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Nurture-U Treating Anxiety and Depression: internet-based cognitive-behavioural therapy for anxiety and depression in UK university students

Submission date
11/10/2022

Recruitment status
No longer recruiting

Registration date
27/10/2022

Overall study status
Ongoing

Last Edited
01/07/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This project seeks to find out which forms of digital therapy students prefer and to understand which therapy works best for whom. Many universities offer some form of digital cognitive-behavioural therapy (CBT) for students who have anxiety and/or depression. This is because there is good evidence that these cognitive-behavioural therapy treatments can be effective. These treatments usually involve a combination of changing what you do (e.g., building up positive activities, reducing avoidance of anxiety-provoking situations) and changing how you think (e.g., spotting and challenging negative thoughts). These therapies can be offered as a treatment that the individual works through on their own or with support from a mental health professional. Some people prefer to complete the treatment on their own: there are no waiting lists, it is completely private, and you can access it when you want. However, for other people, support from a professional may be necessary and a critical part of helping them to recover. We want to find out who does well with digital CBT on their own and who would only benefit when they have support from a therapist. Digital CBT without a therapist can be offered to a really large number of students as there is no limit on capacity based on therapist availability or scheduling, so it is important to know who can benefit just as well from this approach. Equally, we want to know who really needs the support of a therapist so we can make sure they get the right help. This research will therefore help us to improve services by better directing students to the right treatment, and by better planning and resourcing the services required to help the maximum 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 the participating universities in Nurture-U project), although students at other universities can participate.

What does the study involve?
We ask participants to complete brief questions about symptoms of anxiety and depression and well-being twice online. These questions will be asked at the start of the study and then at a follow-up after 3 months. These measures should take about 10-15 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.
At the start of the study, we will ask participants to complete a comprehensive set of questions about their physical and mental health, prior life experiences, demographics, family background, current and past stress, personality and coping skills, social relationships, and attitudes to and experience of therapy. This will take about 30-40 minutes to complete. These questions are critically important because they will help us to predict who might do better in which version of the digital CBT therapy. These questions have been found to predict who does well in therapy before and so we are using them to develop statistical models of who might benefit from the different versions of CBT.
We will offer half of the study participants the option of using digital cognitive-behavioural therapy to reduce anxiety and depression on their own (self-directed) and half of the study participants the option to use digital cognitive-behavioural therapy with the support of a therapist. This support could take the form of video-conferencing, emails or online conversations within the digital therapy platform, approximately once a week. The therapy typically takes 6-8 weeks to complete and we recommend completing one module a week plus practice in between each module. This allocation will be decided by chance (at random). This is so we can learn who might benefit most from each version of the therapy.

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 anxiety and depression. Digital treatments have been proven to be on average effective and so they may be of benefit to them. These interventions are provided to participants for free. It will also help us to improve treatment and services for anxiety and depression for other university students.
Taking part involves participants giving their time to complete the questionnaires and use the digital therapy. Because some of the questions in the assessment ask about past and present negative emotions and difficult experiences, and the therapy asks participants to tackle current difficulties, 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 digital treatment.

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/anxietyanddepression

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
MR/W00242/1/3

Study information

Scientific Title
Developing and evaluating a stepped change whole-university approach for student wellbeing and mental health: Nurture-U trial of unguided versus guided internet cognitive-behavioural therapy for acute depression and anxiety in students

Acronym
Internet CBT

Study objectives
Current study hypothesis as of 15/08/2023:
The aims of the study:
To better understand the heterogeneity of digital cognitive-behavioural therapy (CBT) intervention effects for students:
1. Explore which subgroups of students with elevated anxiety and depression are particularly responsive to unguided digital interventions
2. Identify predictors of who benefits from guided versus unguided digital CBT interventions for anxiety and depression
3. Produce exploratory individualised treatment rules (ITRs) to guide the selection of treatments most likely to be helpful for students with anxiety and depression through the use of machine-learning approaches

Hypotheses:
For university students with depression and/or anxiety, on average, guided transdiagnostic i-CBT will outperform unguided transdiagnostic i-CBT at:
1. Reducing symptoms of depression at 3 months (1a; co-primary outcome, as an index of poor mental health; Patient Health Questionnaire-9 [PHQ-9])
2. Reducing symptoms of anxiety at 3 months (2a); (co-primary outcome, as an index of poor mental health; Generalised Anxiety Disorder Assessment [GAD-7])
3. Improving rates of recovery (defined as both GAD-7 ≤9 and PHQ-9 <=9)

4. Increasing mental well-being (WEMWBS), social and occupational/academic functioning (WSAS), academic outcomes) at 3 months (2c) (secondary outcome)

It is further hypothesized that whilst guided i-CBT will on average be more efficacious than unguided I-CBT, for a subset of users there will be no difference in effectiveness. The aim is to identify the profiles of those students who would benefit most from unguided i-CBT relative to guided i-CBT and those that need to be directed to guided i-CBT interventions.

Previous study hypothesis:
The aims of the study:
To better understand the heterogeneity of digital cognitive-behavioural therapy (CBT) intervention effects for students:
1. Explore which subgroups of students with elevated anxiety and depression are particularly responsive to unguided digital interventions
2. Identify predictors of who benefits from guided versus unguided digital CBT interventions for anxiety and depression
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Hypotheses:
For university students with depression and/or anxiety, on average, guided transdiagnostic i-CBT will outperform unguided transdiagnostic i-CBT at:
1. Reducing symptoms of depression at 3 months (1a; primary outcome, as an index of poor mental health; Patient Health Questionnaire-9 [PHQ-9])
2. Reducing symptoms of anxiety at 3 months (2a); (secondary outcome, as an index of poor mental health; Generalised Anxiety Disorder Assessment [GAD-7])
3. Increasing mental well-being (WEMWBS), social and occupational/academic functioning (WSAS), academic outcomes) at 3 months (2c) (secondary outcome)

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Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/09/2022, CLES Psychology Ethics Committee (Queens Drive, Exeter, EX4 4PZ, United Kingdom; +44 (0)3005550444; I.P.L.McLaren@exeter.ac.uk), ref: 520569

Approved 27/09/2022, Faculty of Health and Life Sciences Psychology Ethics Committee (Psychology, University of Exeter, Washington Singer Building, Perry Road, Exeter, EX4 4QG, UK; Tel: not available; c.civile@exeter.ac.uk, i.p.l.mclaren@exeter.ac.uk), ref: 523095

Study design
Phase III superiority parallel two-arm randomized 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)
Treatment

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

Health condition(s) or problem(s) studied
Depression and anxiety

Interventions
Two intervention groups: unguided transdiagnostic online CBT for anxiety and depression (i.e., without any therapist support); guided transdiagnostic online CBT for anxiety and depression (i. e., with therapist support from psychological wellbeing practitioner – typically online, asymmetric support). Treatment duration is typically completed over 6-12 weeks, with a 3-month follow-up. Randomisation to the two arms (unguided vs guided i-CBT) is conducted automatically via a secure service created and managed by Exeter Clinical Trials Unit (ExeCTU).

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 15/08/2023:
Depression is measured using the PHQ-9 and anxiety is measured using the GAD-7 across the 3-month follow up

Previous primary outcome measure:
Depression is measured using the PHQ-9 across the 3-month follow up

Secondary outcome measures
1. Worry is measured by the short-form Penn State Worry Questionnaire at 3 months
2. Rumination is measured by the 5-item Brooding Scale at 3 months
3. Resilience is measured by the Brief Resilience Scale at 3 months
4. Stress is measured by the Perceived Stress Scale-7 and an abbreviated version of the post-secondary student stressors index at 3 months
5. Use of services/treatment received is self-reported at 3 months
6. Treatment satisfaction is measured with the Adapted Client Satisfaction Questionnaire – Internet-based interventions at 3 months
7. Self-report of use of intervention at 3 months

Overall study start date
01/09/2021

Completion date
31/03/2026

Eligibility

Key inclusion criteria
1. Aged 16 years plus based in the UK, attending university (predominantly one of the six partner universities: Exeter, Oxford, Southampton, Cardiff, Newcastle, King's College London or other HE institution or associated HE institution, e.g., Falmouth University for University of Exeter)
2. Reporting PHQ-9>9 and/or GAD-7 >9
3. Basic literacy in English as indicated by ability to complete consent and online questionnaires (12-year-old reading age or better)
4. Ability to provide informed consent
5. Available for the full duration of the study (3 months)
6. Regular access to a relevant smartphone/tablet/laptop or PC able to run the intervention (using Android or IOS systems)

Participant type(s)
Other

Age group
Mixed

Lower age limit
16 Years

Sex
Both

Target number of participants
720 for whole cohort

Key exclusion criteria
1. Meeting criteria on self-report electronic screening questionnaires for any of the following:
1.1. Active suicidality
1.2 Any history of severe mental health problems (i.e., bipolar/psychosis/mania/drug/alcohol dependence)
2. Currently receiving psychological therapy or counselling
3. Currently receiving antidepressants or other psychiatric medication that has been changed within the last 4 weeks (in this instance the participant has the option to join the trial once stable for 4 weeks)

Date of first enrolment
10/07/2023

Date of final enrolment
31/05/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Exeter
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Sponsor information

Organisation
University of Exeter

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Sponsor type
University/education

Website
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)
Medical Research Council (United Kingdom), 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 release of data to coordinate activity between partners, determine appropriate authorship and avoid duplication and replication of effort.

Intention to publish date
31/03/2026

Individual participant data (IPD) sharing plan
The datasets analysed during the current study will be stored in a publicly available repository called DATAMIND. The datasets will be anonymised and will be available indefinitely from March 2026. Requests for access to use the datasets will be governed by DATAMIND and the Nurture-U trial team. Participants have consented to their data being shared and/or used in future research.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2.0	05/06/2023	15/08/2023	No	No