

Chief Investigator: Dr Blake Dear

PARTICIPANT INFORMATION AND CONSENT FORM

The Chronic Conditions Course: A Phase III randomised controlled trial of an online psychological program for adults with chronic physical health conditions

You are invited to participate in a research trial of an online program, the *Chronic Conditions Course*, for Australian adults with chronic physical health conditions. The program is designed to provide good information and skills for managing the impact of chronic physical health conditions on people's emotional wellbeing and quality of life. The research team have been developing the course over the last several years based on feedback from thousands of adults living with significant chronic physical health conditions. To date, the results have been very encouraging, with participants reporting significant reductions in their disability levels and improvements in their emotional wellbeing.

This research is being conducted by:

- Dr Blake Dear, Director eCentreClinic and Clinical Psychologist, Macquarie University.
- Dr Rhiannon Fogliati, Clinical Psychologist / Research Fellow, Macquarie University.
- Dr Amelia Scott, Clinical Psychologist / Research Fellow, Macquarie University.
- Dr Madelyne Bisby, Clinical Psychologist Registrar / Research Fellow, Macquarie University.
- Dr Andreea Heriseanu, Clinical Psychologist Registrar / Research Fellow, Macquarie University.
- Dr Joanne Dudeney, Clinical Psychologist / Research Fellow, Macquarie University.
- Dr Milena Gandy, Clinical Psychologist / Research Fellow, Macquarie University.
- Dr Eyal Karin, Statistician / Research Fellow, Macquarie University.
- Dr Sarah McDonald, Clinical Psychologist / Research Fellow, Macquarie University.
- Dr Lauren Staples, Database Manager / Research Fellow, Macquarie University.
- Professor Louise Sharpe, Clinical Psychologist / Researcher, Sydney University.
- Professor Olav Nielssen, Psychiatrist / Researcher, Macquarie University.
- Professor Nick Titov, Director MindSpot Clinic, Macquarie University.
- Professor Heather Hadjistavropoulos, University of Regina, Canada.

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 Chronic Conditions Course when offered to large numbers of Australians with different chronic physical health conditions. So far the course has been evaluated in trials involving approximately 1000 people. However, larger trials are needed to properly evaluate any treatment. We are also interested in learning from participants about what they find



most helpful from the course and how they manage their emotional wellbeing and the impacts of their conditions over the long-term.

2. Background to the trial?

Research tells us that chronic conditions have a very significant impact on people's day-to-day lives and their emotional wellbeing. We also know that access to good information and learning several practical psychological skills can make a big difference. However, research also indicates that many people cannot access the kinds of services that provide this information and teach these skills.

We are developing the Chronic Conditions Course to increase access to helpful information and to teach skills to help people manage the impact of chronic physical conditions on their lives.

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

You are eligible to participate in this trial if:

- (1) You have a diagnosed chronic physical health condition
- (2) The condition is affecting your mental health and quality of life
- (3) You are 18 years or older
- (4) You are living in Australia

Currently, we cannot include people who:

- (1) Are imminently suicidal or unable to keep themselves safe
- (2) Do not have access to the internet or a computer
- (3) Are unable to read or understand English

PLEASE NOTE: We strongly recommend you discuss your participation in the course with your doctors and any other health professionals involved in the management of your health conditions.

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. Following completion of these questionnaires, we will contact eligible participants via telephone to talk more about the course, ensure it is likely to be helpful and address any questions or concerns you may have.

Participants will be randomly allocated to one of two groups: (1) a group who receive access to the course immediately (i.e., the Treatment Group); or (2) a group who receive delayed access to the course (i.e., the Control Group). The delayed access group receive the course 8 weeks following the immediate access group. There are no other differences between the two groups.

The *Chronic Conditions Course* consists of 5 online lessons. You will be asked to complete these lessons over 8 weeks and to complete some simple exercises that will help you to think through the ideas in the



lessons and practice the skills. Each lesson provides information and skills that are proven to help in managing the impact of chronic conditions on your day-to-day activities and emotional wellbeing. Each lesson takes about 20 to 30 minutes to complete and the exercises will take a further 4 hours each week. Through the course you will be provided with lots of additional resources, and stories and examples from previous participants with different chronic conditions and difficulties.

You will also receive weekly automatic emails, and be provided with the option of brief weekly contact with an eCentreClinic psychologist. These services are to help guide and support you as you go through the course.

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. They help us to evaluate the course and also to understand how people manage the impacts of their condition over the long term.

Participants will be asked to complete online questionnaires:

- Week 1 of the course (approx. 15 to 20 minutes)
- At the end of the course (approx. 15 to 25 minutes)

Participants will also be asked to complete online questionnaires:

- 3 months after the course (approx. 10 to 15 minutes)
- 12 months after the course (approx. 10 to 15 minutes)
- 24 months after the course (approx. 10 to 15 minutes)

Importantly, participants will have ongoing access to the course for the duration of your participation in this research. We will also provide some feedback about participants' responses each time they complete the questionnaires.

6. 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 being funded by the Australian National Health and Medical Research Council (NHMRC) via an Investigator Grant to Dr Blake Dear.



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

Based on our previous research, we expect that you will find this course helpful. We expect it will help you to manage the impacts of your condition(s) on your quality of 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 would recommend it to others. 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 or the course. However, we strongly encourage all participants to talk to their health professionals about their participation in this course. This is particularly important where participants are unsure about some aspects of the course and what may and may not be relevant in terms of their physical health conditions.

The course is based on leading face-to-face psychological programs for adults with chronic conditions. Psychological treatment programs can be confronting and distressing at times for some people, especially early on in treatment. This is partly because helpful psychological treatments require people to think about the difficulties they are having and how they might use different skills or make certain changes to manage their emotional wellbeing.

Importantly, any distress usually reduces over time as people learn about emotional wellbeing and several skills for managing their emotional wellbeing. Participants are also provided with access to an eCentreClinic psychologist to help them through the course and to manage any psychological distress.

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. Please also let us know at a convenient time so that we may assist.

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 course (i.e. the treatment program), 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 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 Chronic Conditions Course 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 or Macquarie University, Sydney Australia.
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 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.