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PARTICIPANT INFORMATION SHEET

Project Title

The feasibility and therapeutic utility of a 12-week telehealth delivered environmental enrichment program for young stroke survivors experiencing cognitive impairment.

Short Title

Environment enrichment for young stroke survivors

Project Sponsor

This research project is supported by the Neurotrauma Research Program

Project Investigators

Dr Travis Cruickshank, Dr Danielle Bartlett, Prof David Blacker, Dr Johnny Lo, A/Prof Mandy Stanley, Prof Amanda Devine, Prof Simon Laws, Dr Onno Van De Groen, Prof Natalie Ciccone, Dr Yvonne Learmonth, Mr Mitchell Turner, Mrs Manja Laws, Ms Leah Dempsey, Ms Kirsten Van Rijn and Mr Philipp Beranek

Study Site Location

Perth, Western Australia.

What does my participation involve?

This research project, which is part of the Systematic Profiling in Neurological Conditions (SPIN) Research Program, aims to evaluate the feasibility and therapeutic effects of environmental enrichment compared to lifestyle guidance, on cognition, activities of daily living and quality of life in young stroke survivors (aged 18-65) at least three months post stroke. 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

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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:

- 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.

What is the purpose of the study?

The purpose of the study is to evaluate the feasibility and therapeutic effects of a 12-week telehealth delivered environmental enrichment program, compared to lifestyle guidance, for young stroke survivors experiencing cognitive impairments. Environmental enrichment has demonstrated neural and clinical benefits in animal models with an induced stroke. However, the extent to which environmental enrichment positively impacts on clinical function, particularly cognition, in young stroke survivors has not been investigated. Here, we aim to determine whether the effects of telehealth-delivered environmental enrichment compared to lifestyle guidance on cognition in young stroke survivors.

Who is conducting this research?

This study is being conducted by researchers at Edith Cowan University and the Perron Institute.

What does participation in this research project involve?

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

Eligibility: If you have been contacted via the SPIN Observational Study, your eligibility for the study will have been confirmed prior to the study team contacting you. However, if you are not part of the SPIN Observational Study, you will need to complete a 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, cardiopulmonary exercise test (environmental enrichment group) and several questionnaires asking about your clinical condition and capacity to undertake the intervention. This screening call is expected to take 30 minutes and we will contact you within a week following this call to discuss your eligibility for inclusion in the study. You will also be asked to provide a letter from your doctor regarding your capacity to safely engage in the

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study interventions. 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.

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 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 Treatments

You will be randomly assigned to receive an intervention of either environmental enrichment or lifestyle guidance. Both interventions will run for twelve weeks. If you are randomised to the lifestyle guidance group you will receive guidance on physical activity, sleep health, eating healthy and cognitively enhancing activities from a lifestyle coach At the end of the study period people in the lifestyle guidance group will be provided with the details of the environmental enrichment program, if effective.

If you are randomised to the environmental enrichment program, you will be provided with a specialised environmental enrichment program designed to improve your health, particularly your cognition, activities of daily living and quality of life. As part of this program, you will be asked to undertake specific aerobic and strengthening exercises and computerised cognitive training. You will also be asked to wear light therapy glasses and will be provided with documents regarding sleep health and healthy eating.

Study Procedures: In order to test the effectiveness of both therapies, you will be asked to complete testing at three time points: 1) upon enrolment into the study, 2) following the 12-week intervention period and 3) following a 12-week "washout" period (this period enables researchers to determine the duration of treatment effects). All assessments will be conducted by highly trained and blinded examiners (people who do not know which treatment group you belong to). Some testing procedures will be conducted using Microsoft Teams and REDCap, which are secure digital platforms used extensively for telehealth and questionnaire-based studies.

Study Assessments: You may be asked to undertake cognitive, activities of daily living, quality of life, fatigue, sleep, mood, lifestyle and biological assessments as part of this research project. This diverse array of assessments is being utilised as environmental enrichment and lifestyle guidance interventions have the capacity to positively impact on a number of clinical areas

All assessments can be completed in your home. A detailed overview of assessments is provided below. In addition to the measures below, we will be assessing the feasibility

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(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 environmental enrichment and lifestyle guidance to ensure that they can be more seamlessly integrated into clinical practice and the community.

- Demographics Questionnaire: You will be asked to complete a demographics questionnaire encompassing your general information including your date of birth, sex, medical history, presence of comorbid conditions and current pharmaceutical and non-pharmaceutical therapies. Data will also be collected about your clinical characteristics and date of diagnosis.

- Cognitive Assessment: You may be asked to complete a battery of examiner-administered and self-report cognitive assessments that evaluate your memory, language, attention and emotion recognition and flexibility. Examiner-administered assessments are expected to take 30 minutes to complete with regular breaks and will be conducted through Microsoft Teams or over the phone. You may be asked to complete a self-reported cognitive assessment which is expected to take 10 minutes to complete and can be undertaken at home.

- Activities of Daily Living: You may be asked to complete a questionnaire pertaining to your activities of daily living. This questionnaire is expected to take you 10 minutes and can be completed at home in your own time.

- Quality of Life Assessment: You may be asked to complete a questionnaire to assess changes in your quality of life. This questionnaire is expected to take you 5 minutes to complete and can be undertaken at home.

- Fatigue Assessment: You may be asked to complete questionnaires to assess changes in your fatigue. These questionnaires are short in duration (5 minutes) and can be completed at home.

- Sleep Assessment: You may be asked to complete questionnaires to assess your habitual sleep patterns and quality. These questionnaires are expected to take no longer than 15 minutes to complete and can be completed at home. You may also be asked to wear an activity monitor called an ActiGraph monitor on your wrist each night for one week. This monitor is designed to measure movement while you are awake and asleep, allowing for the detection of your sleep continuity and sleep efficiency. You may also be asked to monitor your sleep environment by means of a light and temperature sensor placed on the bedside table for a period of one week. This will provide important information on your exposure to light sources and different temperatures in your usual sleep environment.

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- Mood Assessment: You may be asked to complete questionnaires to assess changes in your mood state. These questionnaires are short in duration (10 minutes) and can be completed at home.

- Lifestyle Behaviour Assessment: You may be asked to answer questionnaires pertaining to your habitual physical activity levels, eating behaviours, cognitive reserve, sleep-wake habits and socialisation. These questionnaires are expected to take 1 hour to complete.

- E-Health Assessment: You may be asked to complete a questionnaire pertaining to your ability to use a computer. This questionnaire is expected to take 10 minutes and will be used to guide the dissemination of the intervention and assess its efficacy.

- Cardiopulmonary Exercise Test: A requirement of this study is to undertake a cardiopulmonary exercise test to evaluate your fitness level. This assessment is needed to determine whether it is safe for you to engage in this intervention. This assessment will involve you performing submaximal aerobic exercise until exhaustion on a stationary bicycle or treadmill (dependent on functional capacity). The information obtained from this test will also enable the exercise component of the intervention to be tailored to your exercise capacity.

- Biological Assessment: You may be asked to provide a saliva sample by passively drooling into a special collection tube at baseline and following the intervention and washout periods 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. Saliva 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.

As part of this study, we would 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.

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

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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.

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.

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 environmental enrichment and lifestyle guidance will positively impact on your cognition, activities of daily living and quality of life as well as other aspects of health. Furthermore, we believe that participating in this study will provide you with the knowledge and resources to undertake environmental enrichment interventions aimed at improving your health.

What are the possible risks and disadvantages of taking part?

Time commitments are associated with the study. While not likely, there are some risks associated with assessments and interventions in the study. In particular, you will be asked to undertake a cardiopulmonary exercise test prior to participation in either intervention. This test is designed to assess your aerobic capacity and ascertain whether it's safe for you to participate in the interventions. While unlikely, cardiopulmonary exercise tests can lead to cardiovascular events (e.g., heart attacks), although this is highly rare (1 per 100,000). Engagement in the interventions, particularly exercise components can also lead negatively impact health. Please read the following sections carefully for information on risks associated with study interventions.

What do I need to know about the environmental enrichment and lifestyle guidance interventions?

Engagement in the interventions may cause you to become physically and/or mentally tired, which may impact your activities of daily living. These effects are normally and typically transient (passing with adequate rest). Importantly, the programs have been purposefully designed to incorporate rest periods. Although unlikely, performing exercise training may result in an adverse event, such as a muscle strain. In very rare circumstances, performing exercise may result in a serious adverse event, such as a cardiovascular event. If you feel comfortable in doing so, it is encouraged that you perform exercises with a support person. You will also have contact with an intervention coach and in your intervention package you will receive a flyer that will explain what to do in the case of an adverse event.

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Light therapy 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, eye strain, nausea or hyperactivity as a result of using the light therapy glasses. These effects are transient and expected to pass upon cessation of light therapy. If you are randomised to the intervention group that will be using the light therapy glasses, you will be contacted for the first three days of using the glasses to ensure that there are no adverse effects. You will then be asked to report any negative effects of using the light therapy glasses as they arise. In the rare event of an adverse effect, you will be followed up by a study investigator for more information and you may be asked to stop using the glasses.

While unlikely, undertaking computerised cognitive training can be challenging. It may reveal problems in your cognitive abilities that may be confronting. However, it is important to note that everyone has strengths and weaknesses with respect to their cognition. You will be provided with a list of phone numbers for helplines that you can call if you feel that you need to talk to someone at any point throughout the study.

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.

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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 undertaken in medical research. It helps us learn more about conditions and what causes them. In doing so, it may assist in clinical management of patients with such conditions. 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.

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.

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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.

What if I change my mind?

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.

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.

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 (detailed below), 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.

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

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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 the lead 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.

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.

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.

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.

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.

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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:

Dr Travis Cruickshank
Ph: 6304 3416
E: t.cruickshank@ecu.edu.au

Mr Mitchell Turner
Ph: 6304 3416
E: mitchel.turner@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