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

You are invited to take part in this research study. The research study aims to test a smartphone app for students that aims to reduce distress and improve mental well-being through mindfulness, physical activity, or sleep hygiene. The study is a randomized controlled trial, which means that each person taking part will be randomly assigned to try either one of the treatment strategies described above or, alternatively, complete a ‘control’ consisting of daily brief mood surveys.

The study will use an artificial intelligence (AI) research method to try find the most effective treatment for psychological distress as quickly as possible. This method works by running a series of ‘mini-studies’, each lasting 3-4 weeks. During each mini-study, each of the treatments described above will be tested in a separate group of people. The AI decides how many people are assigned to try each treatment. If you take part, you will join one of these mini-studies and be assigned to one of the treatment groups or a control group. After each mini-study, the effects of each treatment on distress will be measured. The AI will use this information to gradually improve a mathematical model of how well the treatments and control work; continuing only until we are certain we know which is/are the best. The trial can then stop; potentially saving time and money compared to a traditional study.

The study will also try to identify individual characteristics that are associated with a) psychological distress and b) what intervention works best for different people. To do this we would like to explore whether there is any relationship between your routines and behaviour, measured automatically using the sensors in your smartphone, and changes in your mood or distress levels. This part of the study is optional and opt-in – you can still take part in the main trial without agreeing to this sensor data collection.

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

The study is being carried out by the following researchers:Professor Helen Christensen (Principal Investigator) and subinvestigators at:

* Black Dog Institute, UNSW Sydney (Dr Jo Beames, Dr Jin Han, Dr Kit Huckvale, Dr Jill Newby, Dr Eileen Stech, Dr Aliza Werner-Seidler, Dr WuYi Zheng);
* Applied Artificial Intelligence Institute, Deakin University (Dr Scott Barnett, Mr Stuart Cameron, Dr Sunil Gupta, Dr Leonard Hoon, Ms Rena Logothetis, Professor Kon Mouzakis, Dr Thom Quinn, Dr Santu Rana, Ms Manisha Senadeera, Dr Truyen Tran, Professor Rajesh Vasa, Professor Svetha Venkatesh); and
* Macquarie University Centre for the Health Economy (Professor Henry Cutler, Dr Liz Schroeder).

**Research Funder:** This research is being funded by the Australian Federal Government Medical Research Future Fund (MRFF) Applied Artificial Intelligence Research in Health scheme. Grant number: MRFAI000028.

1. **Inclusion and exclusion criteria**

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

* 18 years or older;
* Living in Australia;
* Currently studying at an Australian university, TAFE or other higher education institution;
* Fluent in English;
* Own an up-to-date smartphone, with active mobile number and internet access; and
* Are experiencing psychological distress (e.g., anxiety, stress or low mood).

People who meet any of the following criteria are not eligible to take part in this study. If you meet any of these criteria, you should not take part.

* People who have experienced significant thoughts of suicide in the past month.
* People with a current diagnosis of psychosis or bipolar disorder.
* People who have previously participated in this study.
* People who have limited availability to participate in the next 2 months.
* People who can’t safely undertake physical activity for any reason.

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 can withdraw from the study at any time without giving a reason (see **Section 8**).

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

* Read this study information carefully (ask questions if necessary);
* Electronically sign a consent form; and
* Download a copy of this form to keep.

1. **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 activities:

|  |
| --- |
| 1. Complete a set of online questionnaires to confirm your basic eligibility (up to 5 minutes). 2. If you may be eligible to take part, provide electronic consent and complete some additional questionnaires about your background and mental health (up to 15 minutes). 3. When asked, download the Vibe Up app to your smartphone, and allow it to send you study reminders. There may be a delay of up to 4 weeks between completing screening and consent and starting the study by downloading the app. 4. Complete a baseline questionnaire (5 minutes) via the app, then a brief survey (3 minutes) two times per day for the next week about your ‘in the moment’ feelings and coping strategies. 5. Complete a pre-intervention questionnaire (5 minutes) via the app.   6a. Complete a two-week programme via the app involving daily practice activities (you can choose how much, but consider up to 30 minutes/day) that focusses on one of the following:   * + increasing physical activity;   + increasing mindfulness; or   + improving sleep hygiene.   6b. Or, instead of a two-week programme, continue to answer brief surveys about your ‘in the moment’ feelings and coping strategies each day for two weeks. (If assigned to this ‘control’ group, you’ll be able to access all the other activities at the end of the mini-study period.)   1. Complete a post-intervention questionnaire (5 minutes), via the app. 2. Complete a follow-up set of online questionnaires (10 minutes) eight weeks after the end of the mini-study period. 3. If you explicitly agree to this during consent; we will also collect data about your activities and routine from your smartphone’s sensors throughout the study. |

The study will last 3-4 weeks depending on how quickly you complete activities such as questionnaires. The overall time commitment required for study activities, spread over that time, is about 8 hours.

More details about each of these research procedures is provided below.

**Screening:** A web-based screening questionnaire will ask about your eligibility, physical and mental health, symptoms of psychological distress and your contact details; this will determine if you are eligible to take part. Completing the screening measures will take approximately 10 minutes.

* If the screening questionnaire shows that you meet the criteria for inclusion, then you will be able to provide consent and then start the research project. We will also ask for your contact details so we can send you study reminders and contact you if necessary.
* If the screening questionnaire shows that you cannot be in the research project, we will provide you with a list of online self-help resources for issues with stress and psychological wellbeing.
* If the screening questionnaire shows that you have recently been having significant thoughts of suicide, we will also provide you with details of crisis support services and give you the option to provide your contact details so a clinician (Psychologist or Psychiatrist) from the Black Dog Institute can call you back during business hours to talk about options for further support.

**Consent:** We will ask you to complete an electronic form confirming your consent to take part in the study. A print version of this form is provided as part of this information statement.

**Questionnaires/Surveys:** You will be asked to complete several questionnaires during the research study:

* After screening, you will be asked to complete additional questions via the online platform about your demographic details, health, mental wellbeing, study and work, use of health services, and social support. This questionnaire should take approximately 10-15 minutes to complete.
* You will then be asked to download a mobile phone application and allow it to send you notifications. You will be asked to complete a baseline questionnaire about your mood, anxiety and stress levels, and wellbeing (5 minutes) via the app.
* You will then receive prompts from the app to complete a brief survey (3 minutes) two times per day, for up to nine days, about your ‘in the moment’ feelings and coping strategies.
* Following this, you will be asked to repeat the questionnaire about your mood, anxiety and stress levels, and wellbeing (5 minutes) before being randomised to a participant group. You will also be asked to repeat that questionnaire two weeks later, at the end of the study.
* Lastly, eight weeks after you finish the mini-study, you will also be asked to complete a set of follow-up questionnaires (10 minutes) via the online platform. These will ask about your mood and wellbeing, study and work, and use of health services.

For each set of questionnaires, you will receive an initial notification via the app (or SMS for follow-up), then an SMS reminder 36 hours later, followed by an email reminder at 48 hours if you have not yet responded.

Completing questionnaires is an important aspect of participating in a research study. Therefore, if you do not complete the questionnaires, you will not be able to continue to the next phase of the research study.

**Randomisation:** The aim of the research is to compare the outcomes of mindfulness, physical activity and sleep hygiene interventions delivered via a mobile phone app, and daily monitoring of ‘in the moment’ feelings and coping strategies (the control condition).

To ensure that each participant has an equal chance of being placed in any group to start with, a computer will allocate everyone into one of the following four groups randomly, much like the flip of a coin. Neither we nor you have any control over who gets allocated to which group.

An overview of the research procedures that you will be asked to complete, should you be allocated to a particular group, is provided below. All will be delivered using the Vibe Up App.

|  |  |
| --- | --- |
| Mindfulness | * Watch a brief video that introduces mindfulness and its benefits for students. * Complete a brief mindfulness practice each day, using audio guides provided. * Log the number of minutes you spend practicing mindfulness each day. |
| Physical activity | * Read brief information about the benefits of increasing your physical activity. * Do some form of physical activity each day. You will be provided with a 7-minute workout option. * Log the number of minutes you spend doing physical activity each day. |
| Sleep hygiene | * Read brief information about the benefits of improving your sleep. * Read brief information about practical strategies to improve sleep and practice up to three per day. * Log the number of hours you sleep each night. |
| Control condition (monitoring) | * Continue recording your ‘in the moment’ feelings and coping strategies twice per day, when prompted. |

**Smartphone Sensor Data:** A secondary aim of the study is to explore whether behaviour, measured automatically using smartphone sensors, is associated with changes in distress and mood. If a link is found then this might mean, in the future, being able to design mental health apps that respond automatically to your mood and offer personalised support.

To do this, we will ask for your permission to collect data about your location (using GPS) and activity (using the accelerometer sensor, step count and health data collected automatically by your phone’s operating system). We will only use this information for our research into the link between behaviour and mental health. This information will not be shared with anyone else. If you agree to sensor data collection, this will continue for 4 weeks or until you uninstall the Vibe Up app, whichever is sooner.

This part of the study is optional. We will ask you on the consent form whether you agree to us collecting data from your smartphone sensors. If you do not agree, you do not have to give a reason and you can still take part in the rest of the trial.

**Reminders:** If you complete screening and consent, we will send you reminders when particular study activities become available.

The main way we will do this is using smartphone notifications generated by the Vibe Up Study app. If you don’t respond to any of these, we will follow up first with an SMS after 36 hours and then an email after 48 hours. So we can send these reminders, we will ask for your contact details during screening. After sending an SMS and email, if you don’t respond, we won’t send any further reminders.

**Treatment outside the study:** If possible, we would like you to avoid starting any new treatment or activity to support your mental health while taking part in the study. However, if you experience an urgent health problem, you should not delay seeking help. You should always prioritise advice given by a healthcare professional, even if this means having to withdraw from the study.

**Additional Costs and Reimbursement:** There are no costs associated with participating in this research project, nor will you be paid.

However, if you complete the study (including the questionnaire after the intervention period) you will receive a personal summary of the data you have provided during the study and a $30 electronic gift card in recognition of your contribution to the study. In addition, if you complete the set of follow-up questionnaires eight weeks after the end of the mini-study, you will go into a draw to win one of three $50 electronic gift cards available to your group.

Regardless of which study group you were assigned to, you’ll also be able to access all the treatments, for a period of 8 weeks, after the end of the mini-study.

**Psychological Distress:** You may feel that some of the questions we ask are stressful or upsetting. If you do not wish to answer a question, you may stop immediately.

If you become upset or distressed as a result of your participation in the research project, information for several free contactable support services are available in the online screening platform and the study app (see also **Section 10**). These support services are available 24 hours a day, 7 days per week.

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

By signing the consent form, you consent to the research team collecting and using information about you for the research study. The research team will store the data collected from you for this research project for 15 years after the completion of the research. The information about you will be stored in a re-identifiable format where any identifiers such as your name, age and telephone number will be replaced with a unique code.

We would also like to seek your consent to re-use data collected from you for future research purposes. This is optional. If you agree to this, we will keep your information in a secure, storage databank. We will remove your name so that nobody can ever find out that it is about you. Any future use of this data will need to be approved by The Black Dog Institute.

All information collected from you will be stored electronically, encrypted and password protected, adhering to the data security standards and policies of UNSW Sydney. It will only be accessible to members of the Vibe Up research team for approved purposes. We will not share your information with anyone else.

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 report the results of the research. All Information will be published in a way that will not identify you.

If you would like to receive a copy of the results you can let the research team know by indicating this preference and inserting your email address on the consent form. We will only use these details to send you the results of the research.

1. **What if I want to stop participating or withdraw from the research study?**

If you do consent to participate, you can choose to stop engaging in the study activities at any time. If you stop doing study activities (e.g. you don’t complete questionnaires in time to progress to the next phase of the study), you may be contacted by the research team (once by SMS and once by email) to seek feedback on your experience and why you did not continue with the study.

If you consent to participate, you may also 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 contact 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, Black Dog Institute, Deakin University, or Macquarie University.

If you notify the research team that you have decided to withdraw from the research study, the researchers will not collect additional information from you. You can also request that any identifiable information about you be removed from the research project. However, you should be aware that if you withdraw *after* completing the baseline questionnaire, we won’t collect any more information from you, but any data we already have about you will still be included in trial analyses. This is because analysing every included participant is a key quality control measure for this trial.

If you choose to withdraw from the study, you should uninstall the Vibe Up App. This will ensure data collection stops and will prevent any further study notifications from being sent to you.

1. **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** | UNSW Human Research Ethics Coordinator |
| **Telephone** | 02 9385 6222 |
| **Email** | [humanethics@unsw.edu.au](mailto:humanethics@unsw.edu.au) |
| **HC reference number** | HC200466 |

1. **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:

**Research Team Contact Details**

|  |  |
| --- | --- |
| **Name** | Associate Professor Jill Newby |
| **Position** | Associate Professor, Clinical Psychologist & Head of Clinical Research, Black Dog Institute |
| **Telephone** | 02 9065 9108 |
| **Email** | [vibeup@blackdog.org.au](mailto:vibeup@blackdog.org.au) |

**Principal Investigator**

|  |  |
| --- | --- |
| **Name** | Professor Helen Christensen |
| **Position** | Director and Chief Scientist, Black Dog Institute |
| **Telephone** | 02 9382 4530 |
| **Email** | [h.christensen@blackdog.org.au](mailto:h.christensen@blackdog.org.au) |

**Support Services**

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

|  |  |
| --- | --- |
| **Organisation** | Lifeline  *Crisis support and suicide prevention* |
| **Telephone** | 13 11 14 available 24/7 |
| **Online chat** | [www.lifeline.org.au/crisis-chat](http://www.lifeline.org.au/crisis-chat) available 19:00 – 23:59 AEDT/AEST |
| **Web** | [www.lifeline.org.au/get-help](http://www.lifeline.org.au/get-help) |

|  |  |
| --- | --- |
| **Organisation** | Suicide Call Back Service  *Counselling and support for people affected by suicide* |
| **Telephone** | 1300 659 467 available 24/7 |
| **Online chat** | [www.suicidecallbackservice.org.au/phone-and-online-counselling/suicide-call-back-service-online-counselling](http://www.suicidecallbackservice.org.au/phone-and-online-counselling/suicide-call-back-service-online-counselling) available 24/7 |
| **Web** | [www.suicidecallbackservice.org.au](http://www.suicidecallbackservice.org.au) |

|  |  |
| --- | --- |
| **Organisation** | Beyond Blue  *Suport and information experiencing depression or anxiety* |
| **Telephone** | 1300 22 4636 available 24/7 |
| **Online chat** | [online.beyondblue.org.au](https://online.beyondblue.org.au/) available 11:00 – 23:59 AEDT/AEST |
| **Web** | [www.beyondblue.org.au](http://www.beyondblue.org.au) |

For information on other online mental health services that are available, including support services tailored to specific communities (e.g. LGBTIQ+, Aboriginal and Torres Strait Islander peoples, carers), and services specific to the state you live in, visit: [www.headtohealth.gov.au](http://www.headtohealth.gov.au)

**Consent form – Participant providing own consent**

The Vibe Up Study uses electronic consent. A print version of this electronic form is provided below so you can see what we will ask you to agree to if you decide to take part in the study.

**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 Statement; |
| |  | | --- | |  | | I understand the purposes, study tasks and risks of the research described in the study; |
| |  | | --- | |  | | I understand that I will be asked about my mental health, including suicidal thoughts, as part of screening after completing this consent form and that this may affect my eligibility to take part in the study; |
| |  | | --- | |  | | I give my consent for the information collected about me to be used for the purposes 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, 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 document to keep;  I understand that the research team may contact me for feedback if I stop engaging in study activities without notifying them that I have decided to withdraw from the study; |
| |  | | --- | |  | | I would like to receive a copy of the study results via email, I have provided my email address below and ask that it be used for this purpose only;   |  |  | | --- | --- | | Email address | (OPTIONAL) | |

**Optional consent items**

|  |  |  |
| --- | --- | --- |
| |  | | --- | |  | | I consent to the study team collecting data about my location and activity using sensors in my smartphone to enable research about the relationship between behaviour and distress. By consenting, I understand that this will happen automatically for 4 weeks or until I uninstall the study app, whichever is sooner; |
| |  | | --- | |  | | I consent for my anonymised data to be stored in a databank for future research purposes; |
| |  | | --- | |  | | I consent to be contacted about opportunities to participate in similar research studies in the future. |

**Participant signature**

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

**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 UNSW Sydney, Black Dog Institute, Deakin University or Macquarie University.

In withdrawing my consent, I would like any information which I have provided for the purposes of this research study withdrawn. I understand that if I withdraw *after* completing the baseline questionnaire, my information cannot be removed and will be included in the trial analyses. (This is because analysing every included participant is a key quality control measure for this trial.)

**If you have chosen to withdraw from the study, please uninstall the Vibe Up App.** This will ensure that data collection stops and prevent any unwanted study notifications.

**Participant signature**

|  |  |
| --- | --- |
| Name (please print) |  |
| Mobile number\* |  |
| Signature |  |
| Date |  |

\* Your mobile number is needed to confirm your identity and locate your study data.

**This completed Withdrawal of Participation form should be sent to:**

|  |  |
| --- | --- |
| **Name** | Associate Professor Jill Newby |
| **Position** | Associate Professor, Clinical Psychologist & Head of Clinical Research, Black Dog Institute |
| **Telephone** | 02 9065 9108 |
| **Email** | [vibeup@blackdog.org.au](mailto:vibeup@blackdog.org.au) |
| **Postal address** | The Black Dog Mental Health Institute, Hospital Road, Randwick, NSW 2031 |
| **HC reference number** | HC200466 |