

## Participation Information and Consent Form

**Chief Investigator: Associate Professor Shane Cross**

### **PARTICIPANT INFORMATION AND CONSENT FORM**

*Testing a new online psychological treatment for depression and anxiety: the ACT Course.*

You are invited to participate in a research trial of an online psychological treatment for anxiety and depression.

This research is being conducted by:

- Assoc. Professor Shane Cross, Director of Service Development MindSpot, Macquarie University
- Dr Madelyne Bisby, Clinical Psychologist / Research Fellow, Macquarie University
- Assoc. Professor Lauren Staples, Macquarie University
- Professor Blake Dear, Director eCentreClinic, Macquarie University.
- Professor Nick Titov, Executive 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 Assoc. Professor Shane Cross via phone (02 9850 8724) or email ([contact@ecentreclinic.org](mailto: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 test a new online treatment for anxiety and depression. Many different treatment options are available to help people manage anxiety and depression. This new treatment is based on a psychological treatment called Acceptance and Commitment Therapy (ACT), which has proven to be effective in face-to-face treatment.

In this study, we are interested in testing the acceptability, satisfaction, and outcomes from this therapy when delivered in an online delivery format. We're also interested in learning from participants how we can improve the ACT Course.

#### **2. Background to the trial**

Hundreds of studies have proven ACT to be effective for treating a wide range of psychological difficulties, including anxiety and depression. Most of these studies were conducted in face-to-face settings. There has been less research conducted on delivering ACT online with therapist support, but we believe that this treatment will also be effective in this format. This study will help us get important information about whether the treatment material can be successfully delivered online, whether it results in substantial reductions in depression and anxiety symptoms, and what participants have to say about their experiences when receiving this type 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) The main difficulties you are experiencing are 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](http://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.

If suitable, participants will then be given online access to the new ACT Course.

The ACT Course consists of five modules, each taking approximately 30-60 mins to complete, delivered over a 8-week period and will have the option of contact with a psychologist from the eCentreClinic for the duration of the intervention.

### **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 treatment and help improve it.

Participants will be asked to complete online questionnaires, which take approximately 10-15 minutes, every week.

### **6. How is this research being paid for?**

This research is unfunded. 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, and 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 repercussions.

You may elect to not continue with the treatments while still remaining in the research (i.e. completing the questionnaires). 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 Associate Professor Shane Cross or the eCentreClinic to discuss this research and ask any questions you may have at any time.



## **PARTICIPANT CONSENT FORM**

*Testing a new online psychological treatment for depression and anxiety: the ACT Course*

**Once you have read this Participant Information and Consent form, you can click the ‘consent’ button to enrol in this research trial.**

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 can 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 Assoc. Prof Shane Cross (shane.cross@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](mailto: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 Assoc. Prof Shane Cross by **emailing the text below back to** [contact@ecentreclinic.org](mailto: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 future treatment or my ongoing relationship with the eCentreClinic or Macquarie University.