Chief Investigator: Dr Milena Gandy

PARTICIPANT INFORMATION AND CONSENT FORM

A Comparative Effectiveness Trial of Digital Mental Health Care Models for Adults with Epilepsy

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

This research is being conducted by:

- Dr Milena Gandy, Clinical Psychologist / Research Fellow, Macquarie University.
- Ms Tanya Balakumar, Psychologist, Macquarie University.
- Mr Thomas Woldhuis, Research Assistant, Macquarie University.
- Ms Bareena Scott, Psychologist, Macquarie University.
- Ms Wendy Wu, Provisional Psychologist / Research Assistant, Macquarie University.
- Dr Andreea Heriseanu, Clinical Psychologist / Research Fellow, Macquarie University.
- Mr Eyal Karin, Senior Research Assistant, Macquarie University.
- Professor Nick Titov, Professor and Director MindSpot Clinic, Macquarie University.
- Dr Madelyne Bisby, Clinical Psychologist / Research Fellow, Macquarie University.
- Professor Blake Dear, Director eCentreClinic and Clinical Psychologist, Macquarie University.
- Professor Mike Jones, Associate Dean Research Partnerships & Integration, Macquarie University.
- Professor Henry Cutler, Professor and Director Centre of Health Economics, Macquarie University.
- Professor Patrick Kwan, Professor of Neurology, Monash Institute of Medical Engineering.
- Dr Kaitlyn Parratt, Neurologist, Royal Prince Alfred Hospital.
- Dr Genevieve Rayner, Clinical Neuropsychologist, University of Melbourne.
- Dr Toby Winton-Brown, Neuropsychiatrist, Alfred Hospital.

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 (e.g. neurologist), as needed.

PLEASE NOTE: You are also welcome to contact the eCentreClinic via email contact@ecentreclinic.org with any questions regarding this research or your participation at any point.

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 in supporting the emotional wellbeing of adults with epilepsy. Importantly, we will compare results when the Course is delivered with or without guidance from a clinician. We also aim to gather feedback from participants to inform further improvements to the program.

Research tells us that neurological disorders such as epilepsy 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 their 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. We expect the findings of this study to inform the development and implementation of more accessible and cost-effective mental health care options for adults with epilepsy and other neurological conditions.

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 epilepsy.
(2) You are experiencing difficulties with your emotional health (e.g., stress, anxiety, depression).
(3) You are 18 years or older.
(4) You are living within Australia.

Currently, we cannot include people who:
(1) Are experiencing severe cognitive difficulties with day-to-day memory, attention, and ability to learn basic information.
(2) Are immediately suicidal or unable to keep themselves safe.
(3) Are unable to read or understand English.
(4) Do not have access to the internet.

PLEASE NOTE: We strongly recommend you discuss your participation in the course with your doctors and any other health professionals involved in the management of your health conditions.

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. You can also choose to withdraw from the research at any time without any consequence. Importantly, any information and data you provide up until your withdrawal cannot be deleted or withdrawn; consistent with the standard principles for health research.

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). This application process takes about 10 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. Following completion of these questionnaires, we will contact eligible participants via telephone to talk more about the course, ensure it is likely to be helpful, and address any questions or concerns you may have. We will also conduct a brief semi- structured interview of mood or anxiety disorders.

Participants will be randomly allocated to one of three groups:

(1) A group who receives access to the course and will have weekly access to support from an eCentreClinic clinician (i.e., the Guided Treatment Group);
(2) A group who receives access to the course only (i.e. the Unguided Treatment Group); or

(3) A group who receives delayed access to the course (i.e., the Control Group). The delayed access group receives the course three months after the other groups complete the course and can choose to undergo the course in a guided or unguided format.

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 about a further 4 hours each week.

The course is provided with lots of additional resources, and stories and examples from previous participants with different neurological disorders and difficulties.

Participants will receive weekly automatic emails that help to guide and support them as they go through the course. In addition, participants randomly allocated to receive guided treatment also have access to brief weekly contact with an eCentreClinic mental health clinician.

5. What else does this research trial involve?

Participants will be asked to complete questionnaires as a part of this research trial. These questionnaires are essential. They help us to evaluate the course and to understand how people manage the impacts of their condition over the long term.

Participants will be asked to complete online questionnaires:

- Week 1 of the course (approx: 20 minutes)
- Weekly during treatment (approx: 3 minutes)
- At the end of the course (approx: 20 minutes)
- 3 months after the course (approx: 20 minutes)
- 12 months after the course (approx: 10 minutes)

Importantly, participants will have ongoing access to the course for the duration of the research. We will also provide some feedback about participants' responses each time they complete the questionnaires.

Participants are also asked to have their data linked with their Medicare and Pharmaceutical Benefits Schedule and Public Hospital records. This will inform our evaluation of cost-effectiveness by providing information about health service usage and expenditure.

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 NHMRC Medical Research Futures Fund (MRFF) Grant awarded to Dr Milena Gandy and Macquarie University.

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

Based on our previous research, we expect you will find this course interesting and helpful, and that it will help you to manage the impact of your neurological disorders on your day-to-day life as well as your wellbeing. To reflect this, more than 90% of participants in our previous studies found these courses worth their time and indicated 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 risks associated with participating in this research or the course. However, we strongly encourage all participants to talk to their health professionals about their participation in this course. This is particularly important where participants are unsure about some aspects of the course.

The course is based on leading face-to-face psychological programs for adults with chronic conditions. Psychological treatment programs can be confronting and distressing at times for some people, especially early on in treatment. This is partly because helpful psychological treatments require people to think about the difficulties they are having and how they might use different skills or make certain changes to manage their emotional wellbeing.

Importantly, any distress usually reduces over time as people learn about emotional wellbeing and several skills for managing their emotional wellbeing. Psychologists at the eCentreClinic will also monitor the progress and symptoms of participants throughout the course and will be available to get your feedback and discuss any concerns.

PLEASE NOTE: If you experience a significant deterioration in your mood or feel at risk of self-harm or become concerned about your health, please arrange to see your GP or contact emergency services on 000. Please also let us know at a convenient time so that we may assist.

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. For example, if 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. Are there any risks to having my data linked with my health records?

There are no foreseeable security risks associated with the data linkage component of the study. We will obtain participants' health record information via the Centre for Health Record Linkage (CHeReL), which is a national government service dedicated to secure linkage of health data for research purposes. Only authorised personnel at CHeReL will be able to view your healthcare information. The information we receive from CHeReL will contain de-identified data for all participants as a cohort, meaning we will be unable to use it to identify you or any other participant.

10. 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.

Thank you for taking the time to consider this study. If you wish to take part in it, please see the consent form. This information sheet is for you to keep.

PARTICIPANT CONSENT FORM

A Comparative Effectiveness Trial of Digital Mental Health Care Models for Adults with Epilepsy

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. However, withdrawing from the study will result in the discontinuation of your treatment (i.e., treatment via the Wellbeing Neuro Course).
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. Data obtained from the trial may be linked with your medical record, specifically your Medical and Pharmaceutical Benefits Schedule and Public Hospital (e.g. number of hospital admissions, emergency department presentations) data.
7. You give permission for state, territory and Commonwealth government departments and agencies to release information to the research team concerning your medication and health care service usage for the purposes of this research project. You understand that such information will be in a de-identified and remain confidential.
8. 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.
9. 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 or Standards Committee.
10. You can raise any questions or concerns about this research project with Dr Milena Gandy (02 9850 4152) or any staff (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). 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**.

I hereby wish to **WITHDRAW** my consent to participate in the research proposal described above and understand that such withdrawal **WILL NOT** jeopardise my relationship with Macquarie University. I also understand that withdrawing my consent from the research proposal above will result in the discontinuation of my treatment via the Wellbeing Neuro Course.