Participation Information and Consent Form

Chief Investigator: Dr Madelyne Bisby

PARTICIPANT INFORMATION AND CONSENT FORM

The 'Things You Do': a randomized controlled trial of a minimal psychological intervention

You are invited to participate in a research trial of the 'Things You Do' intervention. The 'Things You Do' is a list of things that are linked to emotional wellbeing. Our research shows that doing these things regularly helps reduce symptoms of anxiety and depression.

This research is being conducted by:

- Dr Madelyne Bisby, Clinical Psychologist / Research Fellow, Macquarie University
- Professor Nick Titov, Executive Director MindSpot Clinic, Macquarie University.
- Professor Blake Dear, Director eCentreClinic and Clinical Psychologist, Macquarie University.
- Assoc Professor Shane Cross, Director of Service Development MindSpot Clinic, Macquarie University.
- Assoc Professor Lauren Staples, Database Manager / Research Fellow, Macquarie University.
- Dr Eyal Karin, Statistician / Research Fellow, 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 Dr Madelyne Bisby via phone (02 9850 8724) or email (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 the impact of the 'Things You Do' intervention on symptoms of anxiety and depression. We want to know if increasing how often people do the things listed in the 'Things You Do' Questionnaire affects psychological wellbeing.

2. Background to the trial

Research tells us that how often we engage in the activities listed on the 'Things You Do' Questionnaire is linked with emotional wellbeing. We also know that encouraging people to engage in these behaviours as a part of more intensive treatment programs can lead to improvements in anxiety symptoms. However, we don't yet know whether this intervention can reduce symptoms without needing to undergo a formal treatment program.

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

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 to participate in the 'Things You Do' on the eCentreClinic website (www.ecentreclinic.org).

Participants will be randomly allocated to one of two groups:

- Group 1: Will receive access to the 'Things You Do' intervention immediately, and will also receive daily text message reminders to do those things; or
- Group 2: Will receive delayed access to the intervention 4 weeks later.

The 'Things You Do' intervention consists of an informational resource outlining the purpose of the trial, a description of the target behaviours, and suggestions for how you might increase the frequency of these behaviours. Participants will also receive daily text messages encouraging participation in the target behaviours. Text messages will be delivered once per day Monday to Friday, and you can opt-out at any time. The intervention duration is 4 weeks.

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 to understand how people manage the impacts of their condition over the long term.

Participants will be asked to complete online questionnaires (approximately 10 minutes) at the start of treatment (Week 1), halfway through treatment (Week 3), and after treatment (Week 5). Participants will also be asked to complete online questionnaires 3-months later.

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.

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

Based on our previous research, we expect that you will find this intervention helpful. We expect that it will help you increase how often you engage in helpful behaviours, and result in improvements in anxiety, depression, and life satisfaction. 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. The intervention is based on daily actions which are linked to good psychological health. 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 make changes in their daily routines. 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. Please also let us know at a convenient time so that we may assist. If your responses indicate that you are at risk of self-harm or suicide, we will 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 repercussion.

You may elect to not continue with the 'Things You Do' intervention 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 Madelyne Bisby 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 enrol in this research trial.

Importantly, by submitting an application, you consent to the points below:

1. You would like to participate in the 'Things You Do' 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, 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 Dr Madelyne Bisby at the eCentreClinic (contact@ecentreclinic.org) 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 +61 2 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 Madelyne Bisby 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 the eCentreClinic or Macquarie University.