



Chief Investigator: Dr Alana Fisher

PARTICIPANT INFORMATION AND CONSENT FORM

Assessing the health literacy of people accessing digital mental health treatment for depression and/or anxiety

You are invited to participate in a research study of people accessing a self-management course, the *Wellbeing Course*, a self-guided online psychological treatment for adults with depression and/or anxiety.

This research is being conducted by:

- Dr Alana Fisher, Research Fellow, Macquarie University
- Prof Blake Dear, Director eCentreClinic and Clinical Psychologist, Macquarie University.
- Dr Amelia Scott, Clinical Psychologist / Research Fellow, Macquarie University.
- Dr Madelyne Bisby, Clinical Psychologist / Research Fellow, Macquarie University.
- Dr Milena Gandy, Clinical Psychologist / Research Fellow, Macquarie University.
- Dr Andreea Heriseanu, Clinical Psychologist / Research Fellow, Macquarie University.

Before you decide to participate in this research study, 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 primary physician or specialist, as needed.

PLEASE NOTE: You are also welcome to contact the Chief Investigator Dr Alana Fisher at contact@ecentreclinic.org with any questions regarding this research or your participation at any point.

1. What is the purpose of this research study?

The purpose of this research study is to look at the health-related beliefs, motivations, skills, and support needs of people who access online psychological treatment, and how these influence whether and how people engage with and respond to treatment.

There is already a lot of research to support the safety, acceptability, and effectiveness of the *Wellbeing Course* for adults with depression and/or anxiety. Now, we wish to build our understanding about how different people may engage with and respond to the Course differently, so that we can develop practical strategies and supports to help people engage in way that best suits their needs and priorities.

2. Who is eligible to participate in this research study?

You are eligible to participate in this research study if you: (1) are aged 18 years and older; (2) have internet and computer access for the duration of the study; (3) are currently having difficulties with depression and/or anxiety; (4) can read and understand English.

Currently, we cannot include people who are experiencing significant suicidal thoughts or have any intention or plan to harm themselves. You can be living anywhere in the world (within or outside Australia) to participate in this research.



PLEASE NOTE: We strongly recommend you discuss your participation in the *Wellbeing Course* with your doctors and any other health professionals involved in the management of your mental health.

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

Participation in this research study is 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 without any repercussion. If you choose to withdraw from the study, the data you have provided up until that point will be retained for the purpose of unbiased analysis and reporting.

4. What does this research study involve?

Once you have read this information sheet and decide you wish to participate, you can submit an application to participate in this research study via the eCentreClinic website (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 emailed further information for participating in the trial.

The *Wellbeing Course* consists of 5 lessons. You will be asked to complete these lessons over 8 weeks and to complete some simple homework assignments that will help you to remember the material you have learned. Each lesson provides important information about techniques for managing your mental health and emotional wellbeing, with illustrated examples of how people learn these techniques. Each lesson takes about 30 minutes to complete and the homework will take a further 4 hours each week. You will also receive weekly automatic emails to support you going through the course.

We will ask you to complete online questionnaires:

- At application (approx. 15 mins)
- In the first week of the course, before you start (time needed: 15 - 20 minutes).
- Half-way through the course (in week 5) (time needed: 10 – 15 minute).
- At the end of the course weeks (in week 9) (time needed: 15 – 20 minutes).

These questionnaires will help us to better understand your characteristics and 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. You will have access to the *Wellbeing Course* for approximately 6 months should you continue to participate in the research.

Also, if you tell us that you are living in Australia and have a Medicare card, you will be contacted via email shortly after you enrol in/start the *Wellbeing Course* to be invited to take part in an interview about your views and experience. In the email, you will receive a separate Participant Information Statement explaining what this part of the study is about.

5. How is this research study being paid for?

There are no costs for participants in this research trial and participants cannot be remunerated for their participation. This research is funded via the eCentreClinic, Macquarie University.

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

Based on our previous research, we expect that you will find this course interesting and helpful. We expect it will help you to manage your mental health as well as your emotional wellbeing. For example, based on previous research, we know that more than 90% of participants find the course 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 study?

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 encouraged to speak about these issues with your primary care physician or other mental health professional. You are also welcome to withdraw from this research at any time if you do not wish to continue with the trial.

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.

PLEASE NOTE: In the event that you feel a significant deterioration in your mood or feel at risk of self-harm or become concerned about your mental health, please arrange to see your primary care physician or contact emergency services. If you are unsure of the telephone helpline services in your area, please use the befrienders website (www.befrienders.org) to find a telephone crisis service. **NB:** Although befrienders.org attempts to gather the details of crisis services internationally, the service may not list crisis services in your country. In this case, please contact your local primary care physician for assistance and support.

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. 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. This is because the information will be presented at an aggregate (group) level (in the case of survey findings) and/or presented with a participant code or ID (in the case of interview findings). Moreover, only key researchers at the eCentreClinic will have access to your personal information.

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

You are welcome to request a copy of any research manuscripts that are published. You are also welcome to contact Dr Alana Fisher at contact@ecentreclinic.org to discuss this research and ask any questions you may have at any time.



PARTICIPANT CONSENT FORM

Assessing the health literacy of people accessing digital mental health treatment for depression and/or anxiety

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 study.

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

1. You would like to participate in the Wellbeing Course.
2. You have read the Participant Information Statement.
3. You have been given the opportunity to raise any questions or concerns with us at any time.
4. You can withdraw from the research at any time without prejudicing your relationship with the researchers or Macquarie University, Sydney Australia.
5. 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.
6. Research data gathered from the present research may be used in future studies not described in the Participant Information Statement; however, all data would be in a de-identified format and all uses will be subject to approval from an Australian Human Research Ethics Committee.
7. You are happy to be contacted to be invited to take part in an interview as part of this project (Australia-based participants only).
8. You can raise any questions or concerns about this research project with Dr Alana Fisher (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 +612 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 Dr Alana Fisher by **emailing the text below back to** contact@ecentreclinic.org

I hereby wish to **WITHDRAW** my consent to participate in the research proposal “*Assessing the health literacy of people accessing digital mental health treatment for depression and/or anxiety*” and understand that such withdrawal **WILL NOT** jeopardise my relationship with Macquarie University.