

Reducing Worry and Building Confidence in University Students

This is a summary of the Nurture-U Reducing Worry trial.
More information can be found in the Participant Information Sheet (PIS) on page 2

Why is the research being done?

Worry and overthinking are common in university students. We are testing if a self-guided mobile app can reduce worry and build confidence in students. *See Page 2*

Who can take part?

All UK university students over 16 years old who have elevated levels of worry/overthinking and are not currently depressed, suicidal or have a diagnosis of bipolar disorder or psychosis. Our initial screening process will check if you are eligible (suitable). If you are not eligible you may be directed to another trial if appropriate. *See Page 2*

Will I benefit?

We hope the app will help you. You will also help other students and receive £10 electronic shopping vouchers each for completing all 8 weekly measures, the 3-month and 12-month follow-up.

See Page 2

Are there any risks?

There are no known risks - you can contact the research team if there are any problems.

See Page 5

What would taking part involve?

- Answer 'baseline' questions online about symptoms, worry and overthinking (approx. 15 mins)
 - You have 50% chance of receiving the self-guided app now and 50% chance of carrying on as normal, with the option of accessing the app in 12 months
 - If you are allocated to the app now, commit to log on and trying it out over at least 8 weeks
 - Complete modules at your own pace
 - Answer questions online each week for 8 weeks to track your progress (1-2 mins)
 - Answer questions online at 3 months and 12 months to see if the therapy was helpful (approx. 10 mins).
- See page 2*

Can I withdraw from the trial?

Taking part is voluntary. You can withdraw at any time without giving a reason. We will retain any data we already have for the research to be reliable.

See page 5

What data will you keep about me?

You will be given a unique study number to keep your contact details separate from any data you provide in the questionnaires or treatment (i.e., pseudo-anonymised). We need your name, email, mobile number to do the research and keep in touch. This personal data will be stored for no longer than required (at least 10 years) and will be kept strictly confidential, private, and secure, unless you report risk to yourself or others, where we may contact your doctor or relevant services. Anonymised data will be stored indefinitely.

See page 3 and our Privacy Personal Data Protection Policy

Page 5 has our contact details

Visit [Reducing Worry | Nurture-U \(nurtureuniversity.co.uk\)](https://www.nurtureuniversity.co.uk) to read more about this trial

This trial has been reviewed and approved by the Psychology Research Ethics Committee at the University of Exeter



Finding better ways to support student wellbeing

Reducing Worry Participant Information Sheet

TITLE: Reducing Worry and Building Confidence in University Students

What is this study about?

This project seeks to find out if a self-directed mobile app focused on reducing worry, self-criticism, and overthinking and on building confidence is helpful in university students and whether it promotes wellbeing and prevents poor mental health. We know that worry and stress are common in university students. We are trying to see if this digital training approach can help students with these difficulties. If it is helpful, it could easily be made widely available to a large number of students.

What will I have to do?

We ask you to complete questions about worry and overthinking, symptoms of anxiety and depression and well-being 3 times online. These questions will be asked at the start of the study and then at follow-ups after 3 months and 12 months. These measures should take about 15-20 minutes to complete each time. We also ask you to complete very brief measures (taking about 1-2 minutes) once a week for the first 8 weeks after the baseline. These measures will help us to understand what is helpful or not helpful. We will offer half of the study participants the option of using the self-directed app to reduce worry and build confidence in addition to whatever help they are already getting (called usual practice) and half of the study participants will carry on with their usual practice. This will be decided by chance (at random). This is so we can learn whether this app improves well-being in students.

What payment will I receive?

As a thank you and reward for completing each follow-up assessment, you will be sent electronic shopping vouchers for £10 value by email for completing all of the 8 weekly measures and after you complete each of your 3 and 12 month follow ups (i.e., up to a maximum of £30).

Why take part and what are the possible advantages of taking part?

By taking part, you will play a major role in improving well-being and mental health for university students. Taking part may help you learn about, understand, and better manage your own worry and self-criticism and build your confidence. It will also help us to improve well-being and mental health for other young people.

Who can take part?

University students (undergraduate or postgraduate, above the age of 16) in the UK, principally students at the Universities of Exeter, Oxford, Cardiff, Newcastle, Southampton, or King's College London (as partner universities in Nurture-U), although students at other universities can participate. We will ask you to complete online questionnaires to see if the study is likely to be right for you. To be eligible you need to be reporting some elevated worry or overthinking on measures during our initial screening questions. If you currently

have clinical depression or suicidal thoughts or have ever had a diagnosis of bipolar disorder (mania) or psychosis, you cannot take part because the study and the intervention is focused on promoting well-being and preventing poor mental health rather than treating current problems. However, you may be eligible for one of the other Nurture-U studies – for example a study of digital therapy for people with anxiety and depression and the screening website may guide you to these other studies. If you can't take part, our automated pages can direct you to other sources of help and advice, and you can find more information at our website www.nurtureuniversity.co.uk.

Allocation to the App

All eligible individuals within the study are selected at chance to either simply continue with what they are doing already to look after themselves and promote their wellbeing (1/2 chance) or are offered the use of the digital app specifically designed to reduce worry and build confidence (1/2 chance). This self-directed training will be accessed through a mobile app. It involves chapters that you can work through to learn new strategies and try and practise out new skills. By comparing these conditions, we will find out whether the app can improve confidence and wellbeing over 12 months.

How do I access the App?

If the study is right for you and you consent to take part and are allocated to the app, one of our team will set you up on the app and you will receive a link via email to sign in and set up your own password. You will need to have access to the internet via mobile data or Wi-Fi for the App to work.

How long would I need to use the App for?

You can use the App for as often as you like during your year in the study. We recommend working through all the treatment chapters to get the most benefit, as some will be more relevant to you than others. Most people find that the app is most helpful if it is used regularly, for example 5-10 minutes every day.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you agree to take part you will need to sign a consent form online. Taking part is entirely voluntary. If you take part, you are free to withdraw at any time without giving a reason.

How will we use information about you?

We will need to use information from you for this research project. This information will include your name, contact details (email, mobile number). We will use this information to do the research or to check your records to make sure that the research is being done properly.

We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results.

Is my data confidential and private?

All information collected about you will normally be kept strictly confidential. The main exception is if in an email or a telephone call with us, you reported significant difficulties or risk of harm to yourself. In this case, we may contact your doctor (if you provide their contact details).

Your information will be kept confidential and stored securely and password protected. Your contact details (name, email, telephone number) will be kept separately from all other data that you provide to use such as your responses on the online questions and in the app. This data will be only linked to a project identification code number, not with your contact details, to keep your personal responses private and confidential.

Who will have access to my data?

Only selected researchers within the Exeter Nurture-U consortium team can access your contact details. This is so they can contact you about follow-ups, to arrange for vouchers to be sent out, or to respond to your questions or requests for help. Other project researchers will only have access to the information you enter into the assessment website and the mobile app, linked to a code number. People who do not need to know who you are will not be able to see your name or contact details. In these cases, your name and contact details are replaced with a code number in the research data. That means that specific data can only be linked to a unique individual when this data is combined with other pieces of data, which are stored and protected separately. This is called in technical terms 'pseudonymised data'.

The third-party electronic shopping voucher provider will be given your name and email address only but no other information so they can send you access to the vouchers you have earned. Your contact details will not be used by any party for sales or marketing purposes.

The data you enter when you complete your screening, baseline assessment and follow-ups will be collected and stored in a secure password-protected information technology system managed by the University of Exeter clinical trials unit. Data from the mobile app/self-directed digital intervention will be collected and stored by our subcontractor who provide the app, before being sent to the Exeter Clinical Trials Unit.

The University of Exeter as the sponsor of the trial is the data controller with respect to your personal data, and as such will determine how your personal data is used in the study. The provider of the mobile app platform is a data processor with respect to your personal data and processes this data as instructed by our research team. As data controller, the University will take the appropriate measures to ensure your data is collected, transferred, processed, and stored according to relevant data protection legislation, including ensuring appropriate due diligence is performed on our data processors (who may perform tasks on our behalf, such as survey software or provide online therapy platforms).

Our research team and the app provider will process your personal data for the purpose of the research outlined above. Research is a task that we perform in the public interest. Further information about your rights with respect to your personal data is available from our privacy and personal data protection policy.

If you are allocated to use the mobile app, we will collect data on how you use the App. This includes how often you use it, which elements you use, etc. We will also collect your responses on the App, such as the scores or text answers you enter. We collect this data so we learn what is helpful or not in the App and improve it. Your camera, messages, phone calls, contacts and location will not be accessed, read, listened to, or recorded at any time.

The website and the App routinely collect technical data such as hardware configuration, software configuration, access provider, data exchanges and site usage. We collect this so that we can run the website and App efficiently and keep your data secure. Technical data will not be linked to your contact information unless you ask us for technical support as we will need to contact you to provide help.

Free-text responses you provide in the App or online assessments may be used in the form of anonymous quotes on our advertisements, promotional materials, social media accounts or in future publications. You will not be named or identified in any quotes and any references to named individuals or contact details will also be removed.

After the study ends it may be that academic journals and other research teams will ask for the data from the study to be made public (so they can carry out further research or check our findings). The data they use will not include your name or any of your contact details.

How long will my data be held?

Your data will be held no longer than required (at least 10 years). To safeguard your rights, we will use the minimally required Personal Identifiable Data possible. Our data protection and privacy policy is provided with this information sheet here.

What if I want to withdraw from the study or delete my data?

You can withdraw from using the App or taking part in the trial at any time without giving us a reason, but we will keep information about you that we already have. Researchers need to manage your data in specific ways for the research to be reliable. This means that they won't be able to let you change the data they hold about you. Research could go wrong if data is removed or changed.

What are the possible disadvantages of taking part?

Taking part involves giving of your time to complete the questionnaires and use the App (if allocated to it). Because some of the questions in the assessment and the App ask about past and present negative emotions and the app asks you to try new strategies, there is a small chance that this may produce mild and brief upset if you are reminded of an unpleasant event. However, this would be no more than usually experienced in daily life. We are not aware of any other side effects, disadvantages or risks of using the App.

What help is provided?

The study only offers self-monitoring and self-help. The App is not directly monitored nor supported by clinicians or therapists. If you report increased distress or thoughts of harming yourself on our website, we will give you automated advice and point you to sources of help. You can also contact us for further advice at any time and we will (wherever possible) respond within 2 working days. Your GP (family doctor) remains responsible for your medical care. It is your responsibility to contact them for further help.

What will happen to the results?

We will analyse the information received from all those taking part together at the end of the study. We aim to publish the work in academic journals. We will write our reports in a way that no-one can work out that you took part in the study. We will publish a summary of the findings on our website. We will also send this report to all participants who request it.

Who has reviewed the study?

This study has been reviewed and given a favourable opinion by the Psychology Research Ethics Committee at the University of Exeter and the contacts for this committee are Co-Chairs, Ciro Civile (c.civile@exeter.ac.uk) and Ian McLaren (I.P.L.McLaren@exeter.ac.uk).

What if I have more questions?

If you have any questions about taking part in the trial, please contact the Nurture-U Trial Manager, Dawn Phillips: telephone 07890 384247 and email Nurture-U@exeter.ac.uk

If you wish to complain about any aspect of the research team's work you can complain to the Study Principal Investigator, Professor Edward Watkins, from the University of Exeter, UK.