

Participation Information and Consent Form

Chief Investigator: Dr Madelyne Bisby

PARTICIPANT INFORMATION AND CONSENT FORM

Examining different options for helping people manage anxiety and depression.

You are invited to participate in a research trial of two different psychological treatments for anxiety and depression: a Single Session Intervention and a Multi Session Intervention.

This research is being conducted by:

- Dr Madelyne Bisby, Clinical Psychologist / Research Fellow, Macquarie University
- Ms Tanya Balakumar, Psychologist, Macquarie University
- Dr Amelia Scott, Clinical Psychologist / Research Fellow, Macquarie University
- Dr Eyal Karin, Data Analyst, Macquarie University
- Professor Nick Titov, Executive Director MindSpot Clinic, 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 compare two different online treatment options in reducing symptoms of anxiety and depression. Many different treatment options are available to help people manage anxiety and depression. Some of these treatment options are longer, and some are shorter.

The available data suggests that shorter and longer treatments may be similarly effective in helping people managing anxiety and depression. In this study, we are interested in comparing a brief, 1-lesson, internet-delivered intervention with a longer, 5-lesson, internet-delivered intervention.

We also know that a meaningful proportion of people improve and/or recover from anxiety and depression without any formal treatment or help. So, in this trial, some participants will also be asked to participate in a group that waits roughly 8 weeks to start an intervention.



2. Background to the trial

While there are many psychological treatments available for anxiety and depression, there is very little data for us to help people decided between longer and shorter treatments. There is evidence that both types of treatments work, and have different pros and cons. We want to explore how effective longer and shorter treatments are when delivered via the internet, and get participants feedback and experiences about these two types of treatment.

3. 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) You are experiencing difficulties with anxiety and/or depression

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

4. 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 assessment, and then will be contacted by a clinician to complete an assessment interview over the telephone.

Participants will be randomly allocated to one of three groups:

- Group 1: The 1-lesson intervention (the Single Session Intervention)
- Group 2: The 5-lesson intervention (the Multi Session Intervention)
- Group 3: The waiting group (who get the Multi Session Intervention after 8 weeks)

The Single Session Intervention group will receive access to one lesson including information and skills about the development, maintenance, and treatment of anxiety and depression. Participants will have the option of contact with a clinician from the eCentreClinic for the 1-week following the release of the lesson.

The Multi Session Intervention will receive access to five lessons over an 8-week period and will have the option of contact with a clinician from the eCentreClinic for the duration of the intervention. Those participants who are allocated to the waiting group will receive access to the Multi Session Intervention after the 8-week waiting period.

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 as they help us to evaluate the two interventions.

Participants will be asked to complete online questionnaires, which take approximately 10-15 minutes at the following times:

- The 1st week of treatment
- 3 weeks after starting treatment
- 8 weeks after starting treatment
- 3 months after starting treatment

6. How is this research being paid for?

This research is funded, in part, 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.

7. 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, irrespective of the treatment you receive. 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.

8. 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. 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.

9. 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 treatments 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.

10. 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.

11. 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.



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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 and all uses will be subject to approval from an Australian Human Research Ethics Committee.
7. You can raise any questions or concerns about this research project with Dr Madelyne Bisby (madelyne.bisby@mq.edu.au) 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 madelyne.bisby@mq.edu.au**.

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.