1. **What is the research study about?**

The Black Dog Institute has designed a smartphone mobile application (app) for adults with anxiety and/or depression, which can be used with psychologist alongside in-person or telehealth therapy sessions. You are invited to take part in this research study which will assess whether this new blended care way of conducting therapy (i.e., using a mobile app together with psychological therapy) is acceptable, feasible, and effective for improving anxiety and/or depression.

1. **Who is conducting this research?**

The study is being carried out by the following researchers: A/Prof Jill Newby, Dr Kathleen O’Moore, A/Prof Katherine Boydell, Dr Alexis Whitton, Dr Peter Baldwin, Dr Becca Hardy, Dr Melissa Black and Jane Cockburn from the Black Dog Institute. This research is being funded by the HCF Foundation and the Black Dog Institute.

1. **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 adults who meet the following criteria:

* Are seeing a psychologist to help manage anxiety and/or depression
* 18 years of age or over
* Currently residing in Australia
* English speaking
* Mobile number and email address
* Owns a smartphone device using a supported operating system (Apple: iOS 13 released 1999 or newer; Android: 7.0 released 2016 or newer)

Participants who meet the following criteria will be excluded from the study:

* Participants aged under 18 years (as this study is focused on evaluating a program for adults)
* Acutely suicidal or experiencing a psychotic disorder (as alternative support options may be more helpful).
1. **Do I have to take part in this research study?**

Participation in this 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:

* Read the information carefully and ask your psychologist questions if necessary (you can also email the research team with questions);
* Complete the consent form online if you decide to participate in this study
* Download a copy of this form (we will also email you a copy of the signed version)
1. **What does participation in this research require, and are there any risks involved?**

If you agree to participate in this study, you will be asked to complete the following research procedures:

**Brief online screening:** A brief screening questionnaire asking about the inclusion criteria above (e.g., your age, if you live in Australia, are experiencing anxiety and/or depression) to confirm if you are eligible to take part in the study. Completing the screening measures will take approximately 5 minutes. If the screening questionnaire shows that you meet the criteria for inclusion, then you will be able to start the first online survey.

**Online surveys:** Online surveys will be administered on three occasions: after the screening survey, then 3 months and 6 months after this. The first survey will include demographic questions to get a sense of the types of people who completed the study (e.g., age, gender, current levels of anxiety, depression, stress), as well as questions regarding your expectations about using the smartphone app and your use of online mental health programs.

The second online survey will be sent to you after you have used the smartphone app for 3 months. The third and final online survey will be administered 3 months after this (i.e., 6 months after the first survey). The second and third surveys will include questions outlined above (excluding demographics and expectations about the smartphone app). In addition, the second survey will include questions about how you used the smartphone app during the prior 3 months and your satisfaction with the smartphone app. Each survey should take around 60 minutes to complete. You will receive up to three follow-up reminders to complete each survey.

**Intervention:** The mobile app was designed by the project team through an extensive consultation process with Australians with a lived experience of anxiety and/or depression. The activities are based on gold-standard treatment for depression and anxiety, and includes approaches from Cognitive Behavioural Therapy, values-based goal setting, mindfulness, and emotion regulation techniques. The app is designed to deliver an individually tailored program, that is focused on harnessing individual strengths, and improving mental wellbeing. You will have free access to the Adult Wellbeing app for three months, during which time you may use the smartphone app with your psychologist and/or in your own time. Every month, you will be reminded by the app to complete a questionnaire in the app that will assess your current levels of anxiety, depression, and stress.

**Risk screening:** Your total scores on surveys measuring anxiety, depression and stress and suicidal thinking will be automatically shared with your psychologist when you complete the baseline, 3-month and 6-month surveys. They may receive an email that you have completed the questionnaire and they can see your scores on a secure website. Your psychologist may not see your scores immediately and may not be able to provide urgent help. If you think you need help urgently, visit the Get Help section of the app.

**Interview:** If you would like to take part in an online interview, there is a section at the bottom of this information sheet where you can consent to be contacted for future research. A small number of people (around 20) who have indicated they would like to be involved in the interview will be randomly selected by a researcher not involved in the current study to take part in an online interview (which will take approximately 1 hour). If your participant number is randomly selected a member of the research team will send you the Participant Information Sheet and Consent form to read to see if you are interested in taking part. If you are not randomly selected, you will have an opportunity to provide feedback on the app via the final online feedback survey.

If you experience discomfort or feelings of distress while participating in the research and you require support, you can stop completing the study at any time. You can also email a member of the research team at wellbeingapp@blackdog.org.au and they will provide you with assistance or alternatively a list of support services. If at any stage during the study, you become distressed or require additional support from someone not involved in the research please contact your local GP, BeyondBlue (1300 22 4636), or Lifeline (13 11 14).

1. **What are the possible benefits of taking part?**

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include improvements in depression and/or anxiety.

1. **What are the alternatives to taking part in the research?**

You do not have to take part in this research project to receive treatment from your psychologist. Your psychologist will discuss these options with you before you decide whether to take part in this research project.

1. **What will happen to information about me?**

You will be asked to provide your consent to participate in the research online. Clicking the ‘I agree’ button on the consent page will indicate to the research team that you consent to take part in the study, and you are providing your permission for the research team to collect and use information about you for the research study.

The information about you will be stored in a re-identifiable format where your identity will be unknown (i.e., your responses will be linked to a number and not to any information that could identify you). We will keep your personal information private. This information is stored on the UNSW OneDrive servers and is protected by encryption. A copy of the de-identified data will be stored on UNSW servers for a minimum of 15 years after the publication of the research findings. Only the research team can access this information.

You will also be asked if you are interested in being involved in a component of the research study (e.g., providing feedback about any barriers or facilitators of app usage in one-on-one interviews). If you are interested, you can provide consent by selecting the box that says, ‘I provide my consent for my email address to be saved in a password-protected file so I can be contacted by the research team about other research projects in the future’. If you are not interested in being involved in future components of the research study, do not select this box, and continue to complete the online survey.

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](https://www.legal.unsw.edu.au/compliance/privacyhome.html).

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

The research team intend to publish and/or report the results of the research in a range of publications, presentations, and on the Black Dog Institute website. All information will be published in a way that will not identify you. If you would like to receive a copy of the results, then please select the box on the PISCF that says, ‘I would like to receive a copy of the study results via email. I have provided my details below and ask that they be used for this purpose only’ and add your email address to the online consent form. We will only use these details to send you the results of the research.

1. **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 completing the ‘Withdrawal of Consent Form’ 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 the Black Dog Institute or UNSW Sydney. 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.

1. **What if I have a complaint or any concerns about the research study and will I receive compensation if suffer any injuries or have complications?**

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** | UNSW Human Research Ethics Coordinator |
| **Telephone** | + 61 2 9385 6222 |
| **Email** | humanethics@unsw.edu.au  |
| **HC Reference Number** | HC 220527 |

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

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:

**Research Team Contact Details**

|  |  |
| --- | --- |
| **Name** | Dr Kathleen O’Moore |
| **Position** | Senior Clinical Research Manager |
| **Telephone** | (02) 9382-4530  |
| **Email** | k.omoore@unsw.edu.au  |

**Chief Investigator**

|  |  |
| --- | --- |
| **Name** | A/Prof Jill Newby |
| **Position** | Associate Professor & MRFF Career Development Fellow |
| **Telephone** | (02) 9382-4530 |
| **Email** | j.newby@unsw.edu.au |

**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 someone has read it to me in a language that I understand.
* I understand the purposes, study tasks and risks of the research described in the study.
* I provide my consent for the information collected about me to be used for the purpose of this research study only.
* I have had an opportunity to ask questions and I am satisfied with the answers I have received.
* 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 will be given a signed copy of this document to keep.
* I understand that the results of the research will be made available on the Black Dog Institute website.
* I would like to receive a copy of the study results via email, I have provided my details below and ask that they be used for this purpose only.

**Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Email Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Optional Consent for reuse of data and future research:**

 I provide my consent for my email address to be saved in a password-protected file so I can be contacted by the research team about other research projects in the future

**Participant Signature**

|  |  |
| --- | --- |
| Name of Participant (please print) |  |
| Signature of Research Participant  |  |
| Date |  |

**Declaration by Researcher\***

* I have given a verbal explanation of the research study; its study activities and risks and I believe that the participant has understood that explanation.

**Researcher Signature\***

|  |  |
| --- | --- |
| Name of Researcher (please print) |  |
| Signature of Researcher  |  |
| Date |  |

**+An appropriately qualified member of the research team must provide the explanation of, and information concerning the research study. All parties signing the consent section must date their own signature.**

**Form for Withdrawal of Participation**

I wish to **WITHDRAW** my consent to participate in this research study described above and understand that such withdrawal **WILL NOT** affect my relationship with The University of New South Wales, or the Black Dog Institute.

* I am withdrawing my consent and I would like any identifiable information collected about me which I have provided for the purpose of this research study withdrawn.
* I am withdrawing my consent to participate in further components of this research and provide my permission for the research team to retain and/or use information collected about me which I have provided for the purpose of this research.

**Participant Signature**

|  |  |
| --- | --- |
| Name of Participant (please print) |  |
| Signature of Research Participant  |  |
| Date |  |

**Please send to:**

|  |  |
| --- | --- |
| CI Name: | A/Prof Jill Newby |
| Email: | j.newby@unsw.edu.au |
| Phone: | (02) 9382-4530 |
| Postal address: | Black Dog Institute, Hospital Rd, Randwick NSW 2031 |