

PARTICIPANT INFORMATION STATEMENT

Please read this Participant Information Statement and be sure you understand its contents before you consent to participate. If there is anything you do not understand, or you have questions, please contact the researchers.



PROJECT TITLE

Reducing burnout risk and promoting sustainable wellbeing among medical students using an online individualised psychological flexibility skills training App:
A pilot feasibility study

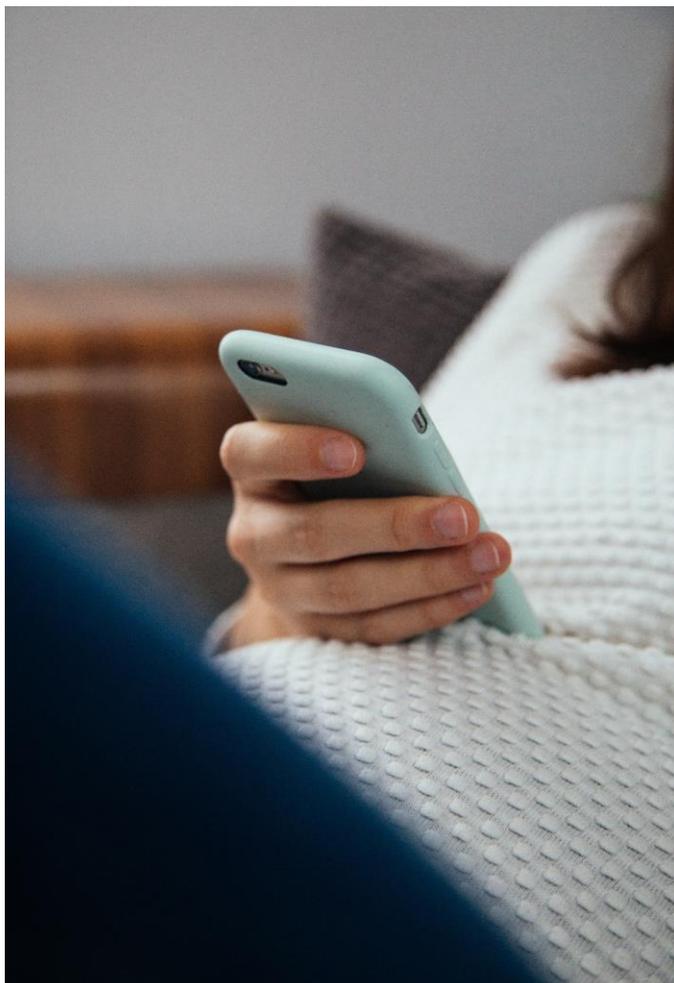


THE UNIVERSITY OF
NEWCASTLE
AUSTRALIA

WHO IS CONDUCTING THIS RESEARCH?

Centre for Rehab Innovations and School of Medicine and Public Health (University of Newcastle)

Ms Elizabeth Ditton	Undertaking research as partial fulfilment of PhD program	Elizabeth.Ditton@newcastle.edu.au
Professor Michael Nilsson	Lead investigator and research supervisor	Michael.Nilsson@newcastle.edu.au
Professor Rohan Walker	Investigator and research supervisor	Rohan.Walker@newcastle.edu.au
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Dr Graeme Horton	Investigator and research supervisor	Graeme.Horton@newcastle.edu.au



WHY IS THE RESEARCH BEING DONE?

Psychological flexibility is a set of adaptive life skills that are associated with a range of important wellbeing outcomes. For people whose careers may involve engagement with challenging situations and/or conditions, psychological flexibility skills training may reduce the risk of future burnout, and improve wellbeing and career sustainability. We are interested in assessing the feasibility of an online psychological flexibility skills training App for busy medical students. The findings of this feasibility study will be used to inform an upcoming RCT of the App. Both studies will assist in our development of practical and accessible skills training programs that help people foster sustainable wellbeing in their career. Findings may also be used to inform future commercially-available programs.

WHO CAN PARTICIPATE?

We will be running this pilot study with a small number of volunteers. You can volunteer to participate in this study if you are a third year medical student at University of Newcastle or University of New England. You will need regular access to the internet and a device to access the online skills training App for the duration of the study.

DO I HAVE TO PARTICIPATE?

Participation is entirely your choice. This research is **not** a requirement of your University studies. There is no penalty for choosing not to participate.

HOW DO I PARTICIPATE?

Please read this Participant Information Statement and ensure you understand its contents. If you decide you would like to participate, the study URL and QR code are provided at the end of this document. Enrolment for this study will be open until 7th June 2021, or until we have recruited 10 participants, whichever occurs first.

WHAT ARE THE BENEFITS?

By participating in this study, you will be given access to an evidence-informed skills training App that was developed by experienced clinical psychologists, and will be tailored to your current situation and goals that have personal meaning for you. You will learn skills that have been associated with positive outcomes in over 400 RCTs. These skills may help you learn to respond more effectively to challenging situations, thoughts, and emotions, as well as helping you take action towards what is most important in your life. Benefits may include improved wellbeing, reduced burnout risk, and improved learning and work performance. By participating, you have the opportunity to provide important information that will help shape the research and development of future wellbeing and burnout-prevention Apps for people who are at an early stage of their career. You would be helping us determine the best ways of delivering engaging training programs that are tailored to meet individual needs, while also reaching large numbers of people who might not otherwise have access to training.

As a thank you for helping us evaluate our program, you will receive a \$30 (AUD) Amazon online gift voucher once you have completed the program and final evaluations.

ARE THERE ANY RISKS?

We do not expect there to be any significant risks associated with participation in this study. However, at times during both the assessments and skills-training program, we will ask you to pay attention to challenging thoughts, emotions, and/or actions. The skills-training program will provide strategies for managing these experiences more effectively. Some people may find this difficult. Please consider this when deciding whether to participate. This program is not intended as an alternative to psychological assistance. If you are concerned or distressed at any time, we encourage you to contact your usual medical practitioner and/or access the resources listed at the end of this information sheet.

WHAT IS INVOLVED IF I DECIDE TO TAKE PART?

THE TRAINING APP

Part 1: Introductory Psychological Flexibility Skills Training Module

You will learn how to:

- Recognise and respond optimally to challenging thoughts, emotions and situations
- Identify what is most important in your life, and what might be getting in the way
- Choose actions that can enhance your sense of purpose, wellbeing and career sustainability

The module takes approximately 1 hour to complete and can be completed over multiple sittings if needed.

You will have 1 week to complete this module.

Part 2: On-Demand Psychological Flexibility Skills Training

- Once you have completed the introductory module and program evaluations, you will be given access to the on-demand psychological flexibility skills training component of the App for 4 weeks

“What happens each time I access the on-demand skills training?”

- Answer 1 short question about your current situation (<1 min)
 - Practice a short (5-7 min) psychological flexibility skills activity that is relevant to your current situation (presented in written and/or video/audio format)
- Use the App to practice the skills when, where, and as often as you like (we recommend at least twice a week, and more frequent use to maximise skill learning)
 - Activities are designed to be brief, practical and relevant to your everyday life
 - We will send you daily reminders to use the program

THE PROGRAM EVALUATIONS

You will be asked to complete questionnaires at three time points, in order to help us evaluate the program:

1. **Baseline** (before you engage in any of the online training activities)
2. **Introductory module evaluation** (after you complete the introductory module)
3. **Final follow-up evaluation** (at the end of the study, after you have had access to the skills-training program for 4 weeks)

At each time point, these questionnaires will take approximately **15 mins** to complete. You will be asked questions about thoughts, emotions, coping behaviours, psychological flexibility, and your experience of using the App.

We may be interested in contacting you after the study to provide more detail about your experiences of using the App. You will have the option of consenting or declining further contact from us when you complete your evaluation forms.

We will collect individual usage data from the program, including login and skill engagement counts, as well as time spent using the App.

Once you have completed the final follow-up evaluation questionnaires, we will send a \$30 (AUD) Amazon gift voucher to the email address you have provided us.

WHAT WILL HAPPEN WITH INFORMATION ABOUT ME IF I CONSENT TO PARTICIPATE?

- When you enrol in the study, you will be given a unique Participant ID that will be used for your study login.
- We will collect two types of data from you: Personal Information (your name and contact email address and/or mobile number) and Study Data (your responses to questionnaires and App usage data). Personal Information and Study Data will be stored in *separate databases* so that there is no personally identifiable information about you stored with your Study Data. This is de-identification of your Study Data protects the privacy of your questionnaire responses and App use, both with respect to data storage and analyses. All data analyses will be conducted using the de-identified aggregate data.
- The Personal Information and Study Databases will be password-protected and stored on a secure server. Both databases will only be available to the research team and we will **never** share your information with other parties.
- Members of our research team who are also affiliated with your University course will **not** have access to any information about you that is personally-identifying, nor will any other staff outside the research team. Your Personal Information will only be accessible by the Lead Investigator and Student Investigator, and will only be accessed directly if we wish to contact you for future feedback or studies. All other contact that we make with you will be automated confidentially by the App.
- The App and data collection will run on the Cogniss digital education and health solutions platform. This system complies with the [Commonwealth Protective Security Policy Framework to the ICT Systems](#), [Australian Government Information Security Manual to the ICT Systems](#), and [Commonwealth Strategies to Mitigate Cyber Security Incidents](#). This platform has been used by many Australian government departments. The audio and video content delivered within our App are hosted on third party sites. When signing up for our App, you will be asked to accept the Terms and Conditions of these third party sites (Privacy policies for [YouTube](#) and [Soundcloud](#))
- Any Data will be retained securely for a minimum period of 5 years from completion of the research and managed/stored in accordance with the University's [Research Data and Materials Management Guideline](#) or any successor Guideline, and applicable University of Newcastle policy provisions (as amended from time to time).
- De-identified data from this study will be analysed and summarised for Elizabeth Ditton's PhD research and will be presented in her research thesis. The data may be presented in publications in peer-reviewed journals, reports and presentations.
- No personally identifiable information about you will be reported in any presentations of the data from this study. Individual participants will not be identifiable in any reports arising from the study, although individual anonymous responses may be quoted.
- Non-identifiable data may be used for future ethically approved research.

WHAT IF I WANT TO HEAR ABOUT THE RESULTS OF THE STUDY?

A brief summary of the findings of this study will be available at www.centrerehabinnovations.com.au. It is anticipated that this summary will be available during late 2022. If you consent to participate in the study (next step), you will be given the opportunity to indicate if you would like us to send you a link to this summary when it is available.

WHAT IF I WANT TO WITHDRAW FROM THE STUDY?

If you consent to participate, you may withdraw at any time by following the *Withdraw from the Study* link within the App or any email we send you about the study. This will remove your email address from the study contact list, after which you would not receive further correspondence about the research. Alternatively, you may simply cease to participate in the study activities (you would continue to receive reminder emails during the study). Any information you have provided up to the point of your withdrawal from study will be retained and included in the study in a de-identified/anonymised form, in accordance with the data protection policy outlined above. There will be no adverse consequences for withdrawing from the study.

WHERE CAN I ACCESS MORE INFORMATION?

If you would like further information please contact Elizabeth Ditton (elizabeth.ditton@newcastle.edu.au) or Professor Michael Nilsson (michael.nilsson@newcastle.edu.au)

I WOULD LIKE TO PARTICIPATE

Thank you for your interest in this study. You can use either method below to access the online consent form and eligibility assessment. If you are eligible, you will be given access to the App.

Follow the link

<https://redcap.link/PsychFlexApp>

Scan the QR code



External Resources

<i>Head to Health</i>	www.headtohealth.gov.au
<i>Beyond Blue</i>	www.beyondblue.com.au
<i>Black Dog Institute</i>	www.blackdoginstitute.org.au
<i>Lifeline (free 24-hour counselling service)</i>	www.lifeline.org.au or 13 11 14
<i>Suicide call-back service</i>	www.suicidecallbackservice.org.au or 1300 659 467
<i>Mental Health Service (24 hours)</i>	1300 669 757

University Resources

UON Counselling Service	Student Services Building Room SC212 (02) 4921 6622 counselling@newcastle.edu.au
UNE Counselling & Psychological Services	Cnr. Elm Avenue and Queen Elizabeth Drive (02) 6773 2897 AskUNE or studentcounselling@une.edu.au

Complaints about this research

This project has been approved by the University's Human Research Ethics Committee, Approval No. **H-2020-0311**. Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the Chief Investigator Professor Michael Nilsson (Ph: 4042 0570; E: michael.nilsson@newcastle.edu.au), or, if an independent person is preferred, to the Ethics Officer, Research and Innovation Services, The University of Newcastle, University Drive, Callaghan NSW 2308, Australia, telephone (02) 4921 6333 or email Human-Ethics@newcastle.edu.au.