Chief Investigator: Dr Madelyne Bisby

PARTICIPANT INFORMATION AND CONSENT FORM

A randomised controlled trial of the 'Brief Perinatal Wellbeing Course' for women with perinatal depression or anxiety

You are invited to participate in a research trial of an online ultra-brief psychological treatment for women with perinatal 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
- Dr Alana Fisher, 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 evaluate a highly accessible, ultra-brief psychological treatment for women with perinatal depression or anxiety. We are interested in such treatments because research shows many women do not want or have difficulty accessing more traditional, longer, treatment options.

We designed the treatment in consultation with women who have had perinatal depression or anxiety. This research trial is designed to comprehensively evaluate the helpfulness of this treatment and get further feedback from participants, which we can use to further improve the treatment.

2. Background to the trial

Ultra-brief psychological treatments can be effective for some adults with depression or anxiety symptoms. We are currently evaluating the *Perinatal Wellbeing Course* for women with depression or anxiety symptoms during the perinatal period and have observed positive results so far. This treatment has been tailored to meet the specific needs of women during pregnancy and postpartum.

The current trial is designed to evaluate how effective the treatment is for reducing perinatal depression and anxiety for up to 3-months.

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

You are eligible to participate in this trial if you are:
(1) A woman (or person assigned female at birth) living in Australia

Please download this document for future reference.

(2) 18 years or older
(3) In the perinatal period [pregnancy to 12-months postpartum]
(4) Experiencing symptoms of depression or anxiety

Currently, we cannot include people who are:
(1) Imminently suicidal or unable to keep themselves safe
(2) Significant risk of harm to others
(3) Not living in Australia
(4) Unable to read or understand English

We hope to be able to provide this treatment for individuals from non-English speaking backgrounds in the future.

4. What does this research trial involve?

Once you have read this information sheet and decide you wish to participate, you can complete an initial screening assessment for the research trial on the eCentreClinic website (www.ecentreclinic.org). The purpose of the assessment is to make sure the treatment is likely to be suitable and helpful. 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: Immediate treatment
- Group 2: Delayed treatment (will receive access after 2-months).

The treatment involves one online lesson including information and skills about the development, maintenance, and treatment of depression and anxiety during the perinatal period. There is also one practice guide, case stories, and one additional resource. It will take 60-90-minutes to read all the materials. Participants will have the option of contact with a clinician from the eCentreClinic for the 1-week after they access the lesson.

You may be contacted after the completion of this study to participate in future research.

5. What else does this research trial involve?

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. Online questionnaires will be available at the following times and take 15-20 min:

- The first week of treatment
- 1-month later (Week 5)
- 2-months later (Week 9)
- 3-months later (Week 13)
- 4-months later (Week 17).

6. How is this research being paid for?

This research is funded with support from Macquarie University and via a grant from the Liptember Foundation awarded to Dr Madelyne Bisby, Dr Alana Fisher, Dr Amelia Scott, Dr Nicole Highet, Professor Blake Dear, and Professor Nickolai Titov.

Please download this document for future reference.

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. 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 is usually temporary and 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.

For non-crisis support, you can contact the For When Helpline for new and expecting parents (1300 24 23 22) or the PANDA National Helpline (1300 726 306). These perinatal services are not designed for crisis support and have limited operating hours.

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 you 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, consistent with best practice for health research, any information and data you provide up until your withdrawal cannot be deleted or withdrawn.

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.

Only those members of the eCentreClinic who require access to your personal information (e.g., psychologists, clinical supervisors) will be able to access your personal information. We will publish the results of this research

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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.

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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PARTICIPANT CONSENT FORM

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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 applying, 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.

Please download this document for future reference.