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Bounce Back: Enhancing resiliency in university students

Submission date 11/10/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 27/10/2022	**Overall study status** Ongoing	
Last Edited 01/07/2025	**Condition category** Other	

Plain English summary of protocol
Background and study aims
From a student's perspective, the university is to educate and help them develop their careers. University life also presents students with the opportunity for greater independence and to develop problem-solving skills they can use in everyday life. University life however also presents students with many challenges such as living within a budget, making relationships, and managing study demands. For some students, this can be challenging and affect their resiliency and therefore their ability to bounce back from daily challenges faced. Over time struggling to meet everyday challenges at university can increase the likelihood of students experiencing mental health difficulties.

Efforts made by universities to address the emotional well-being of students are largely targeted at treating mental health difficulties once they begin to impact their study and daily lives. However, continuing to invest in and expand student well-being services to meet demand and avoid long waiting times is becoming increasingly unrealistic. Another approach to addressing increased demand to treat mental health difficulties could be to enable students to become more resilient in the face of challenges they are faced with before such difficulties emerge.

An approach based on Cognitive Behavioural Therapy and delivered by a psychological practitioner has recently been developed to enhance resiliency. The intervention follows four steps, whereby the student is supported to identify their strengths to construct a Personal Model of Resilience and apply this to a challenge being faced. In doing so they will hopefully realise the strengths they have in other areas of their life and be able to apply these to enhance their resiliency and overcome challenges they are struggling with.

Who can participate?
Students aged 16 years or over who are a resident in the UK and are currently attending the University of Exeter will be able to undergo a screening assessment to determine if they will be eligible to take part in this trial.

What does the study involve?
The main aim of this study is to understand any problems that may arise when running a bigger

study to examine if a written intervention helps enhance resiliency in a student population or not. If suitable for the study, students will be randomised to receive the 6 week intervention straight away or after a delay. Comparisons will be made between the two groups at different time points to see if the intervention looks like it has potential to improve resiliency. If it does and interviews indicate the intervention has good levels of acceptability, results will inform a much larger study to enable us to be more confident drawing conclusions.

What are the possible benefits and risks of participating
Working with students, this strength-based approach to enhancing resiliency has informed the development of a written self-help intervention. Being self-help offers greater flexibility for students to work through the intervention at a time and place of their choice. However, in the case of any student struggling with any feature of the self-help intervention, support can be requested from someone trained in the approach to help them overcome difficulties and continue to work through the intervention.

Where is the study run from?
The study is being run from the 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?
The study is being funded by the UKRI – MRC Adolescence, Developing Mind and Mental Health Scheme (UK)

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

Study website
https://www.nurtureuniversity.co.uk/buildingstrength

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/W00242/1/2

Study information

Scientific Title
Developing and evaluating a stepped change whole-university approach for student wellbeing and mental health: feasibility study with embedded pilot RCT of a written strength-based low-intensity CBT Intervention to enhance resiliency

Acronym
Bounce Back

Study objectives
This study aims to examine the effectiveness of a written strength-based intervention based on Cognitive Behavioural Therapy to enhance resiliency in young people that are currently well.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 22/09/2022, CLES Psychology Ethics Committee, University of Exeter (Queens Drive, Exeter, EX4 4PZ, United Kingdom; +44 (0)3005550444; I.P.L.McLaren@exeter.ac.uk), ref: 520569

Study design
Interventional 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 the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Emotional wellbeing

Interventions
A Phase II single centre feasibility RCT with embedded pilot where participants will be randomly selected to the 2 arms (sbLICBT vs delayed treatment control – block randomized 30 participants per arm) which will be conducted automatically by means of a secure service created and managed by the Exeter Clinical Trials Unit (CTU) in conjunction with the trial statistician. Block randomization will continue until 120 participants are randomized.

One intervention group. Written strength-based CBT intervention with choice of support on demand (email, face to face [in person v. videoconference]) for up to 6 weeks.
Control is delayed treatment control.

Intervention Type
Behavioural

Primary outcome measure
Feasibility outcomes at measured using participant records up to 3 months follow-up:
1. Number of people directed to this research study
2. Number meeting inclusion criteria
3. Number of people consented
4. Demographic information
5. Number randomised
6. Study drop-out
7. Number completing outcome measures
8. Semi-structured interviews will determine intervention acceptability

Secondary outcome measures
Measured at 3 month follow up:
1. Resilience is measured by the Brief Resiliency Scale (BRS)
2. Depression is measured by PHQ9
3. Anxiety is measured by GAD-7
4. Functioning is measured by Work and Social Adjustment Scale (WSAS)

Overall study start date
01/09/2021

Completion date
31/03/2026

Eligibility

Key inclusion criteria
1. Aged 16 years old or over
2. PHQ9=<9; GAD7=<9
3. Suicide risk: PHQ9; Q9=<1 and R2=No and R3= No
4. Resident in the UK
5. Student at the University of Exeter

Participant type(s)
Learner/student

Age group
Mixed

Lower age limit
16 Years

Sex

Both

Target number of participants
120

Key exclusion criteria
Current participant exclusion criteria as of 14/08/2023:
1. Aged < 16 years old
2. PHQ9>9; GAD7>9
3. Suicide risk: PHQ9; Q9>1 and R2=Yes and/or R3 =Yes
4. Past history of psychosis, mania, substance/alcohol dependence

Previous participant exclusion criteria:
Past history of psychosis, mania, substance/alcohol dependence

Date of first enrolment
10/07/2023

Date of final enrolment
16/12/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Sir Henry Wellcome Building for Mood Disorders Research
Clinical Education Development and Research (CEDAR)
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Sponsor information

Organisation
University of Exeter

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Research Ethics and Governance Office
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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
Research council

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
Intention is to publish results in peer reviewed journals, presentation at a relevant conference and results will be available on Nurture-U web site when online.

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 1.0	05/06/2023	14/08/2023	No	No