Improving Sleep Health
ISH

PARTICIPANT INFORMATION SHEET

What is the purpose of the study?

This research project aims to comprehensively characterise sleep health in people living with a neurological condition or working with people living with a neurological condition and is run within the Systematic Profiling in Neurological Conditions (SPIN) Research Program. Comprehensive sleep health characterisation for people living with a neurological condition or working with people living with a neurological condition has not been undertaken in Australia and is the first step towards developing individualised interventions. You are invited to participate in this research project as you live with a neurological condition or working with people living with a neurological condition.

This participant information sheet provides specific details about the research project. In particular, it discusses the assessments and procedures involved in the project. This information will help you decide if you want to participate in this research project.

Please read through all the information carefully. If you do not understand or want to know more about specific aspects of the project, please email the principal investigator, Dr. Mitchell Turner (mitchel.turner@ecu.edu.au). It is worthwhile discussing with a relative, friend or healthcare provider prior to participating in this research project.

Participation in this research project is voluntary. If you do not wish to participate in this research project, you do not have to. You will receive the best possible care regardless of whether you participate in this research project.

If you decide to participate in the research project, you will be asked to provide consent via an online form. By providing consent, you are indicating to us that you:

- Understand the information provided in the participant information sheet and consent form
- Consent to participate in the research project
- Consent to undertake the assessments and procedures that are described
- Consent to the use of your information as described

You can download a copy of this participant information sheet for your personal records.

Study Location

This project will be conducted remotely via online surveys, and all required materials will be sent to you.

Who is conducting this research?

This project is being conducted by researchers of the SPIN Research Program at Edith Cowan University.

Project Sponsor

This project and the SPIN Research Program are supported by MSWA.

What does participation in this research involve?

Participant Eligibility: To be included in the project, you need to have been formally diagnosed with a neurological condition or working with people living with a neurological condition. You need to be between 18 and 85 years of age and able to follow verbal or written instructions.

Written and Informed Consent: Prior to the commencement of study procedures or any engagement in the project procedures, you will be required to provide consent via an online form. By completing this consent form, you are indicating that you have read and understood the requirements of the research project, have had all questions answered to your satisfaction and are freely agreeing to participate.

Study Assessments: You will be asked to complete a demographics questionnaire and four questionnaires pertaining to multiple aspects of your sleep and sleep environment. You may also be asked to answer a short questionnaire pertaining to your current disease status (Patient Derived Disease Step, PDDS). These will be made available via the survey link. You may decide to undertake an objective sleep assessment (described below, which will involve wearing a device that measures your sleep).
A detailed overview of study procedures is provided below for your review.

Study Procedures consist of the following:

Demographics Questionnaire: We will ask you questions regarding your comorbidities, contact details, education and occupation. These will not take more than five minutes to complete.

Sleep Environment Questionnaire (SEQ): You will be asked to answer 7 questions about your sleep environment. It should only take several minutes to complete.

Sleep Health Index (SHI): We will ask you to answer 14 questions to gain an understanding of your overall sleep health (such as sleep satisfaction and sleep efficiency). It should not take more than ten minutes to complete.

STOP BANG Questionnaire: We will ask you to fill out 8 questions to gain an understanding regarding your risk of sleep apnoea. This questionnaire should take no longer than five minutes to complete.

Insomnia Severity Index (ISI): We will ask you to fill out 7 questions to gain an understanding regarding any insomnia you may experience. This questionnaire will take approximately five minutes to complete.

Patient Derived Disease Step (PDDS): We will ask you to rate your mobility on a 6-step scale. This will not take more than three minutes of your time.

These five questionnaires should not take more than 33 minutes to complete.

You will be given the opportunity to undergo voluntary sleep and circadian assessments in addition to the above-outlined questionnaires. Please indicate if you would like to participate in this component in the online consent form.

Sleep and Circadian Assessment: You will be asked to wear a sleep monitor on your forehead for seven consecutive nights. The monitor is attached to an electrode, which will adhere to your forehead for the duration of your sleep. The sleep monitor measures your brain activity while you are asleep, allowing for the measurement of sleep stages, quality and restlessness. We will also ask you to place a temperature sensor on your bedside table for 7 day/nights to record the light and temperature conditions in your usual sleep environment.

All materials will be delivered to you and collected via paid delivery service at no cost to you.

Do I have to take part in this research project?

Participation in this research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage without any prejudice. Your decision on whether or not to take part or to withdraw at any point during the study will not affect your normal treatment or your relationships with those treating you.

What are the alternatives to participation?

You do not have to participate in this research project. Declining to participate in this research project will in no way affect your normal treatment or your relationships with your health professional, community associations or the research team.

What are the benefits of participating in this research?

Assessments used in the study can provide you with important information on your sleep, which can benefit your overall well-being. These results will be made available to you, your nominated health professional (with your permission). Your participation will mean that we collect information about your sleep, which could be useful for your health professional in providing you with the best treatment. We expect the information we collect within this study will inform the development of new sleep interventions for people with neurological conditions.

What are the possible risks and disadvantages of taking part?

Time commitments are associated with this study; however, these are small. Additionally, while unlikely, the monitoring of sleep could result in increased sleep anxiety.

What if I change my mind?

You have the right to withdraw your consent at any time. If you wish to withdraw, please notify the project coordinator via email. If you withdraw your consent during the research project, the research team will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and comply with the law. You should be aware that any data collected by the research team up to the time you withdraw will form part of the research project results. If you decide that you do not want your results used for the research project, please communicate this via email to the project coordinator.

What will happen to my test results?

Your test results will be de-identified and stored on password-encrypted computers for seven years. Access to your data in digital format is restricted to study personnel. After seven years, your data will be permanently deleted.

All test results will be communicated via research publications and seminars in general terms. All participant data will be de-identified prior to presentation and will be presented as a cohort to ensure your confidentiality.

Will I receive my data at the end of the research project?

We will be providing you and/or your nominated health professional with a report of your results upon completion of the project.

Will my data be kept confidential?

Please be assured that any information obtained about you as part of this project will be treated with the strictest of confidence. Your data will be available to researchers only and will be securely stored on password-protected computers as well as password-encrypted hard drives and servers.

Can I have other treatments during this research project?

It is understood that during a research project, other opportunities for treatments may arise. You can choose to undertake these treatment options.

Who has reviewed this research project?

An independent group of people called the Human Research Ethics Committee (HREC) reviews all research in Australia involving people. The ethical aspects of this research project have been approved by the HREC at Edith Cowan University (study identification number 2023-04402-TURNER).

What if I have complaints?

If you suffer any injuries or complications as a result of the research project, you should contact the research team as soon as possible. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital. If you

would like to speak to an independent party about this research project, you may contact the Edith Cowan University Human Research Ethics Committee (phone: (08) 6304 2170, email: research.ethics@ecu.edu.au). Kindly mention the study identification number (2023-04402-TURNER) in your communications to help with the processing of your request.

Contacting the research investigators?

We are happy to answer any questions you may have now or at any point throughout the study. Please contact the principal investigator:

Principal Investigator

Dr Mitchell Turner (Edith Cowan University)

School of Medical and Health Sciences Edith Cowan University
270 Joondalup Drive
JOONDALUP WA 6027
Email: mitchel.turner@ecu.edu.au
Phone: 6304 2210

If you have concerns about the research and wish to speak to an independent party, you may contact:

Edith Cowan University Human Research Ethics Committee
Phone: (08) 6304 2170
Email: research.ethics@ecu.edu.au

Thank you for taking the time to read through this information sheet.
To take part, please scan the QR code provided below to access the consent form.

https://redcap.ecu.edu.au/surveys/?s=RLHKYY8AJP3F4N3X