



**Chief Investigator: Dr Milena Gandy**

## **PARTICIPANT INFORMATION AND CONSENT FORM**

*The Wellbeing Neuro Course: Examining the Efficacy of an Online Treatment Program for Adults with Neurological Disorders.*

You are invited to participate in a research trial of a self-management course, the *Wellbeing Neuro Course*, for adults with neurological disorders impacting their emotional (e.g., stress, anxiety, depression) and cognitive (e.g., memory, attention, organisation) health. The Wellbeing Neuro Course is designed to provide good information and skills for managing the impact of significant neurological disorders on wellbeing and quality of life.

This research is being conducted by:

- Dr Milena Gandy, Clinical Psychologist / Research Fellow, Macquarie University.
- Dr Rhiannon Fogliati, Clinical Psychologist / Research Fellow, Macquarie University.
- Dr Joanne Dudeney, Clinical Psychologist / Research Fellow, Macquarie University.
- Dr Amelia Scott, Clinical Psychology Registrar/ Research Fellow, Macquarie University
- Dr Lauren Staples, Research Fellow/ Research analyst, Macquarie University.
- Mr Eyal Karin, Senior Research Assistant, Macquarie University.
- Professor Nick Titov, Professor and Director MindSpot Clinic, Macquarie University.
- A/Prof Blake Dear, Director eCentreClinic and Clinical Psychologist, Macquarie University.

Before you decide to participate in this research trial it is important for you to understand why the research is being done and what participation will involve. Please take the time to read the following information carefully and discuss with others, including your GP or specialist, as needed.

**PLEASE NOTE:** You are also welcome to contact the eCentreClinic via email [contact@ecentreclinic.org](mailto:contact@ecentreclinic.org) with any questions regarding this research or your participation at any point. You can contact Dr Milena Gandy directly on 02 9850 4152 or via email at [milena.gandy@mq.edu.au](mailto:milena.gandy@mq.edu.au).

### **1. What is the purpose of this research trial?**

The purpose of this research is to investigate the acceptability, efficacy, and long-term outcomes of the Wellbeing Neuro Course and to gather feedback from participants to inform further improvements to the program.

Research tells us that neurological disorders have a very significant impact on the lives and wellbeing of Australians. We also know that access to good information and learning several core self-management skills can make a big difference to people's lives and confidence to manage the impacts of their neurological disorders. However, research also indicates that most Australians cannot access the kinds of self-management programs that provide this information and teach these skills. There are a number of barriers that commonly prevent access to these programs, including cost, distance, waitlists, stigma and mobility limitations.

To meet the aims of this research, participants will be randomly allocated to one of two groups: (1) an Immediate Participation Group; or (2) a Delayed Participation Control Group. If randomly allocated to the

Delayed Participation Control Group, you will start the program 10 weeks later than if you were randomised to the Immediate Participation Group.

## **2. Who is eligible to participate in this research trial?**

You are eligible to participate in this trial if: (1) you have a confirmed diagnosis of one of the following neurological disorders; Multiple Sclerosis, Epilepsy, Parkinson's Disease, Stroke, Traumatic Brain Injury, or Acquired Brain Injury and it is having an impact on your emotional (e.g., stress, anxiety, depression) and cognitive (e.g., memory, attention, organisation) health; (2) you are 18 years or older; (3) you are living within Australia; and (4) your neurological disorder has been assessed and is being managed by a doctor. Currently, we cannot include people experiencing severe cognitive difficulties with day-to-day memory, attention and ability to learn basic information. We also cannot include people experiencing very severe depression or who have any intention or plan to harm themselves. Or, anyone who has harmed themselves in the previous 12 months. You will also need access to the internet to participate in this research.

## **3. What if I do not want to participate or I want to withdraw later?**

Participation in this research trial is entirely voluntary. It is up to you whether or not you decide to participate and your decision will not impact your relationship with the research investigators or their respective institutions. Importantly, you can also choose to withdraw from the research at any time without any consequence.

## **4. What does this research trial involve?**

Once you have read this information sheet and decide you wish to participate, you can submit an application to participate in the research trial via the eCentreClinic website ([www.ecentreclinic.org](http://www.ecentreclinic.org)). This application process takes about 10 to 15 minutes and involves completing some questionnaires via the eCentreClinic website. These questionnaires assist us in understanding your symptoms and difficulties as well as whether the course is likely to be helpful for you. Eligible applicants will be contacted by a member of the eCentreClinic team to conduct a brief telephone interview, discuss the course and answer your questions. You will be provided a start date for the course and create a login name and password for accessing the course.

The *Wellbeing Neuro Course* consists of 6 lessons. You will be asked to complete these lessons over 10 weeks and to complete some simple worksheets that will help you to remember the material you have learned. Each lesson provides important information about techniques for managing poor wellbeing with illustrated examples of how people learn these techniques. Each lesson takes about 30 minutes to complete and the home-based tasks will take a further 4 hours each week. You will also receive brief weekly contact (e.g., 5 to 15 minutes) from an experienced Psychologist who will provide support and answer your questions as you work through the course.

We will ask you to complete online questionnaires:

- In the first week of the course (time needed: 10 to 15 minutes).
- 11 weeks after starting the course (time needed: 10 to 15 minutes).
- 3 months after the course (time needed: 10 to 15 minutes).

These questionnaires will help determine whether the course has been helpful. We will also ask you for feedback about your experience of the course and things you believe we can improve for future participants.



Once you have completed the course, a clinician from the eCentreClinic will contact you regarding your results and answer any questions you might have. You will have access to the Wellbeing Neuro Course for approximately 9 months should you participate in the research.

#### **5. How is this research being paid for?**

There are no costs for participants in this research trial and participants cannot be paid for their participation. This research is funded via a Macquarie University Research Fellowship awarded to Dr Milena Gandy and the eCentreClinic, Macquarie University as well as via a research grant from icare lifetime care.

#### **6. Will I benefit from participating in this research trial?**

Based on our previous research, we expect that you will find this course interesting and helpful. We expect it will help you to manage the impact of your neurological disorders on your day-to-day life as well as your wellbeing. For example, based on previous research, we know that more than 90% of participants find these courses worth their time and that they would recommend them to others. However, we cannot guarantee or promise that you will receive any benefit from participating.

#### **7. Are there risks to participating in this research trial?**

There are no known discomforts or risks associated with participating in this kind of course. It is very unlikely that the present study will result in physical harm. No adverse effects have been reported in similar studies reported in similar research. In order to take part in the course it is essential that you have had your health disorder assessed by a doctor and that your disorder continues to be monitored and managed by a doctor. We will also notify your GP about your participation in the course and encourage you to discuss your participation in this course with your GP.

Although unlikely it is possible that some individuals may become anxious or sad when completing the questionnaires or when reading through the course materials. Importantly, if you become distressed or concerned, you are invited to contact Dr Milena Gandy (02 9850 4152) or any of your other health professionals to discuss this distress. You are also welcome to withdraw from this research at any time and we are available during business hours to discuss your symptoms and further treatment options with you.

#### **8. How will my confidentiality be protected?**

Any identifiable information that is collected about you will remain entirely confidential and will not be disclosed without your express permission - unless we are required to do so by law. Importantly, where we hold significant concerns about your personal safety or the safety of others, particularly children, we are legally required to notify emergency and other governmental services. We will publish the results of this research and discuss these results at national and international scientific conferences; however, in any publication, information will be presented in such a way that you cannot be identified. Moreover, only key researchers at the eCentreClinic will have access to your personal details or information.

#### **9. Can I see a copy of the published research?**

We will ask all participants whether they would like to receive a copy of any published manuscripts resulting from this research. So, you are welcome to request a copy of any research manuscripts that are published. You are also welcome to contact Dr Milena Gandy or the eCentreClinic to discuss this research and ask any questions you may have at any time.



## **PARTICIPANT CONSENT FORM**

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**Once you have read this Participant Information and Consent form, you can click the ‘consent’ button to start your application to participate in this research trial.**

Importantly, by submitting an application, you consent to the points below:

1. You would like to participate in the Wellbeing Neuro Course.
2. You have read the Participant Information Statement, which explains the aims of the study and nature of your participation.
3. You have the opportunity to raise any questions or concerns with us, regarding this research, at any time.
4. You can withdraw from the research trial at any time without prejudicing your relationship with the researchers or Macquarie University, Sydney Australia.
5. The eCentreClinic may contact crisis or emergency services, as required by law, if there are significant concerns about my safety or someone else’s safety during the course.
6. Research data gathered from the present research may be published in a de-identified format; that is, in an entirely anonymous format where individuals cannot be identified.
7. Research data gathered from the present research may be used in future studies not described in the Participant Information Statement. All data would be in a de-identified format and the research would be subject to approval from a Human Research Ethics Committee.
8. You can raise any questions or concerns about this research project with Dr Milena Gandy (02 9850 4152) or any staff ([contact@ecentreclinic.org](mailto:contact@ecentreclinic.org)) at the eCentreClinic at any time.

If you have any complaints or reservations about any ethical aspect of your participation in this research, you may contact the Ethics Review Committee through the Director, Research Ethics and Integrity (telephone 9850 7854; email [ethics@mq.edu.au](mailto:ethics@mq.edu.au)). Any complaint you make will be treated in confidence and investigated, and you will be informed of the outcome.

## **REVOCATION OF CONSENT FORM**

If at any time you wish to withdraw from this study please contact the Dr Milena Gandy at any time or **email the text below back to [contact@ecentreclinic.org](mailto:contact@ecentreclinic.org).**

I hereby wish to **WITHDRAW** my consent to participate in the research proposal described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with Macquarie University.