PARTICIPANT INFORMATION AND CONSENT FORM

Chief Investigator: Dr Madelyne Bisby

A randomised controlled trial of a self-guided online ultra-brief treatment for depression and anxiety

You are invited to participate in a research trial of a self-guided online ultra-brief psychological treatment for people with depression or anxiety.

This research is being conducted by:

- Dr Madelyne Bisby, Clinical Psychologist / Research Fellow, Macquarie University
- Ms Noni Jervis, Clinical Psychologist, Macquarie University
- Dr Amelia Scott, Clinical Psychologist / Research Fellow, Macquarie University
- Professor Blake Dear, Director eCentreClinic, 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 primary physician or specialist, as needed.

PLEASE NOTE: You are also welcome to contact Dr Madelyne Bisby via phone (02 9850 8724) or email (contact@ecentreclinic.org) 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 examine the acceptability and efficacy of a self-guided version of the Single Session Course. The Course is an ultra-brief psychological treatment designed to help adults manage depression and anxiety symptoms.

We have previously offered the Single Session Course in a mostly self-guided format with one optional telephone or secure messaging discussion with participants. These trials found positive outcomes and we now wish to evaluate the course in a self-directed format without a telephone or secure messaging discussion.

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

You are eligible to participate in this trial if:
(1) You are 18 years or older
(2) You are living in Australia
(3) Experiencing symptoms of depression or anxiety

Currently, we cannot include people who:
(1) Are imminently suicidal or unable to keep themselves safe
(2) Are not living in Australia
(3) Are unable to read or understand English

Individuals are allowed to participate in other treatments during this trial. The Single Session Course may be used as a stand-alone treatment or as an adjunct to other psychological treatment or medication.

3. What does this research trial involve?

Once you have read this information sheet and decide you wish to participate, you can apply for the research trial on the eCentreClinic website (www.ecentreclinic.org). All interested individuals must complete an online assessment.

Participants will be randomly allocated to one of two groups:

- Group 1: Immediate treatment
- Group 2: Delayed treatment (will receive access after 9-weeks).

The Single Session Course involves one lesson including information and skills about the development, maintenance, and treatment of anxiety and depression. The lesson takes approximately 45-60 minutes to read. There are also downloadable guides with skills practice worksheets and illustrative examples for how to use the skills, as well as an additional resource designed to provide skills to help manage worry symptoms.

Participants will be asked to complete questionnaires as a part of this research trial. These are essential as they help us to evaluate the treatment. The questionnaires will be available the first week of treatment, and then 1-month later (Week 5), 2-months later (Week 9), and 4-months later (Week 17). These questionnaires will take 10-15 minutes to complete.

4. How is this research being paid for?

This research is funded by a research grant from Macquarie University to Dr Madelyne Bisby. However, there are no costs for participants in this research trial, and participants cannot be remunerated for their participation.

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

Based on our previous research, we expect that you will find participating in this research trial helpful. We expect that it will result in improvements in anxiety and depression. However, we cannot guarantee or promise that you will receive any benefit from participating.

6. Are there risks to participating in this research trial?

There are no known risks associated with participating in this research. Psychological interventions can be confronting and distressing at times for some people, especially early on. This is partly because psychological treatments require people to think about the difficulties they are experiencing, and slowly make changes in their daily routines and how they manage their emotional wellbeing. Importantly, any distress usually reduces over time as people learn skills for improving their emotional wellbeing.

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. You can also contact Lifeline on 13 11 14 for crisis support at any time.

If we notice a significant deterioration in your mood and/or appear to be at risk of self-harm based on your responses to the questionnaires, one of the psychologists at the eCentreClinic will attempt to contact you to ensure your safety. We will contact you to identify additional supports and further treatment options, if required, after participating in the treatment. This contact will occur by phone in the first instance from a landline beginning with 02 9850. If we cannot reach you, we will send you an email to follow-up.

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

Participation in this research trial 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. You can also choose to withdraw from the research without any repercussion.

You may elect to not continue with the treatment while still remaining in the research (i.e., completing the questionnaires). Importantly, any information and data you provide up until your withdrawal cannot be deleted or withdrawn, consistent with the standard principles for health research.

8. How will my confidentiality be protected?

Confidentiality arrangements will follow Australian Law. 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.

PLEASE NOTE: We are required by law to report any instances where we become concerned about your personal safety or the personal safety of others, particularly children.

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 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 Madelyne Bisby or the eCentreClinic to discuss this research and ask any questions you may have at any time.

PARTICIPANT CONSENT FORM

Once you have read this Participant Information and Consent form, you can click the 'consent' button to enrol in this research trial.

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

1. You would like to participate in the research trial.
2. You have read the Participant Information Statement for the research trial.
3. You have the opportunity to raise any questions or concerns with us at any time.
4. You can withdraw from the research trial at any time without prejudicing your relationship with the researchers, the eCentreClinic, or Macquarie University.
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.
7. You can raise any questions or concerns about this research project with Dr Madelyne Bisby (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 Madelyne Bisby by **emailing 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 any treatment or my relationship with the eCentreClinic or Macquarie University.