Chief Investigator: Professor Nick Titov

PARTICIPANT INFORMATION AND CONSENT FORM

Testing the impact of restricting and then resuming the Things You Do actions.

You are invited to participate in this study which examines the effects of restricting and then resuming actions which we have previously found are important for good mental health. We expect that restricting those actions will reduce mental health, but that mental health will return to normal after those actions are resumed. We are comparing these effects with a group of people who are acting as 'control' participants.

This research is being conducted by:

- Professor Nick Titov, School of Psychological Sciences, Macquarie University
- Professor Blake Dear, Director eCentreClinic and Clinical Psychologist, Macquarie University
- Assoc Professor Lauren Staples, Database Manager / Research Fellow, Macquarie University
- Professor Mike Jones, School of Psychological Sciences, Macquarie University
- Dr Rony Kayrouz, School of Psychological Sciences, Macquarie University
- Professor Olav Nielssen, 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 Professor Nick Titov via phone (0488 991 122) or email (contact@ecentreclinic.org) regarding this research or your participation at any point.

1. What is the purpose of this research trial?

The main purpose of this research is to test whether first restricting and then resuming certain actions has an impact on mental health. We will do this by comparing a group of people who receive those instructions with a group who are instructed to continue to do their usual activities. This information will help us understand the things people can do to support their own mental health, which could lead to new public mental health education campaigns and psychological treatments.

2. Background to the trial

We have been developing and evaluating psychological treatments for almost two decades. We have observed that some people can improve their mental health by making changes in their daily routines and habits (that is, their actions), while other people need more intense treatments. Our recent work has identified that some actions appear to be more important than others (the 'Things You Do' which we have recently renamed 'The Big 5'). In a recent trial we demonstrated that asking people to restrict the Things You Do led to a reduction in mental health, and that resuming those actions led to a full recovery of mental health.

This study extends on that study by testing this protocol with a larger number of people and comparing that group with another group of participants who will continue to perform their usual activities.

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

We cannot include people who:

1. Have moderate or higher levels of symptoms of anxiety or depression
2. Are not living in Australia
2. Are unable to read or understand English
3. Are currently receiving psychological treatment
4. At risk of suicide or self-harm

We have contracted BuildClinical, a Health Insurance Portability and Accountability Act (HIPAA) compliant participant recruitment company, to help us to promote the trial. BuildClinical have been instructed to provide people with information about this trial and to share this Participant Information Form. However, any other contact you have about this trial will be with the Macquarie University research team.

4. What does this research trial involve?

Once you have read this information sheet and have decided that you wish to participate, you can apply to participate in the 'Things You Do Trial' on the eCentreClinic website (www.ecentreclinic.org). We will ask you to complete a series of questionnaires, some of which ask about symptoms of depression and anxiety. If you meet the study eligibility criteria we will then telephone you to conduct a brief interview to confirm your eligibility and to tell you more about the Trial.

If you meet the study criteria and choose to continue you will be randomly allocated to one of two 'groups':

1. Things You Do Group. Participants in this group will complete 3 Phases.
    - Phase 1. Participants will go about their daily lives without any changes for two weeks.
    - Phase 2. Participants will restrict how often they do the Things You Do for two weeks.
    - Phase 3. Participants will resume how doing the Things You Do actions for five weeks and we will send you one SMS message each weekday, for four weeks. Each SMS will encourage you to perform the Things You Do activities.
    - During Phase 2 and 3 participants in the Things You Do group will receive weekly phone calls from one of the study clinicians to check on progress and wellbeing.
    - Each week participants will be asked to complete questionnaires about the activities, and about symptoms of depression and anxiety.

2. Waitlist Control Group.
    - Participants in this group will be asked to do their usual activities.
    - Each week participants will be asked to complete questionnaires about the activities, and about symptoms of depression and anxiety.

5. What else does this research trial involve?

An important part of this trial involves completing weekly questionnaires. These questionnaires should take between 5-15 minutes to complete. These questionnaires are essential and will help us to evaluate the benefits of the different actions on mental health. To compensate participants for their time, we will provide gift vouchers valued at $25 for each week questionnaires are completed on time and an additional gift voucher valued at $50 for completing the final set of questionnaires. Vouchers will be sent at the end of the study (9 weeks after you start), with a total possible value of $250.

6. How is this research being paid for?

There are no costs for participants in this research trial. Some of the costs of this research are kindly funded by a grant from the Western Australian Primary Health Alliance (WAPHA).

7. **Will I benefit from participating in this research trial?**
Based on the experience of participants in other trials, we expect that participating in this study will help you learn more about your mental health and the actions you can take each day to stay mentally healthy. However, we cannot guarantee or promise that you will receive any benefit from participating.

8. **Are there risks to participating in this research trial?**
It is possible that that restricting doing the Things You Do may result in a temporary increase in symptoms of depression and/or anxiety. However, we would expect any increase in symptoms to disappear as people start to do the Things You Do again.

If you become concerned about your mental health, please contact us and we will assist you.

However, if you require **urgent help** regarding your mental health, please:

1. Access free telephone information and support from Beyond Blue on 1300 22 46 36
2. Access free psychological assessment and treatment via MindSpot at www.mindspot.org.au or on 1800 61 44 34
3. Speak to your GP about the treatment and support options that might be available to you.

And, if it is an emergency, please call 000 or present to your nearest hospital.

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 at any time.

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.

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.

PLEASE NOTE:

1. 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 inform you if we are required to make a report.
2. We will communicate with you via the email and phone number you provide us. Please only provide us an email and phone number that is secure and it is suitable for us to use to send you sensitive information and where we can leave messages.

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 Professor Nick Titov or the eCentreClinic (contact@ecentreclinic.org) 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 this 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 Professor Nick Titov 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 the eCentreClinic 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.