

Participant Information Statement

Research study: Exploring the scope of physical activity for the management of hypersomnolence – a mixed-methods study.

Sub study: Australian Survey – Lived Experience of Idiopathic Hypersomnia and Exercise Survey

Download a copy of this information [here](#).

1. What is this study about?

We are conducting a research study about central disorders of hypersomnolence, this sub study is regarding idiopathic hypersomnia. This will involve completion of a survey made up of two components. People with hypersomnolence have been shown to have reduced cardiovascular fitness and physical activity compared to people without this condition, and exercise is suggested as a strategy to manage these conditions, but there is limited information about what exercise is like or how it should be approached for people living with these conditions. This study aims to further explore the scope of physical activity (PA) and exercise for people living with HS through a survey. Participation is optional and voluntary.

The study is being carried out by the following researchers:

- Dr Elizabeth Machan (Faculty of Medicine and Health)
- Professor Kieron Rooney, (Faculty of Medicine and Health)
- Dr Sheila Sivam (Royal Prince Alfred Hospital)
- Professor Brendon Yee (Faculty of Medicine and Health and Royal Prince Alfred Hospital)
- Professor Ron Grunstein (Faculty of Medicine and Health)
- Professor Bandana Saini (Faculty of Medicine and Health)
- Miss Evelyn Groves (Faculty of Medicine and Health)
- Mr Jeffrey Doukakis (Faculty of Medicine and Health)
- Ms Michelle Chadwick (Hypersomnolence Australia)

Miss Evelyn Groves is conducting this study as the basis for her Honours degree at the University of Sydney. Miss Groves's degree is a Bachelor of Applied Science (Exercise Physiology) (Honours).

2. Who can take part in the study?

We are seeking the following participants for inclusion in our study:

1. Adults 18 years or older with a confirmed medical diagnosis of idiopathic hypersomnia.
2. People currently living in Australia (for a minimum of 12 months)
3. People willing to complete the surveys described below

However, participants who meet any of the following would be excluded from participating in the study:

1. Are unable to read English.
2. Are unable to provide informed consent.
3. Have been diagnosed with an untreated or unstable sleep condition that would further affect your sleep health (for example, untreated significant obstructive sleep apnea).

3. What will the study involve for me?

If you decide to take part in this study, you will be asked to participate in an online survey delivered by REDcap which is compatible with all software set ups.

The survey will have two parts; part one includes demographic and condition information and part two is regarding your lived experience of exercise with relation to idiopathic hypersomnia.

Part 1: *Demographics and condition specific surveys*

- **Demographics & diagnosis questionnaire:** This is a series of questions including your age, identified sex, health status (which may require proof of diagnosis), time since diagnosis and medications relating to your HS condition. This may take up to 10 minutes to complete.
- **International Physical Activity Questionnaire:** This 27-item questionnaire estimates your physical activity and time spent sitting in the last 7 days. It takes up to 20 mins to complete.
- **Idiopathic Hypersomnia Severity Scale:** This 14-item questionnaire assesses the severity and frequency of idiopathic hypersomnia symptoms in the last month. It takes up to 10 minutes to complete.

Part 2: Consumer Informed *Lived Experience of Exercise Survey*

- This part of the study will invite you to rate your agreement on 33 statements that are about your experience with exercise in relation to your HS condition. These statements have been devised from semi-structured interviews and focus groups with a number of people living with idiopathic hypersomnia. The response style is a scale between 1-7, with one being "Strongly Disagree" and 7 being "Strongly Agree". Please refer to the diagram below. This will take approximately 20 minutes to complete.



Total complete time commitment is estimated to be 60 minutes. You are welcome to pause and resume the survey at any time.

4. Can I withdraw once I have started?

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

Your decision will not affect your relationship with any other consumer group, such as Sleep Disorders Australia and/or Hypersomnolence Australia. If you are a current or former patient of any of the investigators, your decision to withdraw from this study will not affect your relationship with that investigator or your ongoing treatment.

By submitting your survey, you are consenting to take part in the study. You can withdraw any time before submitting by exiting the survey. Once your responses are submitted, you will have provided an email address, however this will not be used for contact unless indicated you would like to be contacted regarding the results or other studies similar to this. However you cannot withdraw after submitting the survey.

Partially completed surveys will be excluded from the data analysis.

5. Are there any risks or costs?

Some questions ask you to consider potentially sensitive information about yourself, your diagnosis and exercise. This may cause some participants to become upset or distressed. If you become upset or distressed, we recommend you consider stopping the survey and consider contacting your usual care GP and/or any one of the following free counselling services:

- Lifeline Australia: <http://www.lifeline.org.au/> ph: 13 11 14
- Australian Psychological Society: <http://www.psychology.org.au/FindaPsychologist/>

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

6. Are there any benefits?

You will not receive any direct benefits from being in the study.

7. What will happen to information that is collected?

Your information will be securely stored, and results may be published. You will not be identifiable in these publications

Sharing research data is important for advancing knowledge and innovation. A de-identified set of the data collected in this study may be made available for use in future research.

8. Will I be told the results of the study?

You have the right to hear the results of this study. If this is the case, please provide your contact details on the consent form provided. This feedback will be provided as a plain language summary.

9. What if I would like more information?

For any questions or further discussions, please contact Evelyn Groves at egro4250@uni.sydney.edu.au.

10. What if I have a complaint or any concerns?

The ethical aspects of this study have been approved by the Human Research Ethics Committee (HREC) of The University of Sydney [ethics identifier: 2022/HE000880] according to the National Statement on Ethical Conduct in Human Research.

If you have any concerns about the study procedures or would like to make a complaint to someone not involved in the study, please contact the University's Human Ethics Manager (human.ethics@sydney.edu.au or +61 2 8627 8176).

Please include this question at the end of the survey to confirm consent:

I consent to my survey responses being used for research purposes.

☐ Yes

☐ No