BMJ Open Supplementary Material 2

OPIN Information Sheet_1, Version 3 dated 18 August 2020

THE UNIVERSITY OF SYDNEY

ABN 15 211 513 464

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Insomnia Symptoms Study

PARTICIPANT INFORMATION STATEMENT

(1) What is this study about?

You are invited to take part in a research study examining the sleeping patterns of people who experience insomnia symptoms. We are interested to understand how insomnia symptoms (such as difficulty falling asleep, or frequent awakenings) change over time. We hope to use the data collected in this study to inform how people might respond to different treatments for insomnia.

You have been invited to participate in this study because you have expressed interest in taking part and identify as having insomnia symptoms. This Participant Information Statement tells you about the research. Knowing what is involved will help you decide if you want to take part. Please read this sheet carefully and get in touch with the researchers to ask questions about anything that you don't understand or want to know more about. Contact details can be found at the end of this information sheet. Participation in this research study is voluntary.

By giving your consent to take part in this study you are telling us that you:

✓ Understand what you have read.

- ✓ Agree to take part in the research study as outlined below.
- ✓ Agree to the use of your personal information as described

(2) Who is running the study?

The study is being carried out by the following researchers:

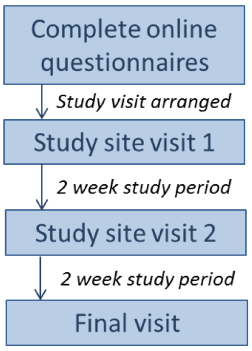
- Ben Colagiuri, Associate Professor, The University of Sydney School of Psychology
- Louise Sharpe, Professor, The University of Sydney School of Psychology
- Nick Glozier, Professor of Psychological Medicine, Central Clinical School of Medicine and Brain & Mind Centre, University of Sydney
- Delwyn Bartlett, Associate Professor, Central Clinical School of Medicine, University of Sydney
- Amelia Scott, PhD, The University of Sydney School of Psychology
- Daniel Costa, Honorary Research Fellow, Pain Management Research Institute, University of Sydney
- Zahava Ambarchi, Study Coordinator, The University of Sydney, School of Psychology

This study is being funded by The University of Sydney and the Australian Research Council.

(3) What will the study involve for me?

The study will take place over four weeks. You will firstly be required to complete an online questionnaire to determine whether you are eligible to take part. If you are eligible, you will be contacted to schedule a time to attend the study site.

The screening questionnaire asks about basic details such as your age and gender, your current insomnia symptoms and treatment, and some brief questions about your mental and physical health. Participating in the study involves wearing a watch-like sleep monitoring device, as well as completing a daily sleep diary and questions about your mental and physical health.



If you agree to participate, you will be asked to attend three visits:

1) On visit one, you will collect the watch and a sleep diary

2) On the second visit, you will complete some brief questionnaires about sleep and other symptoms over the previous two weeks

3) On the final visit you will return the watch and complete some brief questionnaires about sleep and other symptoms over the previous two weeks

Prior to your attendance to any of the three face-to-face study visits, the study coordinator will contact you and ask you some questions regarding cold and flu-like symptoms and contact with positive or potential cases of COVID-19. If necessary, your visit will be rescheduled or conducted via phone, in which case the watch and sleep diary will be mailed to you.

The sleep monitoring device is called an Actiwatch. It is a safe, non-invasive and accurate way to measure people's sleep-wake patterns. You will be asked to wear it continuously (day and night). You will also be asked to complete a brief sleep diary each morning that should take you approximately 2 minutes. An SMS text reminder will be sent to you each morning to remind you to complete the sleep diary.

At visit two and the final visit, you will be required to complete a longer survey. This survey includes questions about your insomnia symptoms, fatigue, mood, other physical symptoms experienced. These questionnaires will take approximately 25 minutes.

You may be asked to take part in Phase 2 of the study. This invitation will be randomly determined so that some people are invited into Phase 2 while others are not. It will be entirely your decision as to whether you choose to participate in Phase 2 and you will be provided with an additional information sheet and consent form regarding this at your second site visit.

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

This screening questionnaire should take you approximately 20 minutes. We estimate that attending the study site on three occasions and completing testing will take 1 hour and 15 minutes in total (i.e., <30min each visit, see the above diagram), excluding travel time. Completing the sleep diary each morning will take approximately 2 minutes per day. Therefore, the total time commitment is approximately 2 ½ hours.

(5) Who can take part in the study?

People eligible to take part will be adults (age over 18), proficient in English, who experience insomnia symptoms of at least moderate severity. People cannot take part if they are currently receiving treatment (such as psychological therapy, prescription or over-the-counter medications, herbal supplements or homeopathic formulations), undertake regular night shift work, are currently pregnant, intending to fall pregnant in the next 3 months, breastfeeding or less than 1 year post-partum, if they seem to have a different kind of sleep disorder (e.g. sleep apnoea), if they are currently experiencing a significant medical condition requiring invasive treatment or surgery, and/or psychiatric condition.

(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 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 informing the study coordinator (by phone or by e-mail) that you no longer wish to take part. If you decide to withdraw from the study, we will not collect any more information from you. Please let us know at the time when you withdraw what you would like us to do with the information we have collected about you up to that point. If you wish your information will be removed from our study records and will not be included in the study results, up to the point that we have analysed and published the results.

(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?

You will receive $60 after you complete the study. This will be provided to you in the form of cash. In terms of other benefits associated with participation, we anticipate that our results will provide benefit to our understanding of insomnia symptoms and their treatment.

(9) What will happen to information about me that is collected during the study?

During the study, we will be collecting various types of information from you. This includes your responses on survey questions, your daily sleep diary, and data that is collected from actigraphy watches.

In order to send you SMS reminders to complete your sleep diary, your phone number (but not your name or other personal details) will be provided to a third-party SMS service provider to perform this service. The SMS provider will only be used to send you reminder texts to complete the sleep diary for the duration of your involvement in the study, and only for that purpose. No other text messages will be sent to you during or after your participation in the study.

Data collected from this study will be published in journal articles and/or conference presentations in summary form without any personally identifying information. In addition, de-identified data may be shared with other researchers or research groups for the purpose of conducting extra analyses of our data, or comparing our results against similar studies. Under no circumstances will we provide identifying information (e.g. names, contact details) to other researchers.

By providing your consent, you are agreeing to us collecting personal information about you for the purposes of this research study. Your information will only be used for the purposes outlined in this Participant Information Statement, unless you consent otherwise. Your information will be stored securely and your identity/information will be kept strictly confidential, except as required by law. Study finding may be published, but you will not be individually identified in these publications.

(10) Can I tell other people about the study?

Yes, you are welcome to tell other people about the study. However, if you know other people participating in the study, it is best to talk with them about the study after you have all completed your sessions, in case your experiences influence theirs.

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

When you have read this information, please get in touch with the researchers if you have any further questions. You can contact either the study coordinator on [redacted] or at psychology.sleepstudy@sydney.edu.au, or Ben Colagiuri at ben.colagiuri@sydney.edu.au or (02) 9351 4589.

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

You have a right to receive feedback about the overall results of this study. You can tell us that you wish to receive feedback by ticking the relevant box below. This feedback will be in the form of a one page summary of the study findings. You will receive this feedback after the study is finished.

As well as the overall results of the study, you will be provided with specific feedback about your sleep-wake patterns based on reporting in a sleep diary as well as wearing the Actiwatch. This will be provided shortly after your participation in the study has been completed.

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

Research involving humans in Australia is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this study have been approved by the HREC of the University of Sydney [2019/552]. As part of this process, we

have agreed to carry out the study according to the *National Statement on Ethical Conduct in Human Research (2007).* This statement has been developed to protect people who agree to take part in research studies.

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the university using the details outlined below. Please quote the study title and protocol number.

The Manager, Ethics Administration, University of Sydney:

- **Telephone:** +61 2 8627 8176
- **Email:** ro.humanethics@sydney.edu.au
- **Fax:** +61 2 8627 8177 (Facsimile)

This information sheet is for you to keep

OPIN Consent Form_1, Version 2 dated 10 September 2020

Insomnia Symptoms Study

CONSENT FORM

If you have read the participant information sheet and would like to take part, you may complete the consent process below.

1) I have read the Participant Information Statement and have been able to discuss my involvement in the study with the researchers if I wished to do so.	Yes / No
2) I understand that participation involves three visits to the University of Sydney, Camperdown, Sydney, and that a researcher will contact me by phone and/or e-mail to arrange this.	Yes / No
3) I understand that my mobile number will be shared with a third-party SMS provider for the sole purpose of sending me a daily text reminder while I am part of the study.	Yes / No
4) First name	
5) Surname	
6) Contact phone: (Note, include area code if using a landline)	

7) Please indicate any preferences regarding a suitable day or time to contact you:

8) Contact email (please note that we will automatically send you a copy of the participant information statement for you to keep).

9) I understand that being in this study is completely voluntary and I do not have to take part. My decision whether to be in the study will not affect my relationship with the researchers or anyone else at the University of Sydney now or in the future.

Yes

No

10) I understand that I can withdraw from the study at any time.

Yes

No

11) I would like to receive feedback about the overall results of the study.

Yes

No

Insomnia Symptoms Study

Optional additional participation - [redacted] for Insomnia Symptoms

PARTICIPANT INFORMATION STATEMENT

(1) What is this study about?

You are invited to take part phase 2 of the study you are currently participating in. The aim of this part is to determine whether [redacted] to improve your insomnia symptoms.

You have been invited to take part in this study by chance. In other words, your participant ID has been randomly selected via a computer programme.

This Participant Information Statement tells you about *the additional parts of this research*.

Participation in this part of the research study is voluntary.

By giving your consent to take part in this study you are telling us that you:

- ✓ Understand what you have read.
- ✓ Agree to take part in the research study as outlined below.
- ✓ Agree to the use of your personal information as described.

(2) What will this part of the study involve?

For the remaining two weeks of the study, your participation in the study will not change, with the exception of two parts;

- You will be required to take [redacted]
- You will be asked to record your [redacted] intake along with your sleep diary

(3) Will this take additional time?

We anticipate that the above additions to your research participation will take very little extra time.

(4) Do I have to be in this part of the study? Can I withdraw from the study once I've started?

At this point in the study, you have a few choices available to you:

A. You may take part in the additional component of the study that involves [redacted]

B. You may choose not to take part in the additional component of the study but continue in the way that you previously agreed to

C. You may choose to withdraw altogether, which you can do at any time

You do not have to agree to take part in this component of the research study, and your decision whether to participate or not will not affect your current or future relationship with the researchers or anyone else at 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 informing the researchers (by phone or by e-mail) that you no longer wish to take part. If you decide to withdraw from the study, we will not collect any more information from you. Please let us know at the time when you withdraw what you would like us to do with the information we have collected about you up to that point. If you wish your information will be removed from our study records and will not be included in the study results, up to the point that we have analysed and published the results.

(5) Are there any risks or costs associated with being in this part of the study?

There are no known risks of taking [redacted]

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

It is possible that you will experience improvements to your insomnia symptoms after taking [redacted]. You will not receive additional reimbursement for this additional component of the study – i.e. you will still receive $60 at the end of the study.

(7) What will happen to information about me that is collected during the study?

We will collect some additional information from you if you take part in this part of the study. This includes your thoughts and expectations about taking [redacted], and your compliance with [redacted]. Otherwise, there are no differences to the way that your information is collected and managed in this part of the study.

(8) Can I tell other people about the study?

You are welcome to speak to others about this study (e.g. a friend, family member, GP), but we ask that you do not speak to other people who may be participating in the study. This is because other people will not have been invited to this part of the study, and we do not wish for this knowledge to affect them in any way.

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

Research involving humans in Australia is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this study have been approved by the HREC of the University of Sydney [2019/552]. As part of this process, we have agreed to carry out the study according to the *National Statement on Ethical Conduct in Human Research (2007).* This statement has been developed to protect people who agree to take part in research studies.

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the university using the details outlined below. Please quote the study title and protocol number.

The Manager, Ethics Administration, University of Sydney:

- **Telephone:** +61 2 8627 8176
- **Email:** ro.humanethics@sydney.edu.au
- **Fax:** +61 2 8627 8177 (Facsimile)

This information sheet is for you to keep

OPIN Consent Form_2, Version 2 dated 10 September 2020

Insomnia Symptoms Study

Optional Additional Consent

PARTICIPANT INFORMATION STATEMENT

I, ... [PRINT NAME], agree to take part in the additional component of this research study.

In giving my consent I state that:

- I understand the purpose of the study, what I will be asked to do, and any risks/benefits involved.
- I have read the Participant Information Statement and have been able to discuss my involvement in the study with the researchers if I wished to do so.
- The researchers have answered any questions that I had about the study and I am happy with the answers.
- I understand that being in this study is completely voluntary and I do not have to take part. My decision whether to be in the study will not affect my relationship with the researchers or anyone else at the University of Sydney now or in the future.
- I understand that I can withdraw from the study at any time.
- I understand that personal information about me that is collected over the course of this project will be stored securely and will only be used for purposes that I have agreed to. I understand that information about me will only be told to others with my permission, except as required by law.

☐ I give consent for the researchers to contact me about future opportunities to participate in research relating to the current study (e.g. to be interviewed about my experiences)

☐ I give consent for the researchers to contact me to see whether I am interested in taking part in any media stories related to the current study

☐ I give consent for the researchers to contact me about future opportunities to participate in research not directly related to the current study

Please note: under no circumstance would we forward your information onto another party without your prior consent.

.....

Signature

.....

PRINT name

.....

Date