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Participant Information Sheet

Title	The Effects of Novel Light Therapy in Individuals with Neurological Disorders- Stroke
Short Title	ENLighTIND-Stroke
Protocol Number	ENLighTIND-Stroke V1.4
Project Sponsor	Edith Cowan University
Principal Investigator	Dr Danielle Bartlett
Associate Investigator(s)	Dr Travis Cruickshank, Prof David Blacker, Prof Simon Laws, A/Prof Mandy Stanley, Mrs Manja Laws, Dr Johnny Lo, Dr Shane Rogers, A/Prof Jennifer Walsh, Dr Kathleen Maddison, Mr Mitchell Turner
Study Site Location(s)	Perth, Western Australia

Part 1 What does my participation involve?

1. Introduction

This research project, which is part of the Systematic Profiling in Neurological Conditions (SPIN) Research Program, aims to evaluate the therapeutic effects of light therapy in combination with sleep health guidelines (SHG) or SHG alone, on fatigue and sleep in people that have experienced a stroke more than three months ago. You are invited to take part in this research project as you have been identified as someone who experienced a stroke at least 3 months ago.

This participant information sheet provides specific details about the assessments and treatments involved in the project. This information will help you decide if you want to participate in this research project.

Please read through all of the information carefully. If you do not understand or want to know more about specific aspects of the study, please do not hesitate to contact the investigators on this project (contact information is provided at the end of this document). It is worthwhile consulting with a relative, friend and/or your health care professional prior to participating in this research study.

Importantly, participation in this research project is voluntary. If you do not wish to participate in this research project, you do not have to. If you do not wish to participate in this project, this will in no way effect your treatment or your participation in the broader SPIN Research Program. You will receive the best possible care regardless of whether you participate in this research project.

If you decide you want to take part in the research project, you will be asked to sign the consent form provided with this document. By signing this document, you are indicating to us that you:

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

You will be provided with a copy of the participant information sheet and consent form for your personal records.

2. What is the purpose of the study?

The purpose of the study is to evaluate the therapeutic effects of light therapy combined with sleep health guidelines (SHG), compared to SHG alone, on fatigue and sleep outcomes in people living with the chronic effects of a stroke. Studies have shown that light therapy can reduce feelings of fatigue and sleepiness in individuals following traumatic brain injury and in those living with Parkinson's disease. Here, we aim to determine whether these effects can also be seen in people living with the chronic effects of a stroke.

3. What does participation in this research project involve?

Prior to the commencement of assessment procedures or engagement in experimental treatments you will be required to sign a study consent form (provided with this participant information sheet). This consent form ensures that you have read and understand the requirements of the research project.

Confirmation of Eligibility

If you have been contacted via the SPIN Observational Study, your preliminary eligibility for the study will have been confirmed prior to the study team contacting you. However, you will be asked to participate in an additional, 5-minute phone call to answer questions about your general health to confirm your eligibility for the study. If you are not part of the SPIN Observational Study, you will need to complete the full screening process over the phone to confirm your eligibility. You will be asked to provide verbal consent prior to undertaking the assessments during the screening call. The screening process includes a cognitive assessment and several questionnaires asking about your fatigue levels, daytime sleepiness and mood. This screening call is expected to take no longer than 30 minutes and we will contact you within a week following this call to discuss your eligibility for inclusion in the study. Many studies have strict inclusion criteria that need to be met to ensure study integrity. If you are not deemed eligible for the study, we will provide you with information on future studies and details on the outcomes of the study if you so wish. If you are deemed eligible for the study, you will be required to provide written consent upon enrolment into the study. Importantly, by signing the attached consent form, you are consenting to the inclusion of your screening data in the study.

Study Randomisation

Following enrolment into the study, you will be randomly assigned by a research statistician to receive one of two interventions (treatments). This randomisation process is carried out

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using specialised computer software and assignment to the group occurs by chance, meaning that the investigators have no influence over which group you will be assigned to.

Study Interventions

You will be randomly assigned to receive an intervention of either light therapy plus SHG or SHG alone. Both interventions will run for four weeks and will be followed by a four-week observational period to assess the duration of the effects of the treatment (also known as a "washout" period). If you are randomised to the SHG only group, at the end of the study period you will be offered a four-week trial with the light therapy glasses. If you are randomised to the light therapy plus SHG intervention, you will be required to wear green-blue light emitting glasses for 30 minutes each morning for every day of the four-week intervention period (the light therapy glasses can be seen in Figure 1 below). This will be accompanied by SHG, which consists of targeted advice about bed and wake times, bedtime routines and lifestyle factors that may influence your sleep. The SHG intervention will consist of these sleep health guidelines only. At the end of each week of the intervention, you will be sent a text message or email (or this can be completed using a booklet if you prefer) asking how many days during that week you adhered to the intervention and, if you are allocated to the light therapy group, how long you wore the glasses for in each instance.

Figure 1. Green-blue light emitting glasses that will be used to deliver light therapy.

Study Procedures

In order to test the effectiveness of the therapies, you will be asked to complete testing at three time points: 1) upon enrolment into the study, 2) following the four week intervention and 3) following a four week "washout" period (to determine the duration of the effects of the therapies). You may also be asked to complete additional assessments throughout the intervention period, including those noting your fatigue, emotional and physical well-being and sleep health. These assessments are expected to take no longer than 5 minutes to complete in each instance. All assessments will be conducted by trained and blinded examiners (people who do not know which treatment group you belong to). All testing procedures can be conducted in your own home using paper and pencil-based questionnaires or online using Microsoft Teams or Qualtrics, which are secure digital platforms used extensively for telehealth and questionnaire-based studies.

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Study Assessments

You may be asked to undertake fatigue, sleep, mood, biological and quality of life assessments as part of this research project. A detailed overview of assessments is provided below. These assessment procedures are expected to take approximately 1 hour to complete. In addition to the measures below, we will be assessing the feasibility (practicality) of the intervention, as well as the assessment battery. This will allow us to optimise the intervention and assessments for any future studies on light therapy and to ensure that they can be more seamlessly integrated into clinical practice. Part of this feasibility assessment is a semi-structured interview asking about your experiences with the intervention and any barriers to participation in the intervention. This interview is expected to take no longer than 15 minutes and can be conducted over video conferencing-based platforms, such as Microsoft Teams. Other assessments that you may be asked to complete are as follows:

- Fatigue Assessment: You may be asked to complete questionnaires regarding your levels of fatigue. These questionnaires will take no longer than 5 minutes to complete.
- *Sleep and Circadian Rhythm Assessment*: You may be asked to wear an activity monitor (actigraph monitor) on your wrist for 7 consecutive nights. An actigraph monitor is an accelerometer that measures any movement while you are awake or asleep, allowing for the measurement of sleep periods and restless sleep. This may be accompanied by a sleep diary that will need to be completed every morning and evening for 7 days and a light and temperature sensor that we may ask you to place on your bedside table for the duration of the one-week period. It is important to undertake these assessments for this length of time to ensure your sleep habits are measured accurately. You may also be asked to complete questionnaires to measure your sleep quality, sleep efficiency and sleep preferences. Completion of the sleep diary and sleep questionnaires should take no longer than 30 minutes in total.
- *Quality of Life Assessment*: You may be asked to complete questionnaires to assess changes in health-related quality of life. These questionnaires are estimated to take no longer than 15 minutes.
- *Mood Assessment*: You may be asked questions about your current mood state and your mood over the previous week. We may also ask you questions about your motivation to participate in the intervention. These questionnaires will take approximately 5 minutes to complete.
- *Biological Assessment*: You may be asked to provide a saliva sample by passively drooling into a special collection tube at baseline and following the initial four weeks of the trial to collect your genetic material (DNA and RNA). We will provide you with a reply-paid envelope to send the sample back to the study investigators via post. The specialised tubes ensure that the sample remains viable for one month at room temperature.

  These biological samples are being collected for genomic (genetic) analyses. This will enable us to investigate the biological factors that may determine whether an individual will respond or not respond to a therapy. Furthermore, provided that you are happy for us to retain your samples, your samples will also be stored for future genomic analyses. However, this is entirely voluntary and you may refuse to provide saliva samples for future, as yet undetermined research. You also have options regarding how your samples are treated and stored- these options are listed in the consent form at the end of this document. Further information about saliva sample collection and storage is provided later in this information letter.

- *Work Productivity Assessment:* You may be asked to complete a questionnaire about your work productivity. This questionnaire is expected to take no longer than 5 minutes to complete.

We would also like to contact your treating physician to access your clinical information. Your clinical information is vital in allowing us to better interpret the results of the interventions.

Reimbursement

No costs are associated with participating in this study. All materials will be accompanied by a reply paid, addressed envelope to cover costs associated with postage of materials.

4. 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. Your decision on whether or not to take part, or to withdraw, will not affect your normal treatment or your relationships with those treating you, or your participation in the SPIN Research Program.

If you decide to take part in this research project, a consent form can be found following this document, which should be signed and returned as instructed. You are encouraged to keep a copy of your consent form and this information sheet.

5. What are the alternatives to participation?

You do not have to participate in this research project. If you do not wish to participate, you will receive your treatment as normal.

6. What are the benefits of participating in this research?

There are a number of potential benefits associated with participation in this research project. Based on previous studies, we believe that light therapy will reduce levels of fatigue and daytime sleepiness and will improve your sleep quality. We believe that this will lead to improvements in quality of life.

7. What are the possible risks and disadvantages of taking part?

A time commitment is associated with the study. While not likely, there are some risks associated with assessments in the study. Please read the following sections carefully for information on risks associated with study procedures.

What do I need to know about the light therapy interventions?

Engagement in the light therapy intervention may cause minor inconvenience, particularly as it may change the way you carry out your normal morning activities. However, we have chosen to deliver the therapy using light-emitting glasses, rather than other options such as lamps, to reduce the impact on your daily routine as much as possible. Some participants may experience headaches or eye strain as a result of using the light therapy glasses. Participants

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using the light therapy glasses will be contacted for the first three days of using the glasses to ensure that there are no adverse effects. In the rare event of an adverse effect, participants will be asked to stop using the glasses.

What information do I need to know about completing mood assessments?

We are asking you to answer a range of questionnaires which look at multiple aspects of your life, such as mood, social network, activities of daily living and quality of life. Though highly unlikely, some people might experience discomfort after answering these questionnaires. Should you experience any discomfort we encourage you to talk to a family member or your treating physician. Should this not be an option for you please find contact details for the following helplines:

Lifeline Australia: **13 11 14**

Beyond Blue: **1300 22 4636**

We will also include these details in your questionnaire pack should you feel the need to speak to someone at any point during the study.

What information do I need to know about DNA (Genetic) testing and storage?

This part of the information sheet is to give you more information about how your DNA (genetic) material will be analysed and stored at Edith Cowan University.

What is DNA?

DNA is the abbreviation for deoxyribonucleic acid, which are chemical compounds that make up your genetic material, or genes.

Your genes are inherited from your (biological) parents. The genes you inherit from your parents may lead to a medical problem in early or late life. A gene mutation is an alteration to your DNA and may also be associated with a particular disease.

Testing of your genes or genetic material can provide us with information on what may happen to your general health, or perhaps that of your family, either now or in the future.

Why is DNA tested?

DNA testing is often undertaken in medical research. It helps us learn more about diseases and what causes them. In doing so, it may assist in clinical management of patients with such diseases. In this study, we will be conducting an exploratory analysis of your DNA. This means that we will be looking for new (novel) genetic information, the clinical significance of which is not yet known. This means that we will not be able to provide you with the results generated from these analyses, as we don't yet know how these potential genes could influence health and disease.

Informed consent

DNA testing will only be carried out if you have given your consent in writing.

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We recommend that you give careful consideration to the important information set out in this information sheet. If you have any questions, we encourage you to ask the person enrolling you. Before you give your consent, we want you to be sure and clear about all aspects of the testing and storage of your genetic material.

How will my DNA be obtained in this study?

In this study, DNA will be extracted from cells in the saliva sample that you provide as part of the study.

Once extracted from your saliva sample, DNA appears as a clear fluid (like water). For storage purposes, it is kept in a small plastic tube and labelled only with an ID number. This sample is stored in an access restricted freezer at Edith Cowan University.

DNA can be stored for an indefinite period of time. Therefore, if your sample remains in storage, it may be used in future tests and research that is currently unknown.

Given this, we give you the option of instructing us on how your saliva/DNA sample is to be used and stored. If you agree to participate in this study and when you sign the consent form, you will be asked to select one of the three options for using and storing your saliva/DNA sample:

1. Test and then store my saliva/DNA sample indefinitely for research only in the field of neurological conditions.
2. Test and then store my saliva/DNA sample indefinitely for future unspecified research.
3. Discard my saliva/DNA sample after it has been tested for the specific purpose of this study.

As we will be using your DNA sample for exploratory (meaning novel) research rather than targeting known disease-carrying genes we will not be able to pass results of this specific component of the study on to you. The results will be published in a group format (de-identified).

There may be the rare circumstance when the Chief Investigator is placed in the position where disclosure of your genetic material may be required by law. This may be as a result of a court order, for example. Wherever possible, you will be informed if this should occur.

Sometimes blood components, including DNA, are sent to other research institutions within Australia and/or overseas. If this occurs, your saliva/DNA sample will be labelled with an identified code or number, which only the members of this research study team will be able to trace back to you. If collaborative research is undertaken with other research institutions, please be assured that your identity will not be disclosed to individuals working in these other research institutions. Should you not wish to have DNA sample be made available for collaborative research please advise the project coordinator in writing.

What if I change my mind?

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You have the right to withdraw your consent and saliva/DNA sample at any time. If you wish to have your saliva/DNA sample withdrawn, please notify the project coordinator in writing. Be assured that we will promptly discard your saliva/DNA sample in an appropriate manner (via incineration).
You may wish that your saliva/DNA sample be discarded upon your death, in which case we ask that you make such provisions by advising the project coordinator in writing either at the commencement of or at any stage during the conduct of this study.

8. What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available that may influence your current treatment. This information will be communicated to you.

9. Can I have other treatments during this research project?

It is understood that during a research project, other opportunities for treatments may arise. It is not prohibited for you to undertake these treatment options; however, we do ask that you report any changes in medications during the study period, as this may impact on the results of the study.

10. What if I withdraw from this research project?

If you decide to withdraw from the research project, please notify a member of the research team before you withdraw. This notice will allow that person or the research coordinator to discuss any special requirement linked to withdrawing.

If you withdraw your consent during the research project, the study staff 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 to comply with law. You should be aware that 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, you must communicate this in writing to the research project coordinator.

Part 2 How is the research being conducted?

11. What will happen to my test results?

Your tests results will be stored on password-encrypted computers for a maximum of fifty years. After this time, your data will be permanently destroyed.

Your biological samples will be de-identified and stored in locked freezers in a secure laboratory at Edith Cowan University. We ask that you allow your biological samples to be stored and used for future studies. This is very important to advance research into biological markers of neurological conditions.

All test results will only be used for research purposes. These 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 confidentiality.

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12. Will my data be kept confidential?

Please be assured that any information obtained about you as part of this study will be treated with the strictest of confidence. Clinical information along with your study data will be available to researchers only and will be securely stored in lockable filing cabinets located at Edith Cowan University. All clinical data will be transferred onto password-protected computers and securely stored on password encrypted hard drives and servers. All collected data will be de-identified by study investigators.

All biological samples will be de-identified (allocated a barcode) and securely stored in lockable freezers in a secured-access facility at Edith Cowan University.

Sometimes test results will be sent to other research institutions within Australia and/or overseas. If this occurs, your test results will be de-identified, which means that only the members of this research study team will be able to trace them back to you. If collaborative research is undertaken with other research institutions, please be assured that your identity will not be disclosed to individuals working in these other research institutions. Should you not wish to have your test results be made available for collaborative research please advise the project coordinator in writing.

13. Will my tests results be used for a student research project?

Student researchers may be involved in this research and may use your test results for their research project. Importantly, none of your test results will be identifiable. Students involved in this research project will also have to be approved by the Edith Cowan University Human Research Ethics Committee.

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

The general research results will be provided in a group format (de-identified). Should you wish to receive an overview over your results, with the exception of genetic results (as detailed above), please inform the project coordinator in writing.

In the event that we should discover any significant information at any stage during the study that may impact on your health, we will provide you with a letter that you can then take to a medical practitioner of your choosing.

15. Who is organising and funding the research?

This project was developed by researchers at Edith Cowan University. This project is run by researchers at ECU in collaboration with researchers from other institutions and is funded by MSWA.

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16. Who has reviewed this research project?

An independent group of people called a 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 of Edith Cowan University.

17. What if I have complaints?

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).

Contacting the research investigators

We are happy to answer any questions you may have at this time. For more information about this project, please contact:

Mrs Manja Laws	Phone: (08) 6304 2423	Email: m.laws@ecu.edu.au
Dr Danielle Bartlett	Phone: (08) 6304 3568	Email: d.bartlett@ecu.edu.au

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

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

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Study Site Location(s)	Perth, Western Australia

Declaration by Participant

I have read and understood the participant information sheet and informed consent statement. By signing this consent form, I am confirming that:

- I understand that the study will be carried out as described in the information sheet, a copy of which I have retained.
- The nature and possible effects of the study have been explained to me.
- Any questions that I have asked have been answered to my satisfaction.
- I understand that all research data will be treated as confidential.
- I agree to participate in this study and give my consent freely.
- I understand that my participation in this research study is voluntary and whether or not I decide to participate is solely my decision.
- I also understand that I can withdraw from the study at any time and that I do not have to give any reasons for withdrawing.
- I understand that I need to withdraw in writing in order to withdraw my data.
- I understand that the research team may need to access data that was collected during the screening process to assess my eligibility for the study and agree to this data being used as part of the study.
- I understand that data collected may be used for student research projects.
- I understand that data collected during this study may be made available for future research projects, provided that it is not identifiable.
- I agree that research data gathered for the study may be published provided my name or other identifying information is not disclosed.

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- I understand that Edith Cowan University is not part of the Government of Western Australia and that health professionals involved in the conduct of this study do so in a private capacity and not as employees of the hospital or the State.

Options for Duration of Storage of my saliva/DNA Sample

In regard to my saliva/DNA sample (please tick ONLY one box):

- ☐ I consent to the testing and then storage of my saliva/DNA sample indefinitely for research in the field of neurological disorders.
- ☐ I consent to the testing and the storage of my saliva/DNA sample indefinitely for future unspecified research.
- ☐ I consent to the testing of my saliva/DNA sample for the specific purpose of this study on the condition that my saliva/DNA sample is **discarded** immediately thereafter, as detailed in the information sheet.
- ☐ I do not consent for the testing or storage of my saliva/DNA sample.

If you have consented to providing a DNA sample for the current study, while very unlikely, there may come a time during the life of this project when the clinical implications for a specific gene become known that could be significantly relevant for your health. It is important to note that these genetic studies would be for research purposes only; if you would like this information communicated to you, the findings would need to be verified by a National Association of Testing Authorities (NATA) accredited laboratory and you would need to undergo genetic counselling prior to receiving these results. Additionally, upon conclusion of the study any personally identifying information will be destroyed, meaning that we will not be able to inform you of any specific results when this study concludes.

With this in mind, would you like us to notify you of any clinically significant (relevant for your health) genetic information if it so arises?

- ☐ Yes, I would like to be notified of any clinically relevant genetic information.
- ☐ No, I would not like to be notified of any clinically relevant genetic information.

I would like to be contacted for participation in further research. **YES** **NO**

I give permission for my GP/neurologist to be contacted for further information. **YES** **NO**

**For individuals that are involved in the SPIN Observational Study:*

I give permission for the research team to access data collected about me during the SPIN Observational Study for the purpose of this study **YES** **NO**

***For individuals that are not involved in the SPIN Observational Study:*

I give permission to add my assessment results to the SPIN Observational Study. **YES** **NO**

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In the event that any significant information about my health is discovered at any stage during my participation in this study, I would like (*you may tick more than one box*):

- ☐ These results to be communicated to me in the form of a written letter that I can then take to a medical practitioner of my choosing.
- ☐ These results to be communicated to my nominated medical practitioner in written form *(please nominate your chosen healthcare professional below)*.
- ☐ I <u>would not</u> like these results communicated to me or a nominated medical practitioner.

Name and address of nominated healthcare professional (i.e. GP/neurologist):

_____

_____

_____

_____

Participant

_____	_____	_____
Name	Signature	Date

Researcher:

_____	_____	_____
Name	Signature	Date