



**Black Dog
Institute**



ONLINE PARTICIPANT INFORMATION STATEMENT

Randomised controlled trial of Anchored, a smartphone application-based intervention to support the mental health of Australian workers

Dr Mark Deady, A/Prof Samuel Harvey, Prof Helen Christensen, Mr Daniel Collins, Ms Isobel Lavender

1. What is the research study about?

You are invited to take part in this research study. The research study aims to evaluate a new app, called Anchored. The app is centred around a 30-day challenge of mindfulness and cognitive behavioural tasks designed to upskill users and promote wellbeing. You have been invited because we need employed Australian men and women to test the app to establish its efficacy.

Anchored has been produced in Australia by researchers in the Workplace Mental Health Team at The Black Dog Institute and University of New South Wales (UNSW). It is part of the Prevention Hub, Australia's first integrated research translation initiative for preventing anxiety and depression. This app has been designed by industry experts in mental health including psychiatrists and clinical psychologists, and will be tested with working Australian adults from a range of industries.

This research study is a randomised controlled trial, which means participants will be randomly allocated to one of two groups, either: 1) Use the app immediately; or 2) Receive an online health and psychoeducation resource. At the end of the trial all participants will have access to the condition that was most efficacious.

2. Who is conducting this research?

The study is being carried out by the following researchers:

Role	Name	Organisation
Chief Investigator	Dr Mark Deady	UNSW School of Psychiatry & Black Dog Institute
Co-Investigator/s	A/Prof Samuel Harvey Prof Helen Christensen Mr Daniel Collins Ms Isobel Lavender	UNSW School of Psychiatry & Black Dog Institute Black Dog Institute Black Dog Institute Black Dog Institute

Research Funder: Anchored is supported by funding from the Australian Government Department of Health through The Prevention Hub.

3. Inclusion/Exclusion Criteria

Before you decide to participate in this research study, we need to ensure that it is ok for you to take part. The research study is looking to recruit people who meet the following criteria:

- You are age 18 years or older
- You are currently employed
- You currently reside in Australia
- You own a smartphone
- You have good English comprehension

4. Do I have to take part in this research study?

Participation in any research study is voluntary. If you do not want to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the study at any stage.

If you decide you want to take part in the research study, you will be asked to:

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- Read the information carefully (ask questions if necessary, by contacting the research team via the contact details in Section 10 below);
- Electronically sign the consent form if you decide to participate in the study;
- Print or download a copy of this form for you to keep.

5. What does participation in this research require, and are there any risks involved?

If you agree to participate you will be asked to complete the following research procedures:

Screening: A screening questionnaire asking about stress and how you have been feeling lately; this will determine if you are eligible to take part. Completing the screening measures will take approximately two minutes. The screening questionnaire will be administered to you in an online platform. If the screening questionnaire shows that you meet the criteria for inclusion, then you will be able to start the research project. If the screening questionnaire shows that you cannot be in the research project, we will provide you with some further information and links to referral services that may be helpful. We will retain the information you provide in the answers to the screening questions, however this will not include any identifiable information about you.

If you are eligible for the study, we will ask you to create an account for the study (first name, email, mobile number and password) and then complete an online baseline questionnaire within your account. This should take approximately 10 minutes. You will then be randomised to either the intervention or control group, which means you will either be provided with instructions to download the app immediately, or you will be given immediate access to an online health and psychoeducation resource. If you are in the second group, you will be able to download the app in 6 months' time.

Randomisation: The aim of the research is to compare the outcomes of the Anchored app intervention and the online control condition. To ensure that each participant has an equal chance of being placed in any group to start with, a computer allocates each study participant into a group randomly, like the flip of a coin. Once randomised, participants will be allocated to one of the following participant groups. An overview of the difference in research procedures that you will be asked to complete is described in the table below.

Intervention	Control
You will be asked to use an app over 30 days. This will involve completing one short task (5-10 minutes) per day, which will provide you with quick access to a range of adaptive skills and exercises, such as psychoeducational videos, mindfulness exercises, value-driven activity planning and goal-setting, and coping skills development. The app will automatically collect your usage data, including time spent in the app, number of logins, and specific responses to exercises.	You will be asked to use an online health and psychoeducation resource over 30 days. The online program will provide you with resources and quizzes involving a range of concepts around stress, mental and physical health, and workplace health and safety. The program website will automatically collect your usage data, including number of logins and time spent accessing the health education resource.

At 30 days, 3 months and 6 months after the baseline questionnaire (regardless of which group you are in), you will be contacted via SMS to complete online follow-up questionnaires. Each follow-up



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questionnaire should take approximately 10 minutes and will be completed within your study account. If not completed, you will receive up to two reminders (one SMS and one email) to complete the baseline and follow-up questionnaires.

Participants who participate in the study and complete the 30-day questionnaire will be entered into a draw to win a \$200 visa gift card. Participants who also complete the 3-month follow-up questionnaire will have the chance to win a \$300 visa gift card, and those who in addition complete the 6-month questionnaire will have the chance to win a \$500 visa gift card. For each questionnaire, the prize will be drawn two weeks after the last enrolled participant has been provided with access to the survey. Winners will be randomly selected from anonymous participant ID numbers. In the unlikely event that the winner of a previous draw is randomly selected in a subsequent draw, the random selection will be repeated. Prize winners will be notified by email and will be asked to provide a postal address to send their gift card.

Your in-app/website usage data and questionnaire responses will not include any identifiable information, and will not be linked with your study account details. Your email and phone number will only be used to send you reminders to complete the questionnaires, and to send communication regarding the gift card draw (if applicable).

Investigational Medical and Therapeutic Devices: Medical and Therapeutic Devices have to be approved for use by the Australian Federal Government before they are used in Australia. The following device will be used in this research:

The Anchored app is an experimental treatment. This means that it is not an approved treatment for mental health and wellbeing in Australia. Therefore, it is an experimental treatment for mental health and wellbeing. This means that it must be tested to see if it is an effective treatment for mental health and wellbeing. Although unlikely you may experience distress. If you have any distress, or are worried, talk to the research team who will provide you with assistance.

If you experience discomfort or feelings of distress while participating in the research and you require support, you can stop participating at any time. You can also tell a member of the research team via the contact details below and they will provide you with assistance, or alternatively a list of support services and their contact details can be found via the "get support" page within the app/website. As the study is focused on mental health, there is the risk that some people may react with fear or worry. If this is the case, or if anything within the app or website raises any concerns, we recommend speaking to your GP or consulting the "get support" information within the app/website.

6. What are the possible benefits to participation?

The app is intended to increase mental fitness and resiliency, and reduce risk of future mental health conditions. In this sense we are hopeful that it may be of benefit to you. Similarly, the online resource provides scientifically accurate information about stress, mental and physical health, and workplace health and safety. We also hope to use information we get from this research study to benefit others by allowing us to develop engaging and effective e-mental health programs in the future.

7. What will happen to information about me?

By clicking the 'I agree' button, you consent to the research team collecting and using information about you for the research study.



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The research team will store the data collected from you for this research project for:

- A minimum of 15 years after the publication of research results;

Information collected from you in an electronic format will be stored on a UNSW password protected OneDrive only accessible to the approved research investigators.

The information you provide is personal information for the purposes of the Privacy and Personal Information Protection Act 1998 (NSW). You have the right of access to personal information held about you by the University, the right to request correction and amendment of it, and the right to make a complaint about a breach of the Information Protection Principles as contained in the PPIP Act. Further information on how the University protects personal information is available in the [UNSW Privacy Management Plan](#).

8. How and when will I find out what the results of the research study are?

The research team intend to publish and report the results of the research study. All information will be published in a way that will not identify you.

You have a right to receive feedback about the overall results of this study. This feedback will be in the form of a brief lay summary of our results on the 'Prevention Hub' website (<https://preventhub.org.au/>). You will be able to read this feedback after the study is finished.

9. What if I want to withdraw from the research study?

If you do consent to participate, you may withdraw at any time. You can do so by following the 'Withdrawal of Participation' information which is provided at the end of this document or you can ring the research team and tell them you no longer want to participate. Your decision not to participate or to withdraw from the study will not affect your relationship with UNSW Sydney or the Black Dog Institute. If you decide to leave the research study, the researchers will not collect additional information from you. You can request that any identifiable information about you be withdrawn from the research project.

What if I have a complaint or any concerns about the research study?

If you have a complaint regarding any aspect of the study or the way it is being conducted, please contact the UNSW Human Ethics Coordinator:

Complaints Contact

Position	Human Research Ethics Coordinator
Telephone	+ 61 2 9385 6222
Email	humanethics@unsw.edu.au
HC Reference Number	HC190914

10. What should I do if I have further questions about my involvement in the research study?

The person you may need to contact will depend on the nature of your query. If you require further information regarding this study or if you have any problems which may be related to your involvement in the study, you can contact the following member/s of the research team:



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Research Team Contact / Chief Investigator

Name	Dr Mark Deady
Position	Postdoctoral Research Fellow
Telephone	(02) 9382 8507
Email	m.deady@unsw.edu.au

If the Research Team Contact is not immediately available, they or another member of the Research Team will reply to your enquiry as soon as possible.

If at any stage during the study, you become distressed or require additional support from someone not involved in the research please call:

Contact for feelings of distress

Name/Organisation	<i>Beyond Blue</i> - www.beyondblue.org.au
Position	Counsellors/information
Telephone	1300 22 4636
Email	online.beyondblue.org.au/email/#/send



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Consent Form – Participant providing own consent

Declaration by the participant

- I understand I am being asked to provide consent to participate in this research study;
- I have read the Participant Information Sheet or it has been provided to me in a language that I understand;
- I provide my consent for the information collected about me to be used for the purpose of this research study only.
- I understand that if necessary I can ask questions and the research team will respond to my questions.
- I freely agree to participate in this research study as described and understand that I am free to withdraw at any time during the study and withdrawal will not affect my relationship with any of the named organisations and/or research team members;
- I understand that I can download a copy of this consent form from the Anchored website.

I agree



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Withdrawal of Participation

To WITHDRAW consent to participate in the research proposal described above, email anchored@blackdog.org.au stating that you wish to WITHDRAW your consent and no longer take part in the study. This withdrawal WILL NOT affect your relationship with The University of New South Wales or the Black Dog Institute.