ISRCTN86795807 https://doi.org/10.1186/ISRCTN86795807

Nurture-U: reducing worry and building confidence in university students

Submission date	Recruitment status	[X] Prospectively registered
11/10/2022	Recruiting	[X] Protocol
Registration date	Overall study status	[_] Statistical analysis plan
27/10/2022	Ongoing	[_] Results
Last Edited	Condition category	[_] Individual participant data
03/06/2024	Mental and Behavioural Disorders	[X] Record updated in last year

Plain English Summary

Background and study aims
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 well-being 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.

Who can participate?
University students (undergraduate or postgraduate, above the age of 16 years) 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.

What does the study involve?
We ask participants 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 participants 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 the well-being of students

What are the possible benefits and risks of participating
By taking part, participants play a major role in improving the well-being and mental health of university students. Taking part may help participants learn about, understand, and better manage their own worry and self-criticism and build their confidence. It will also help us to improve the well-being and mental health of other young people.
Taking part involves participants giving their 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 them to try new strategies, there is a small chance that this may produce mild and brief upset if they 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.

Where is the study run from?
University of Exeter (UK)

When is the study starting and how long is it expected to run for?
September 2021 to March 2026

Who is funding the study?
1. UK Research and Innovation (UK)
2. Medical Research Council (MRC) (UK)

Who is the main contact?
Prof. Ed Watkins, teamnurture-u@exeter.ac.uk

Study website
http://www.nurtureuniversity.co.uk/reducingworry

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
MR/W00242/1/1

Study information

Scientific Title
Developing and evaluating a stepped change whole-university approach for student wellbeing and mental health: trial of unguided internet rumination-focused cognitive behavioral therapy to prevent depression and anxiety in students

Acronym
Reducing Worry

Study hypothesis

For university students with elevated worry and rumination, unguided internet rumination-focused cognitive behavioral therapy (i-RFCBT) (delivered via mobile app) added to usual practice will outperform usual practice at:
1. Reducing the incidence of depression across 12 months (1a; primary outcome, structured diagnostic questionnaire
2. Reducing symptoms of depression at 3 and 12 months (2a; secondary outcome, as an index of poor mental health; Patient Health Questionnaire-9 [PHQ-9])
3. Reducing symptoms of anxiety at 3 months and 12 months (2b); (secondary outcome, as an index of poor mental health; Generalised Anxiety Disorder Assessment [GAD-7])
4. Increasing mental well-being (Warwick-Edinburgh Mental Wellbeing Scale [WEMWBS]), social and occupational/academic functioning (Work and Social Adjustment Scale [WSAS]), worry, and rumination at 3 and 12 months (2c) (secondary outcome)

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 29/09/2022, FHLS Psychology Ethics Committee (Queens Drive, Exeter, EX4 4QG, United Kingdom; +44 (0)300 555 0444; i.p.l.mclaren@exeter.ac.uk), ref: 523085

Study design
Phase III superiority parallel two-arm randomised multicentre randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual, University/medical school/dental school

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Condition
Students with elevated worry and anxiety

Interventions
Randomisation: Random selection to the two arms (usual care vs usual care plus unguided i-RFCBT) will be conducted automatically by means of a secure service created and managed by the Exeter Clinical Trials Unit (ExeCTU) in conjunction with the trial statistician.

One intervention group: usual practice plus existing unguided app-delivered rumination-targeting CBT. The active intervention is all entirely self-help and provides psychoeducation, tips, advice and strategies for well-being promotion and reducing worry. Treatment duration:

The unguided self-help digital intervention, typically completed over 6-12 weeks, with follow-up over 12 months: 3 months and 12 months.

Intervention Type
Behavioural

Primary outcome measure
The incidence of major depression as indexed by a diagnostic interview or self-reported equivalent across the 12-month follow-up

Secondary outcome measures
1. Depression is measured by Patient Health Questionnaire -9 (PHQ-9) at 3 and 12 months
2. Anxiety is measured by Generalised Anxiety Disorder -7 (GAD-7) at 3 and 12 months
3. Mental well-being is measured by Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) at 3 and 12 months
4. Social and occupational academic functioning is measured by the Work & Social Adjustments Scale (WSAS) at 3 and 12 months
5. Worry is measured by the short-form Penn State Worry Questionnaire at 3 and 12 months
6. Rumination is measured by the 5-item Brooding Scale at 3 and 12 months
7. Resilience is measured by the Brief Resilience Scale at 3 and 12 months
8. Stress is measured by the Perceived Stress Scale-7 and abbreviated version of the Post-secondary student stressors index at 3 and 12 months
9. Self-reported academic outcomes at 3 and 12 months
10. Use of services/treatment received is reported at 3 and 12 months

Overall study start date
01/09/2021

Overall study end date
31/03/2026

Eligibility

Participant inclusion criteria
1. Aged 16 years plus based in the UK, attending university (predominantly one of the six partner universities: Exeter, Oxford, Newcastle, Southampton, Cardiff, King’s College London or other HE institution e.g., associated HE institution, e.g., Falmouth University for University of Exeter)
2. Reporting elevated levels of worry and rumination on standardised questionnaires (scoring in at least worst tercile and worst quartile on the brooding scale and Penn State Worry Questionnaire: this means scores of >11 for worst tercile, > 12 for worst quartile on the brooding scale and >24 for top tercile and >26 for top quartile on the Penn State Worry Questionnaire short-form
3. Basic literacy in English as indicated by the ability to complete consent and online questionnaires (12year old reading age or better)
4. Ability to provide informed consent
5. Available for the full duration of the study (12 months)
6. Regular access to a relevant smartphone, tablet, PC or laptop necessary to use the intervention (using android or IOS systems)

Participant type(s)
Learner/student

Age group
Mixed

Lower age limit
16 Years

Sex
Both

Target number of participants
648 for overall cohort

Participant exclusion criteria
1. Meeting criteria on self-report electronic screening questionnaires for any of the following:
1.1. Current episode of major depressive disorder
1.2. Active suicidality
1.3. Any history of severe mental health problems (i.e., bipolar/psychosis/mania/drug/alcohol dependence)
2. Currently receiving psychological therapy or counselling or antidepressants or other psychiatric medication

Recruitment start date
10/07/2023

Recruitment end date
30/11/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Exeter
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Sponsor information

Organisation
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Sponsor type
University/education

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http://www.exeter.ac.uk/cgr/researchethics

ROR
https://ror.org/03yghzc09

Funder(s)

Funder type
Government

Funder Name
UK Research and Innovation

Alternative Name(s)
UKRI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Medical Research Council

Alternative Name(s)
UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The trial protocol, full trial report, anonymised participant-level dataset, and statistical code for generating the results will be made publicly available. The researchers' publication policy stipulates that all potential publication plans need to be reviewed by the Project Steering Committee before the release of data to coordinate activity between partners, determine appropriate authorship and avoid duplication and replication of effort

Intention to publish date
01/03/2026

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.0	05/06/2023	14/08/2023	No	No