

## **PARTICIPANT INFORMATION AND CONSENT FORM**

### *The Things People Do That are Associated with Emotional Health, Anxiety and Depression*

You are invited to participate in a trial where we will be offering the Wellbeing Course. This Course is designed to help people with anxiety and depression to learn to manage and overcome symptoms. However, we are not formally evaluating the Wellbeing Course in this study. Instead, we are interested in the relationship between a large range of every day behaviours/activities and emotional wellbeing. We are interested in how these behaviours/activities change over time after participating in a course like the Wellbeing Course. We are also developing a new questionnaire, called the Things You Do Questionnaire, which we hope will measure the everyday behaviours and activities that people use to manage their emotional wellbeing.

This research is being conducted by:

- Professor Nick Titov, Professor and Director MindSpot Clinic, Macquarie University.
- Associate Prof Blake Dear, Director eCentreClinic and Clinical Psychologist, Macquarie University.
- Dr Rhiannon Fogliati, Clinical Psychologist / Research Fellow, Macquarie University.
- Dr Sarah McDonald, Clinical Psychologist / Research Fellow, Macquarie University.
- Dr Milena Gandy, Clinical Psychologist / Research Fellow, Macquarie University.
- Dr Joanne Dudeney, Clinical Psychologist / Research Fellow, Macquarie University.
- Dr Lauren Staples, Research Fellow, Macquarie University.
- Dr Olav Nielssen, Senior Psychiatrist, Macquarie University.
- Mr Eyal Karin, Statistician, Macquarie University
- Dr Rony Kayrouz, Clinical Psychologist, Macquarie University
- Dr Nicole Lees, Psychologist, Macquarie University.
- Ms Katie Ryan, Psychologist, 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 GP or specialist, as needed.

**PLEASE NOTE:** You are also welcome to contact the eCentreClinic via email [contact@ecentreclinic.org](mailto:contact@ecentreclinic.org) with any questions regarding this research or your participation at any point. You can contact A/Prof Blake Dear directly on 02 9850 9979 or via email at [blake.dear@mq.edu.au](mailto:blake.dear@mq.edu.au).

### **1. What is the purpose of this research trial?**

The purpose of this research is to examine the things people do and think that improve their emotional wellbeing. We are also assessing the performance of a revised questionnaire (The Things You Do; TYDQ) which people will be asked to do several times while they participate in the Wellbeing Course. This questionnaire involves 60 items and participants will be asked to complete it fortnightly during the course.

Completing this questionnaire will take approximately 10-15 minutes fortnightly. However, the responses of participants in this research project will help us to understand the relationship between everyday behaviours and our emotional wellbeing. In the long term, this will help us to develop more effective



treatments and to provide more helpful advice to people about the things they can do to maintain their emotional wellbeing.

## **2. 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, and the Australian National Health and Medical Research Council.

This project is supported by Gotcha4Life ([www.gotcha4life.org](http://www.gotcha4life.org)); a not-for-profit Australian Foundation with the goal of positively impacting men's mental health. Gotcha4Life is providing in-kind and financial support to recruitment of men into this research.



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

You are eligible to participate in this trial if: (1) living in Australia; (2) Aged 18 years or older; and (3) experiencing at least mild symptoms of general anxiety and/or depression. Currently, we cannot include people experiencing very severe depression or who have any intention or plan to harm themselves. Or, who have harmed themselves in the previous 12 months. You will also need access to the internet to participate in this research.

## **4. What if I do not want to participate or I want to withdraw later?**

Participation in this research trial is entirely 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.

## **5. 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](http://www.ecentreclinic.org)). This application process takes about 10 to 15 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 contacted by a member of the eCentreClinic team to conduct a brief telephone interview, discuss the Course and answer your questions. You will then be allocated to the Wellbeing groups and given a start date for the Course:

The *Wellbeing 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 anxiety and depression, 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 brief weekly contact (e.g., 5 to 15 minutes) from an experienced Psychologist who will provide support and answer your questions as you work through the Course.

We will ask you to complete online questionnaires:

- In the first week of the course (time needed: 10 to 15 minutes).
- Fortnightly during the course (time needed: 10 to 15 minutes).
- 9 weeks 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. Once you have completed the Course, a clinician from the eCentreClinic will contact you regarding your results and answer any questions you might have. You will have access to the Wellbeing Course for approximately 8 months should you continue to participate in the research.

## **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 anxiety and depression 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 them 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?**

There are no known discomforts or risks associated with participating in this kind of Course. It is very unlikely that the present study will result in physical harm. No adverse effects have been reported in similar studies reported in similar research.

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 invited to contact A/Prof Blake Dear or any of your other health professionals to discuss this distress. You are also welcome to withdraw from this research at any time and we are available at all times (during business hours) to discuss your symptoms and further treatment options with you.

## **8. How will my confidentiality be protected?**

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. Importantly, where we hold significant concerns about your personal safety or the safety of others, particularly children, we are legally required to notify emergency and other governmental services. We will make every attempt to inform you if we are required to contact these services.

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 details or information.

## **9. Can I see a copy of the published research?**

We will ask all participants whether they would like to receive a copy of any published manuscripts resulting from this research. So, you are welcome to request a copy of any research manuscripts that are published. You are also welcome to contact A/Prof Blake Dear or the eCentreClinic to discuss this research and ask any questions you may have at any time.

### **PARTICIPANT CONSENT FORM**

*The Things People Do That are Associated with their Emotional Wellbeing*

**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 Wellbeing Course.
2. You have read the Participant Information Statement, which explains the aims of the study and nature of your participation.
3. You have the opportunity to raise any questions or concerns with us, regarding this research, 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. The eCentreClinic may contact crisis or emergency services, as required by law, if there are significant concerns about my safety or someone else’s safety during the Course.
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 future research subject to Human Research Ethics Committee approval.
8. You can raise any questions or concerns about this research project with A/Prof Blake Dear (02 9850 9979) or any staff ([contact@ecentreclinic.org](mailto: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 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 the A/Prof Blake Dear at any time or **email 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 treatment or my relationship with Macquarie University.