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| The research is being carried out in partial fulfilment of Doctor of Philosophy under the supervision of Dr Dana Wong and Dr Eric Morris. The following researchers will be conducting the study: | | |
| **Role** | **Name** | **Organisation** |
| Chief Investigator | Dr Dana Wong | La Trobe University |
| Associate Investigator | Dr Eric Morris | La Trobe University |
| Associate Investigator | Professor Roshan das Nair | University of Nottingham |
| Associate Investigator | Dr David Gillanders | University of Edinburgh |
| Associate Investigator | Dr Lucy Knox | La Trobe University |
| Research Officer | Bleydy Dimech-Betancourt | La Trobe University |
| PhD Student | Nick Sathananthan | La Trobe University |
| Masters Student | Hannah Miller | La Trobe University |

1. **What is the study about?**

You are invited to participate in a study evaluating a group program to enhance valued living after acquired brain injury (ABI), called VaLiANT (Valued Living After Neurological Trauma). Valued living involves engaging in activities that are consistent with our values (e.g., work, leisure, and social activities) and reconnecting with what gives our lives meaning. Previous research has found that valued living is associated with better recovery after an ABI. However, changes in cognitive function (thinking skills) and emotions (mood), which are common after ABI, can make it more difficult to participate in valued activities. We hope to learn whether the newly designed group program increases participation in meaningful and valued activities while helping you learn strategies to deal with cognitive and emotional changes.

1. **Do I have to participate?**

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Being part of this study is voluntary. If you want to be part of the study, we ask that you read the information below carefully and ask us any questions. You can read the information below and decide at the end if you do not want to participate. If you decide not to participate this won’t affect your relationship with La Trobe University or any other listed organisation.

1. **Who is being asked to participate?**

You have been asked to participate in this research project because you have previously sustained an acquired brain injury (ABI). This project is for adults (aged 18 years or over) who have experienced a change in their thinking skills (e.g. memory, concentration, etc) or mood, which has affected their participation in valued life activities, following their ABI.

1. **What will I be asked to do?**

If you agree to participate in this study, you will be enrolled into one of two groups:

1. Participating in the VaLiANT group program straight after enrolment in the study:
2. Participating in the VaLiANT program after a waiting period of 4 months. You can receive your usual care from other clinicians during this period. You will be placed on a waitlist and have the opportunity to participate in the next group available.

Those who enrol in the study will be randomly assigned (like a toss of a coin) to one of the two groups (immediate treatment or waitlist). A computer program will be used to select which participants receive the group immediately, and which participants continue to receive their usual care and get placed on the waitlist. Each person has a 2/3 chance (better odds) of being placed in the VaLiANT program group initially.

The VaLiANT group sessions take place at the La Trobe Psychology Clinic. The group runs for 8 weeks. Each session goes for 2 hours including breaks. The group is facilitated by an experienced clinical neuropsychologist (Dr Dana Wong) along with 1-2 provisional psychologists. There are between 3-8 participants in the group. In-session activities includes identifying personal values and valued activities, and learning strategies for dealing with cognitive (thinking) and emotional difficulties that can get in the way of participating in those valued activities. Participants are also asked to complete weekly practice activities (‘homework’) assigned at the end of each session. The expected time commitment of the homework is estimated to be an hour each week.

Participation in the group program as part of the research project will be provided to you **free of charge.** The group sessions will be video recorded. These video recordings will be viewed by other psychologists in order to check that the group facilitators are following the protocol for the program accurately and competently. All information about you will be kept confidential by the psychologists who watch the videos. The videos will be destroyed when the project is completed.

You will be asked to undergo an initial assessment at the commencement of the study. You will also be asked to attend two follow up assessments, which will occur 8 weeks and 16 weeks after your enrolment in the study. These assessments can take place at either the La Trobe University Psychology Clinic or at your home, according to your preference. At each assessment you will be asked to complete some paper and pencil type tasks, and to answer questions about your participation in valued activities, mood, quality of life, use of cognitive strategies, cognitive functions (thinking skills) in daily life, and level of independence in everyday activities. These assessments will take up to 2 hours each. Your responses to one of the questionnaires may be audio-recorded, to allow us to analyse your answers to the questions in more detail. At the follow-up assessment after the group program, you will also be interviewed about your experiences in the VaLiANT group, and this interview will also be audio-recorded.

After you have completed all assessments for the study, you will receive a written report that will explain your results, including what may have changed and improved following your participation in the VaLiANT group program.

1. **What are the benefits?**

Potential benefits of participating in the project include learning strategies to help you reduce the impact of cognitive and emotional changes related to your ABI on your daily life; and increasing your participation in activities that you value and enjoy. These benefits may in turn improve your wellbeing and quality of life (i.e., how you feel about yourself and your life).

More broadly, participating in this research may also help others, by adding to our understanding of which treatments are effective in improving the lives of people with ABI.

1. **What are the risks?**

It is possible that participating in the VaLiANT group program may trigger uncomfortable feelings that you may have about your cognitive difficulties and/or your ABI. However, the group program is designed to help you manage and deal with these uncomfortable feelings. Nevertheless, if you become very upset or distressed as a result of your participation in the research and you don’t think you can manage these feelings in the group, the researchers will be able to arrange for individual counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team.

If you experience something that you aren’t sure about, please contact us immediately so we can discuss the best way to manage your concerns.

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| --- | --- | --- | --- |
| **Name/Organisation** | **Position** | **Telephone** | **Email** |
| Dr Dana Wong/La Trobe University | Project Supervisor | 03 9479 5079 | d.wong@latrobe.edu.au |

1. **What will happen to information about me?**

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project.

We will collect and store information about you in ways that will not reveal who you are. This means you cannot be identified in any type of publication from this study. We will keep your information for 7 years after the project is completed. After this time, we will destroy all of your data. We will collect, store and destroy your data in accordance with La Trobe Universities Research Data Management Policy which can be viewed online using the following link: <https://policies.latrobe.edu.au/document/view.php?id=106/>.

The information you provide is personal information for the purposes of the Information Privacy Act 2000 (Vic). You have the right to access personal information held about you by the University, the right to request correction and amendment of it, and the right to make a compliant about a breach of the Information Protection Principles as contained in the Information Privacy Act.

1. **Will I hear about the results of the study?**

The results of the study can be made available to you at the completion of the study. If you would like them sent to you, please email Dr Dana Wong at d.wong@latrobe.edu.au. It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

1. **What if I change my mind?**

At any time you can choose to no longer be part of the study. You can let us know by:

1. Completing the ‘Withdrawal of Consent Form’ (provided at the end of this document);
2. Calling us;
3. Emailing us

Your decision to withdraw at any point will **not** affect your relationship with La Trobe University or any other organisation listed.

When you withdraw we will stop asking you for information. You will have three months after completion of the group program to withdraw your consent. Any identifiable information about you will be withdrawn from the research study. However, once the results have been analysed we can only withdraw information, such as your name and contact details. If results haven’t been analysed you can choose if we use those results or not.

1. **Who can I contact for questions or want more information?**

If you would like to speak to us, please use the contact details below:

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| **Name/Organisation** | **Position** | **Telephone** | **Email** |
| Dr Dana Wong/La Trobe University | Project Supervisor | 03 9479 5079 | d.wong@latrobe.edu.au |

1. **What if I have a complaint?**

If you have a complaint about any part of this study, please contact:

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| **Ethics Reference Number** | **Position** | **Telephone** | **Email** |
| HEC18423 | Senior Research Ethics Officer | +61 3 9479 1443 | [humanethics@latrobe.edu.au](mailto:humanethics@latrobe.edu.au) |

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| The research is being carried out in partial fulfilment of Master of Clinical Neuropsychology/Doctor of Philisophy under the supervision of Dr Dana Wong and Dr Eric Morris. The following researchers will be conducting the study: | | |
| **Role** | **Name** | **Organisation** |
| Chief Investigator | Dr Dana Wong | La Trobe University |
| Associate Investigator | Dr Eric Morris | La Trobe University |
| Associate Investigator | Professor Roshan das Nair | University of Nottingham |
| Associate Investigator | Dr David Gillanders | University of Edinburgh |
| Associate Investigator | Dr Lucy Knox | La Trobe University |
| Research Officer | Bleydy Dimech-Betancourt | La Trobe University |
| Masters/PhD Student | Nick Sathananthan | La Trobe University |
| Masters Student | Hannah Miller | La Trobe Univeristy |
| **Research funder** | This research is being funded by the Research Focus Areas Grant Ready Scheme. | |

**Consent Form – Declaration by Participant**

I (the participant) have read (or, where appropriate, have had read to me) and understood the participant information statement, and any questions have been answered to my satisfaction. I agree to participate in the study, I know I can withdraw at any time. I agree information provided by me or with my permission during the project may be included in a thesis, presentation and published in journals on the condition that I cannot be identified.

I would like my information collected for this research study to be:

Only used for this specific study;

Used for this study and for a future larger trial evaluating the VaLiANT group program

I agree to have the group sessions video recorded

I agree to have my answers to a questionnaire and the interview about my experiences in the program audio-recorded

I agree to be contacted if there are any research studies being conducted in the future that may be relevant to me. If I am contacted about in the future about another study, that does NOT oblige me to participate in that study. I can be contacted using the following details:

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| --- | --- | --- |
| **Name** | **Email** | **Phone number** |
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**Participant Signature**

I have received a signed copy of the Participant Information Statement and Consent Form to keep

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| Participant’s printed name |  |
| Participant’s signature |  |
| Date |  |

**Declaration by Researcher**

I have given a verbal explanation of the study, what it involves, and the risks and I believe the participant has understood;

I am a person qualified to explain the study, the risks and answer questions

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| Researcher’s printed name |  |
| Researcher’s signature |  |
| Date |  |

\*All parties must sign and date their own signature