to find out if insomnia and sleep apnoea (the two most common sleep disorders) can be effectively treated in general practice settings. You recently completed a questionnaire which indicated that you may have symptoms of either insomnia or sleep apnoea. Therefore, you may be eligible for this study.

Insomnia	Sleep Apnoea
Insomnia symptoms include; • Difficulties falling asleep, • Long night time awakenings, • Early morning awakenings • Feelings of fatigue, concentration difficulties, or poor mood during the day.	Sleep Apnoea symptoms include; • Brief narrowing or closure of the upper airway during sleep, • Feelings of non-restorative sleep, • Loud or frequent snoring • Feelings of sleepiness, fatigue, concentration difficulties, or poor mood during the day.

Before you decide if you wish to participate or not, it is important for you to understand why the study is being done and what is involved. Please take the time to read the following information carefully and to ask further questions and discuss it with your partner/family or others if you wish. Your decision to participate or not is entirely voluntary and if you choose not to participate, it will not in any way affect your relationship with your GP in any way.

1.1. Purpose of the Study:

You are being invited to take part in a study aiming to investigate the management of sleep disorders in general practice.

The two most common sleep disorders are insomnia, and obstructive sleep apnoea. Over 4 million Australians suffer from these disorders. Insomnia and obstructive sleep apnoea can reduce quality of life, and daytime feelings and functioning.

In this study, we would like to find out how your sleeping difficulties are managed over the next 12 months. This will include collecting information about the care that you receive from your GP and Practice Nurse, referrals to other care providers, and any other treatments that you access for insomnia or obstructive sleep apnoea.

If you participate in this study, you will be able to work with your GP and a practice nurse who will help you decide which treatment option / options are best for you. During this study, we do not wish to change the care that you receive in any way.

After the study is complete (12-24-months from now), we will provide your GP with several additional treatment options for insomnia and obstructive sleep apnoea.

1.2. Your participation is voluntary

Your participation in this study is completely voluntary. You may incur costs for treatment of your sleep condition, as part of your usual medical care. Furthermore, you are not obligated to undergo treatment for your sleep condition as part of this trial, and you will make the choice as to which treatment, if any, is acceptable to you, following consultation with your medical practitioner. If you do not want to take part in this study you do not have to. You should feel under no obligation to participate in this study. Choosing not to take part in this study will not negatively impact your current or future care from your GP.

You do not have to decide whether or not to participate in this study right now. If you would like to, you can discuss your participating in this study further with your GP, family members, or friends.

1.3. Your withdrawal from the study

If you do choose to participate in this study, you are under no obligation to continue with the research study. You may change your mind at any time about participating in the research. People withdraw from studies for various reasons and you do not need to provide a reason, but should you choose to provide a reason, it may help improve our future research.

You can withdraw from the study at any time by completing and signing the 'Participant Withdrawal of Consent Form'. This form is provided at the end of this document.

If you withdraw from the study, you will be able to choose whether the study will destroy or retain the information it has collected about you. You should only choose one of these options. Where both boxes are ticked in error or neither box is ticked, the study will destroy all information it has collected about you.

If you withdraw from the study, your information that has already been analysed and/or included in a publication may not be able to be withdrawn or destroyed. In such circumstances, your personal information will continue to form part of the project/research study records and results. Your privacy will continue to be protected at all times.

2. HOW MUCH TIME WILL IT TAKE?

If you chose to participate in this study, you will be invited to complete the following tasks:

1. Complete the 'Consent Form' on the next pages, to indicate that you are interested in participating in this study (5 minutes),

2. Complete a brief questionnaire about symptoms of insomnia, obstructive sleep apnoea, and daytime feelings and functioning (30 minutes),

3. Follow-up assessments;
    a. We will ask you to complete a brief questionnaire about symptoms of insomnia, obstructive sleep apnoea, and daytime feelings and functioning, and what treatments/care was recommended to you. This is to help us find out how effective your treatment was in improving these different symptoms. We will ask you to complete this questionnaire at several times, in about;
        i. 3-months,
        ii. 6-months, and
        iii. 12-months (15-minutes each).
    b. We will ask you to complete diaries covering 3 time periods (0-3 months, 4-6 months and 7-12 months) to record your
        i. usage of health services, including hospital admissions and medical appointments,
        ii. costs and time associated with attending any appointments relating to sleep health care.
    c. Appointments will be made for you to attend your general practice for a review with your GP and/or practice nurse at 3, 6 and 12 months from your commencement in the study.

3. ELIGIBILITY:

The following individuals may be eligible and invited to participate in this study;

1. Aged 18 years or older
2. Living in Australia
3. Referred to this study by their GP
4. Because some of the treatments are only available in English, ability to speak and understand English will be required to participate
5. Not currently pregnant
6. Access to Medicare
7. Not a Department of Veterans Affairs card holder

4. POTENTIAL BENEFITS AND RISKS:

Participating in this study will not change the usual care that you receive from your GP.

Patients in this study will be provided with a $10 Coles/Myer gift card for each set of questionnaires that you complete. We will ask you to complete questionnaires before treatment, and approximately 3, 6, and 12 months from now.

5. HOW WILL MY DATA BE USED?

Throughout the study, we will treat your personal information with the strictest security measures.

5.1. Data collection:

We will collect several different types of data during this study:

1. **The treatment option/s that you receive** for insomnia and/or sleep apnoea during the study.

2. **Questionnaire data** – we will ask you to complete a brief questionnaire about your sleep, daytime feelings/functioning, and quality of life at several points during the study. These can be completed either online, via pen-and-paper, or over the phone. This will help us find out what treatment you receive and how effective the treatments is.

3. **Interviews** – we may contact you to invite you to participate in a telephone, face to face or tele-conference discussion about your experiences with the different treatment/s that you choose. You do not have to participate in this interview if you don't want to.

4. **Observation** – one of our researchers may be present to observe the assessment and treatments you receive from general practice staff as part of this study. You do not have to have the researcher present if you do not want them to be there.

5. **GP data** – we will collect some data about your general practitioner (their name, practice, gender, GP clinic, etc.). We will also collect information about the treatments and care that your GP provides to you during this project (e.g. how they assess your sleeping problems, which treatments they refer you to, and how many follow-up appointments you have with your GP).

6. Information about how **much you use your treatment option/s** – we are interested in collecting information about how much you use the different treatment options and how effective they are. For example, if you choose a treatment for insomnia, we will be interested in what treatment you received. Alternatively, if you are treated with continuous positive airway pressure for obstructive sleep apnoea, we will be interested in the frequency and duration of your use of the treatment during sleep.

7. **Services Australia (health) data**; We would like to collect information about your access to different treatments/care from your GP and any specialists during this study. This is to find out if the treatments you access improve your health and reduce your need for additional care in the future. If you participate in this study, we will ask you to complete a consent form providing your permission to access your health data collected by the Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS), so we can measure any changes in your healthcare use and medication prescriptions. This form takes about 5 minutes to complete. Medicare collects information on your doctor visits and the associated costs, while the PBS collects information on the prescription medications that you obtained at pharmacies. The consent form is sent securely to Services Australia who holds MBS and PBS data confidentially.

   We would also like to collect information about the costs of your use of public and private hospital care during this study from hospital administrative costs data.

8. If you are referred to a **specialist sleep physician** during the study, we would also like to collect information about the care that you are provided. This may include information about your overnight sleep study, and the different treatments that are recommended to you.

9. If you are referred to a **psychologist** during the study, we would also like to collect information about the care you are provided. This may include information about the treatment provided by the psychologist, how many sessions you attended and if you continue to follow the advice provided.

5.2. Data storage:

All of your information will be recorded and stored as password-protected files on secure University networks, or hard-copy data stored in locked filing cabinets at FHMRI Sleep Health at Flinders University. Only the researchers directly associated with this research will have access to your data. All of these people will have a duty of confidentiality to you as a research participant, and no information that could identify you will be accessible to anyone else. Your personal information will not be disclosed in any report/presentation.

- CPAP use data: Data about how much you use your CPAP equipment will be stored on password-protected online cloud-based systems. You, your healthcare providers, and researchers on this project will have access to these data.
- MBS/PBS data: If you consent to the use of your MBS and/or PBS data, it will not be sent overseas outside of Australian jurisdiction. The MBS/PBS data will be stored on local Services Australia Networks until completion of the trial. The use of your MBS/PBS data is governed by the Privacy Act 1988.
- Hospital administrative costs data will be stored on password-protected files on the secure Flinders University network.

A separate password protected Data Linkage file will be maintained throughout the trial. The Data Linkage file will be used to 'match' the data the study has collected from different sources (i.e. from you, the participating GPs and MBS/PBS data, hospital administrative costs data). Following 'matching' of the data, the Data Linkage file will be permanently destroyed, and any remaining identifying information will be permanently deleted from all remaining data sources. All de-identified data will be stored as password-protected files, on secure University networks and will be accessed only by researchers working on the trial.

5.3. Data usage and reporting:

We aim to present the result of this study in medical/scientific journals, student research thesis materials, research grant applications, media and Government reports, and at academic conferences. Your confidentiality is our priority, and you will not be identifiable and your personal information will not be disclosed in any report/presentation including this data.

If you consent, we will store and use your de-identified questionnaire, study data for future research related to sleep disorder treatment. This is optional. You are not required to consent to the future use of your data for this purpose.

Your data will never be provided to researchers outside this study for unrelated future research. Similarly, your MBS and PBS data will never be used for future unrelated research. Even if you do consent to your study data being used for future research related to sleep disorder treatment, your MBS/PBS data will not be used for this purpose as Services Australia only permits the use of its data for this particular study.

5.4. Data disposal:

Following completion of the study, we will permanently delete all of the identifying personal information that you will provide (e.g. including your name, email, postal address, and your

other personal identifying information). All MBS/PBS (health) data will be securely deleted 15 years after the publication of the main results. Any hard-copy data (e.g. paper-based questionnaires) will be entered into de-identified digital spreadsheets, and the original copy with any identifying personal information will be permanently destroyed.

5.5. How do I access the results of this research?

During the final questionnaire completed 12-months from now, we will give you an option to tell us whether you are interested in receiving a summarised report of the results of the study. We will email this report to you after all of the participants have finished the study and we have analysed the data. You are also welcome to contact us at any time during the study and tell us that you are interested in receiving a report of the results of the study, after the study is finished.

5.6. Future Studies:

With your consent, we would like to store and use your de-identified Questionnaire data, and data about your use of different treatments (e.g. CPAP therapy for obstructive sleep apnoea, insomnia treatment, specialist care) for future research purposes related to sleep disorder treatment.
You are not required to consent to the future use of your data for this purpose.
Your data would not be provided to researchers outside this study for future research, whether related or unrelated to sleep disorder treatment.
Services Australia does not permit the use of its data for future research outside of this study, so your MBS and PBS data can never be used for future research related to sleep disorder treatment.

5.7. Will my information be sent overseas?

If you consent to the use of your MBS and/or PBS data, it will not be sent overseas outside of Australian jurisdiction and is governed by the Privacy Act 1988.

6. DETAILS OF ETHICAL APPROVAL, CONCERNS OR COMPLAINTS:

This study has been approved by the Southern Adelaide Clinical Human Research Ethics Committee (Application number: 2021/HRE00154). This research project will be conducted according to the National Health and Medical Research Council National Statement on Ethical Conduct in Human Research 2007 (Updated 2018). If you wish to speak with an independent person regarding concerns or a complaint, the National Health and Medical Research Council's policy on research involving human participants, or your rights as a participant, please contact the Southern Adelaide Clinical Human Research Ethics Committee, at Health.SALHNofficeforresearch@sa.gov.au, ph: 8204 6453.

6.1. What if I have any questions or concerns?

Any questions or concerns about your health, sleeping difficulties, or sleeping pill use during the study should be directed to your GP. Any questions about the online questionnaires, or study participation should be directed to Dr Nicole Lovato (nicole.lovato@flinders.edu.au, ph: (08) 7221 8307) at the Flinders Health and Medical Research Institute: Sleep Health.

6.2. What do I do if I have a privacy complaint?

If you have a privacy complaint in relation to the use of your MBS/PBS data you should contact the Office of the Australian Information Commissioner (OAIC). You will be able to lodge a complaint with them.

Website: www.oaic.gov.au
Telephone: 1300 363 992
Email: enquiries@oaic.gov.au
Mail: GPO Box 5218, Sydney NSW 2001

7. IF I WANT TO PARTICIPATE, WHAT DO I DO?

If you want to participate, you should read the 'Consent Form' on the next pages. If you agree with each of these 'consent' points, you can sign the Consent Form. You will then be provided with a brief questionnaire, and practice staff will book the appointments for your study involvement.

Thank you,
On behalf of all study investigators,
Professor Robert Adams.

Study investigators:
Robert Adams, Ching Li Chai-Coetzer, Andrew Vakulin, Nicole Lovato, Alexander Sweetman, Billingsley Kaambwa, Richard Reed, Emer Van Ryswyk, Leigh Roeger, Gabriel Moore, Nigel Stocks, Nick Zwar, Oliver Frank, Doug McEvoy, Leon Lack, Yohannes Melaku, Sutapa Mukherjee, Sarah Appleton, Anne Redman, Jenny Haycock, Elizabeth Hoon, Daniel Byrne, Andrea Natsky, Nicole Grivell, Mandy O'Grady.

Patient Consent Form

Study: Improving Sleep Disorder Management in Australian Primary Care

Ethics Committee Approval Number: 2021/HRE00154

Principal Investigator: Professor Robert Adams, the FHMRI: Sleep Health, Flinders University.

1. I am aware that participating is voluntary, and I am free to withdraw at any time, and this will not impact my relationship or the quality of care provided by my General Practitioner,
2. I have read the Patient Information Form and agree to take part in the study. My consent is given freely,
3. I agree that the following details have been explained to my satisfaction:
    a. That the study aims to improve access to effective treatments for insomnia and sleep apnoea in general practice,
    b. That the study will involve questionnaires completed at several time-points,
    c. I may be contacted to participate in a semi-structured interview (discussion) about my experiences with treatment, and
    d. My GP or practice nurse will assist me in deciding on the most appropriate and effective treatment option.
4. I agree that I have had the opportunity to ask questions about the study, so far as it affects me, and the potential risks and burdens have been fully explained to my satisfaction,
5. I agree to the collection and use of my online questionnaire data, and GP data (referrals to other care providers for sleeping problems, treatment of sleeping problems in general practice) for the purposes of this study.
6. Although I understand the purpose of the research study is to improve the quality of health/medical care, I am aware that this study may not benefit me,
7. I have seen informed that the information gained in the study may be published in journal articles, student theses, media articles, government reports, and conference/media/community presentations,
8. I am aware that all of the information collected during this study including data I provide will be treated with the highest security, and I will remain confidential in all reports including data I provide. Confidentiality of information will be protected by all staff within the limitations of the law,
9. I am aware that a copy of this Patient Information and Consent Form will be provided to me,
10. If I have any questions regarding the study, I am aware that I can contact Dr Nicole Lovato (nicole.lovato@flinders.edu.au) at any time, and to request access to study results after it has concluded
11. I am aware that the Southern Adelaide Clinical Human Research Ethics Committee has granted approval for this study

I agree to all of the above:

☐ Agree. ☐ Do not agree.

12. I agree to participate in the optional brief telephone interview about the study.

☐ Agree. ☐ Do not agree.

13. I agree that my de-identified data (online questionnaires, referrals/management in general practice, administrative cost data) can be used by researchers named on this application for other related research projects. I understand that this is optional and I am not required to agree to use of my data for this purpose in order to participate in this study. Note: Services Australia does not permit the use of its data for future research outside of this study, so your MBS and PBS data can never be used for future research related to sleep disorder treatment.

☐ Agree. ☐ Do not agree.

14. I give permission for my doctors, other health professionals, public and private hospitals or sleep diagnostic and treatment providers to release information to Flinders University concerning my disease(s) and treatment(s) for the purposes of this project. I understand that such information will remain confidential.

    ☐ Agree. ☐ Do not agree.

15. I give permission for Flinders University to provide my general practitioner with any relevant study-related results.

    ☐ Agree. ☐ Do not agree.

Patient to complete:
Name: _____

Signature: _____ Date: _____

PARTICIPANT WITHDRAWAL OF CONSENT FORM
Improving Sleep Disorder Management in Australian Primary Care

I wish to WITHDRAW my participation in the study effective from the date below. I request that the study handles the information they have collected about me in the following way (choose one option):

☐ DESTROY all information collected about me to date so it can no longer be used for research
☐ RETAIN all information collected about me to date so it can continue to be used for research

I understand that:
1. no further information about me will be collected for the study from the withdrawal date;
2. information about me that has already been analysed and/or included in a publication by the study, may not be able to be destroyed; and
3. choosing to withdraw from the study will not affect my access to Health Services or Government benefits.

…… ……
Signature **Date**

……..……
Please print full name

This form should be forwarded by email to: nicole.lovato@flinders.edu.au .

Alternatively, forms can be posted to:
Dr Nicole Lovato
FHMRI: Sleep Health: A Flinders University Centre of Research Excellence,
Level 2A, Mark Oliphant Building
Flinders University,
5 Laffer Drive, Bedford Park, 5042,
South Australia