Chief Investigator: Prof Blake Dear

PARTICIPANT INFORMATION AND CONSENT FORM

Examining the efficacy and acceptability of an internet-delivered treatment program for improving psychological wellbeing and function in people with Endometriosis.

You are invited to participate in a research trial of an internet-delivered pain management course, which we are calling the *Endometriosis Pain Course.* This course is designed for adults experiencing endometriosis-related chronic pain and symptoms which are impacting their emotional wellbeing and daily functioning. The *Endometriosis Pain Course* is a modified version of the *Pain Course*, which has been developed over the last ten years based on feedback from thousands of adults living with chronic pain. Results to date have been very encouraging, with participants reporting significant reductions in their disability and improvements in their emotional wellbeing. Based on feedback from participants, we are now interested in exploring the helpfulness of the course for women with endometriosis.

The *Endometriosis Pain Course* aims to provide good information and skills to assist people with endometriosis to manage the impact of pain and other symptoms on their emotional wellbeing and quality of life. This course has been adapted to include information specific to endometriosis and acknowledges the unique challenges and difficulties that people with the condition may face.

This research is being conducted as a part of a Doctor of Philosophy (PhD) being undertaken by Ms Shanika Chandra at Macquarie University, Australia.

This research is being conducted by:

- Ms Shanika Chandra, Clinical Psychologist / Doctoral Candidate, Macquarie University
- Prof Blake Dear, Director eCentreClinic and Clinical Psychologist, Macquarie University
- Dr Madelyne Bisby, Clinical Psychologist / Research Fellow, Macquarie University
- Dr Amelia Scott, Clinical Psychologist / Research Fellow, Macquarie University
- Ms Ivy Feliciano, Clinical Psychologist / Doctoral Candidate, Macquarie University
- Prof Nick Titov, Director MindSpot Clinic, 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 the Chief Investigator Prof Blake Dear or Ms Shanika Chandra via email at 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 examine the efficacy and acceptability of the Endometriosis Pain Course. We have previously evaluated the Pain Course for adults living with chronic pain across several research trials, with

very positive outcomes. We now wish to evaluate an adapted version of the course for women with endometriosis, a chronic health condition where chronic pain is a commonly reported symptom. Importantly, research has previously found that of all the symptoms and consequences of endometriosis, chronic pain has the most significant impacts on people's lives and emotional wellbeing.

We know from research into treatment for chronic pain that access to good information and learning several core self-management skills can make a big difference. We therefore have good reason to believe that self-management programs which provide this information and teach these skills can be beneficial for people experiencing health conditions, like endometriosis, where chronic pain is a common symptom. However, there is no research to date specifically examining the efficacy of these programs for women with endometriosis.

We are developing the Endometriosis Pain Course to increase access to helpful and relevant information and to teach skills to help people manage the impact of endometriosis-related symptoms, including chronic pain, on their life.

To meet the aims of this research, participants will be randomly allocated to one of two groups: (1) an Immediate Participation Group; or (2) a Delayed Participation Control Group. If randomly allocated to the Delayed Participation Control Group, you will start the program 8 weeks later than if you were randomised to the Immediate Participation Group. There are no other differences between the two groups.

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

You are eligible to participate in this trial if: (1) you have been diagnosed with endometriosis by a medical professional and have chronic pain (pain lasting at least 6 months); (2) the pain is having a significant impact on your quality of life and emotional wellbeing; (3) you are 18 years or older; (4) you are living within Australia; (5) your pain has been assessed and is being managed by a healthcare physician; (6) you are able to 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 will also need access to the internet to participate.

PLEASE NOTE: We strongly recommend you discuss your participation in the Endometriosis Pain Course with your doctors and any other health professionals involved in managing your conditions.

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

Participation in this research trial is voluntary. It is up to you whether 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 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 15 to 20 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 with further information for participating in the trial.

The *Endometriosis Pain 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 pain 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:

- In the first week of the course (time needed: 15 to 20 minutes)
- Mid-way through the course (time needed: 10 to 15 minutes)
- 9 weeks after starting the course (time needed: 15 to 20 minutes)
- 3 months after starting the course (time needed: 10 to 15 minutes)

These questionnaires will help 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 Endometriosis Pain Course for approximately 6 months should you continue to participate in the research.

5. How is this research 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 through an Australian Government Research Training Program Scholarship and via the eCentreClinic, Macquarie University.

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

Based on our previous research, we expect that you will find this course interesting and helpful. We expect it will help you to manage the impact of your endometriosis-related symptoms and pain on your day-to-day life as well as your emotional wellbeing. For example, based on previous research of the Pain Course, we know that more than 90% of participants find the course worth their time and that they would recommend it 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?

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. 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. It is an essential criterion of participation in this Course that you have had your endometriosis and any other health conditions assessed by a doctor and that your conditions continue to be monitored and managed by a doctor.

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 pain, please arrange to see your primary care physician or contact emergency services on 000. For local support over the phone, you are encouraged to contact *Beyond Blue* (1300 22 4636) or *Lifeline* (13 11 14).

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. This may include circumstances in which we have immediate concerns for yours or someone else's safety. 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 information.

PLEASE NOTE: We will use the phone number and email address you provide us to communicate with you. Please only provide a phone number that you are comfortable with us using to contact you and only provide an email address that you are comfortable with us to using to communicate private information with you. If you have concerns about us contacting you via your phone or email, please let us know as soon as possible.

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 Ms Shanika Chandra, Prof Blake Dear or the eCentreClinic to discuss this research and ask any questions you may have at any time.

PARTICIPANT CONSENT FORM

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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 Endometriosis Pain Course and the research.
2. You have had your condition assessed by a medical professional.
3. You have read the Participant Information Statement.
4. You have the opportunity to raise any questions or concerns with us at any time.
5. You can withdraw from the research trial at any time without prejudicing your relationship with the researchers or Macquarie University, Sydney Australia.
6. 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.
7. 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.
8. You can raise any questions or concerns about this research project with Ms Shanika Chandra or Prof Blake Dear (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 Ms Shanika Chandra by **emailing the text below 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 Macquarie University.