PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM

The Carer's Way Ahead: An Online Randomised Control Trial for Families Managing Challenging Behaviour Following Brain Injury

Chief Investigator: Professor Skye McDonald

1. What is the research study about?

You are invited to take part in this research study. The research study aims to determine whether family carers of people with traumatic brain injury find an on-line program about how to manage challenging behaviour useful. You have been invited because you have indicated that you have a family member with a traumatic brain injury and you would be interested in being involved.

2. Who is conducting this research?

The study is being carried out by the following researchers: Professor Skye McDonald & Dr Travis Wearne, School of Psychology, UNSW, Associate Professor Jill Newby, The Black Dog Institute, UNSW, Professor Graeme Simpson, Ingham Institute of Applied Medical Research, Ms Samantha Grant & Dr Emily Trimmer, Inspire Psychology and Mr Paul Gertler, Gertler Psychological Services.

Research Funder: This research is being funded by the National Health and Medical Research Council in collaboration with iCare, NSW. iCare is an insurance provider that provides treatment and care to more than 1300 people who have been severely injured on NSW roads. They provide treatment, services and support to these individuals to improve their quality of life and facilitate to return to work.

3. Inclusion/Exclusion Criteria

Before you decide to participate in this research study, we need to ensure that it is ok for you to take part.

The research study is looking recruit people who meet the following criteria:

- Adults aged 18 years or over,
- Identify as a family member of an individual who has experienced a traumatic brain injury
- Identify as caring for that person
- Have access to a computer and printer,
- Prepared to provide your name, phone number, address, and informed consent.
- Fluent English.

Participants who meet the following criteria will be excluded from the study:

- Do not have access to a computer or the internet.
- Living outside of Australia.
- Insufficient fluency in English to read materials.

4. Do I have to take part in this research study?

Participation in this research study is voluntary. If you do not want 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 study at any stage.

If you decide you want to take part in the research study, you will be asked to:

- Read the information carefully (ask questions if necessary);
- Sign and return the consent form if you decide to participate in the study;
- Take a copy of this form with you to keep.

5. What does participation in this research require, and are there any risks involved?

If you agree to participate you will be asked to complete the following research procedures:

Screening

Once you have completed and agreed to participate, we will ask you to complete an on-line questionnaire. The questionnaire will ask you questions about your age, your relation to your family member with TBI,

whether you are able to read English and ask for contact details. It should take approximately 5 minutes to complete. Information you provide will be linked via a unique participant identification number that is only accessible by the investigators. A member of our research team will then call you to provide more detail about the project at a time that is convenient for you. We will also ask you more questions about your experiences with your family member with brain injury and to determine if you are eligible to take part. The phone conversation should take approximately 20 to 30 minutes. If you meet criteria for inclusion, then you will be able to start the research project. If the screening questionnaire shows that you cannot be in the research project, we can assist you in accessing other services for your areas of concern.

We don't expect this questionnaire or conversation to cause any harm or discomfort, however if you experience feelings of distress as a result of participation in this study you can let the research team know and they will provide you with assistance.

Randomisation

The aim of the research is to compare the outcomes of the Carer's Way Ahead Program and a control group (deferred treatment). To ensure that each participant has an equal chance of being placed in any group to start with, a computer program (i.e., RedCAP) will be used to randomly allocate you to a group. This is to ensure that the investigators have no control over participants being placed in a group. Participants will be randomly allocated to one of the following participant groups:

Immediate treatment: You will be asked to complete 'The Carer's Way Ahead' program, which will involve completing online training modules associated with brain injury and challenging behaviour (described below). In these modules, we will ask you to follow instructions on a screen. You will also be assigned a clinical psychologist who will offer you distant (i.e., telephone and/or email) support throughout the program. The entire project will take approximately 10 weeks.

Deferred treatment: You will be asked to wait ten weeks before treatment commences. You will be asked to complete a second "assessment" session before commencing.

Completion of Online Questionnaires

If you decide to take part in the research study, we will ask you to complete on-line questionnaires through RedCAP. The questionnaires will ask you questions about your mood and information about your experiences with your family members' behaviour. You will also be asked to complete questionnaires about your wellbeing, problem-solving, and quality of life. We will also ask about your programme expectation/satisfaction. It should take approximately 60 minutes to complete. Information you provide will be linked via a unique participant identification number that is only accessible by the investigators. You will also complete the same questionnaires after you complete the program and at six and 12-month follow-up.

We don't expect these questionnaires to cause any harm or discomfort, however if you experience feelings of distress you can let the research team know and they will provide you with assistance.

Participation in the "Carer's Way Ahead" On-line program

You will be provided with access to the online program either immediately or after a wait period (i.e., 10 weeks later). This comprises of completing seven online modules over a 10-week period. You will be able to pick and choose the modules you wish to complete. You will be encouraged to complete one lesson per one to two weeks. You will receive regular phone and/or email contact from us and a clinical psychologist and will be encouraged to carry out practical activities between lessons.

We don't expect the "Carer's Way Ahead" program to cause any harm or discomfort, however if you

experience feelings of distress as a result of participation in this study you can let the research team know and they will provide you with assistance. Regular "check ins" will be made throughout the program and on completion of questionnaires to monitor your distress. If you are experiencing overwhelming distress you can discontinue the program at any time and be referred to alternative sources of support.

Additional Costs: There are no costs for participating in this research project, nor will you be paid.

6. What are the possible benefits to participation?

We hope to use information we get from this research study to benefit others who are also caring for a family member with a TBI and who has challenging behaviour.

7. What are the alternatives to taking part in the research?

You do not have to take part in this research project to receive treatment. Other options are available; these include accessing a clinical psychologist who has expertise in the area of brain injury, a support group for carers of those with a family member with a traumatic brain injury, or discussing your difficulties with your family member's doctor, rehabilitation specialist or case manager. One of our investigators can discuss these options with you before you decide whether or not to take part in this research project.

8. What will happen to information about me?

By signing the consent form you consent to the research team collecting and using information about you for the research study. Your data will be kept for 15 years after the project's completion. Data will be entered into spreadsheets and data analytic software using password protected files, on a locked computer with password protection. Information about your identification will be stored in a secure excel file with password protected file with the decoding information. Responses recorded on paper from the telephone interview will also be stored in locked cabinets, only accessible by the research team.

All online surveys and participation metrics (e.g., logins, details, time since login) will be collected via the RedCAP website, and linked to your unique individual login code. Each time a questionnaire/survey is available to complete, you will login to the RedCAP website with your email and a unique password you chose at application stage, and complete the questionnaire of interest. This ensures that all of your responses are linked. You will also use the RedCAP program to complete the Carer's Way Ahead'. RedCAP is a secure web application for building and managing online surveys and databases. All data the is entered cannot be seen by anyone other than the chief investigators.

Your information will only be used for the purposes of evaluating the "Carer's Way Ahead Program". Information we receive about you will be collated with that from other people and will only ever be disclosed in research publications in a non-identifiable format. By providing your consent, you are agreeable for the research team to share or use the information collected from you in future research that: Will be specific to the aims of this research and/or Will be an extension of, or closely related to, the original project; or is in the same general area of research.

The information you provide is personal information for the purposes of the Privacy and Personal Information Protection Act 1998 (NSW). You have the right of access to 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 PPIP Act. Further information on how the University protects personal information is available in the **UNSW Privacy Management Plan**.

9. How and when will I find out what the results of the research study are?

The research team intend to publish and/ report the results of the research study in a variety of ways. All

information published will be done in a way that will not identify you.
If you would like to receive a copy of the results you can let the research team know by adding your email address to the consent form. We will only use these details to send you the results of the research.

10. What if I want to withdraw from the research study?
If you do consent to participate, you may withdraw at any time. You can do so by completing the 'Withdrawal of Consent Form' which is provided at the end of this document. Alternatively, you can ring the research team and tell them you no longer want to participate. Your decision not to participate or to withdraw from the study will not affect your relationship with UNSW Sydney or iCare lifetime care.

If you decide to leave the research study, the researchers will not collect additional information from you. Any identifiable information about you will be withdrawn from the research project. The research team will destroy any information about you that was collected during your participation in the study.

11. What should I do if I have further questions about my involvement in the research study?
The person you may need to contact will depend on the nature of your query. If you require further information regarding this study or if you have any problems which may be related to your involvement in the study, you can contact the following member/s of the research team:

Research Team Contact Details

Name	Dr Travis Wearne
Position	Research Fellow/Project Manager
Telephone	02-93853310
Email	t.wearne@unsw.edu.au

Name	Professor Skye McDonald
Position	Professor of Neuropsychology
Telephone	02 9385 3029
Email	s.mcdonald@unsw.edu.au

Support Services Contact Details
If at any stage during the study you become distressed or require additional support from someone not involved in the research please call:

Name/Organisation	*LifeLine*
Telephone	*13 11 14*

What if I have a complaint or any concerns about the research study?
If you have a complaint regarding any aspect of the study or the way it is being conducted, please contact the UNSW Human Ethics Coordinator:

Complaints Contact

Position	UNSW Human Research Ethics Coordinator
Telephone	+ 61 2 9385 6222
Email	humanethics@unsw.edu.au
HC Reference Number	HC200245

Consent Form – Participant providing own consent

Declaration by the participant

- ☐ I understand I am being asked to provide consent to participate in this research study;
- ☐ I have read the Participant Information Sheet or someone has read it to me in a language that I understand;
- ☐ I understand the purposes, study tasks and risks of the research described in the study;
- ☐ I provide my consent for the information collected about me to be used for the purpose of this research study only.
- ☐ I have had an opportunity to ask questions and I am satisfied with the answers I have received;
- ☐ I freely agree to participate in this research study as described and understand that I am free to withdraw at any time during the study and withdrawal will not affect my relationship with any of the named organisations and/or research team members;
- ☐ I would like to receive a copy of the study results via email or post, I have provided my details below and ask that they be used for this purpose only;

Name: _____

Address: _____

Email Address: _____

Optional Consent for reuse of data and future research:

- ☐ I provide my consent for the information collected about me to made available to other researchers as described at section 8 of this document.
- ☐ I provide my consent for my name and contact details to be retained in a register so I can be contacted about other research projects in the future.

☐ I understand that I will be given a signed copy of this document to keep;

Participant Signature

Name of Participant (print)	
Signature	
Date	

Declaration by Researcher*

☐ I have given a verbal explanation of the research study, its study activities and risks and I believe that the participant has understood that explanation.

Researcher Signature*

Name of Researcher (print)	
Signature of Researcher	
Date	

***An appropriately qualified member of the research team must provide the explanation of, and information concerning the research study.**
Note: All parties signing the consent section must date their own signature.

Form for Withdrawal of Participation

I wish to **WITHDRAW** my consent to participate in this research study described above and understand that such withdrawal **WILL NOT** affect my relationship with The University of New South Wales, *ICare*. In withdrawing my consent I would like any information which I have provided for the purpose of this research study withdrawn..

Participant Signature

Name of Participant (please print)	
Signature of Research Participant	
Date	

The section for Withdrawal of Participation should be forwarded to:

CI Name:	*Professor Skye McDonald*
Email:	*s.mcdonald@unsw.edu.au*
Phone:	*02-93853029*
Postal Address:	*School of Psychology, UNSW, Sydney, 2052*