Chief Investigator: Dr Blake Dear

PARTICIPANT INFORMATION AND CONSENT FORM

The Pain Course: Exploring the efficacy of an international self-guided online pain management program.

You are invited to participate in a research trial of a self-management course, the *Pain Course*, for adults with chronic pain impacting their emotional wellbeing and quality of life. The Pain Course is designed to provide good information and skills for managing the impact of chronic pain on quality of life and emotional wellbeing. The research team have been developing the course over the last several years based on feedback from thousands of adults living with chronic pain. To date, the results have been very encouraging, with participants reporting significant reductions in their disability and improvements in their emotional wellbeing.

This research is being conducted by:

- Dr Blake Dear, Director eCentreClinic and Clinical Psychologist, Macquarie University.
- Dr Joanne Dudeney, Clinical Psychologist / Research Fellow, Macquarie University.
- Dr Rhiannon Fogliati, Clinical Psychologist / Research Fellow, Macquarie University.
- Ms Bareena Johnson, Psychologist, eCentreClinic, Macquarie University.
- Dr Milena Gandy, Clinical Psychologist / Research Fellow, Macquarie University.
- Mr Eyal Karin, Statistician, Macquarie University.
- Dr Sarah McDonald, Clinical Psychologist / Research Fellow, Macquarie University.
- Professor Nick Titov, Professor and 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 eCentreClinic via email 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 Pain Course when offered in an entirely self-guided format. We have previously evaluated the Pain Course in a mostly self-guided format with a brief telephone discussion with participants before participation. This trial found very positive outcomes. However, we now wish to evaluate the course in an entirely self-guided format.

Research tells us that chronic pain has a very significant impact on people's lives and emotional well-being. We also know that access to good information and learning several core self-management skills can make a big difference. However, research also indicates that many people cannot access the kinds of self-management programs that provide this information and teach these skills.

We are developing the Pain Course to increase access to helpful information and to teach skills to help people manage the impact of 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 experienced 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 outside of 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 Pain Course with your doctors and any other health professionals involved in the management of your pain.

3. 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. Importantly, you can also choose to withdraw from the research without any repercussion.

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 20 to 30 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 *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).

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 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 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 pain on your day-to-day life 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 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 health condition assessed by a doctor and that your condition continues 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. 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?

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. 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.

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

PARTICIPANT CONSENT FORM

The Pain Course: Exploring the efficacy of an international self-guided online pain management program.

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 Pain Course.
2. You have had your pain 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-identifed 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 Dr 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 Dr Blake Dear 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 Macquarie University, Australia.