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Improving engagement with mental health interventions among low-income university students in Brazil: A feasibility hybrid type III cluster randomised controlled trial

Submission date
20/02/2025

Recruitment status
Not yet recruiting

Registration date
24/02/2025

Overall study status
Completed

Last Edited
13/10/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Mental health conditions affect young people worldwide, especially those in poverty. These conditions can impact their physical and mental health, education, employment, and overall well-being. Many young people, particularly in low-and middle-income countries (LMICs), do not receive mental health support due to a lack of access to evidence-based care. Digital interventions can help, but they often face low participation and engagement among low-income students. This study will test whether Strategy 1 and Strategy 2 can improve engagement with a digital group intervention designed to reduce mental health problems among low-income university students in Brazil.

Who can participate?
Approximately 32 to 40 low-income college students (8-10 students per university) from four universities in Brazil can participate. These universities include both public (tuition-free) and private (with tuition fees) institutions from different states. Participants must be aged between 18 and 30, currently enrolled at one of the participating universities, and receiving a scholarship targeting low-income students or come from a family that has benefited from the Bolsa Família Programme.

What does the study involve?
The study involves a cluster-randomised controlled trial where universities are randomly assigned to one of four groups:
a) digital mental health intervention only (control),
b) digital mental health intervention + engagement strategy 1,
c) digital mental health intervention + engagement strategy 2, or
d) digital mental health intervention + engagement strategy 1 + engagement strategy 2.

Participants will be recruited via university email lists and social media advertisements. The digital mental health intervention consists of 10 weekly group sessions, each lasting 1 to 1.5 hours, delivered via Zoom by psychologists.

Facilitators will record attendance and rate behavioural engagement. Participants will complete assessments before and after the intervention, and qualitative interviews will be conducted to explore their experiences.

What are the possible benefits and risks of participating?
Participants may benefit from improved stress management and problem-solving skills, positively impacting their mental health. Although there are no immediate benefits from the assessments, the study will provide valuable insights into the intervention's feasibility and help improve it for future use.

Participants may experience some burden due to the time required to complete questionnaires. The risk of psychological stress during the intervention is low, but support will be provided for those with severe depressive symptoms.

Where is the study run from?
Care Policy and Evaluation Centre (CPEC) at the London School of Economics and Political Science (LSE) (UK)
Universidade Federal de São Paulo and Universidade Presbiteriana Mackenzie in Brazil
King’s College London (UK)
Universidade Federal do Rio Grande do Sul (Brazil)
Unisanté - University of Lausanne (Switzerland)
South African Medical Research Council
New York University (USA)

When is the study starting and how long is it expected to run for?
October 2023 to July 2025

Who is funding the study?
UK Research and Innovation, Medical Research Council (MRC Reference: MR/Y014375/1)

Who is the main contact?
Sara Evans-Lacko (S.Evans-Lacko@lse.ac.uk)

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
MRC Reference: MR/Y014375/1

Study information

Scientific Title
Use of implementation strategies to improve engagement with digital group mental health interventions among low-income university students in Brazil: A feasibility hybrid type III cluster randomised controlled trial

Study objectives
The aim of this pilot clinical trial is to evaluate the feasibility, acceptability and cost of a digital mental health intervention and implementation strategies, and to test the trial procedures and measures to inform a future fully powered multi-site trial.

We anticipate that the digital mental health intervention and its implementation strategies will be feasible and acceptable to participants, with manageable costs and successfully tested trial procedures and measures, providing actionable insights for the future fully powered RCT.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 14/06/2024, Research Ethics Committee of the Universidade Federal de São Paulo (Rua Botucatu, 740, Térreo – Vila Clementino, Sao Paulo, 04023-900, Brazil; +55 (11) 3385-4343 (8699) or (8557); cep@unifesp.br), ref: 6.888.335

2. approved 10/10/2024, Brazil's National Research Committee (CONEP) (SRTVN - Via W 5 Norte - Edifício PO700 - Quadra 701, Lote D - 3º andar - Asa Norte, Brasilia, 70719- 040, Brazil; +55 (61) 3315-5877; conep@saude.gov.br), ref: 7.123.368

3. approved 01/11/2024, Research Ethics Committee of the Universidade do Extremo Sul Catarinense (Avenida Universitária, 1.105 Bloco R1, sala 109, primeiro andar, Criciúma, 88.806-000, Brazil; +55 (48)3431-2606; cep@unesc.net), ref: 7.199.126

4. approved 23/12/2024, Research Ethics Committee of the Hospital das Clínicas de Porto Alegre (Av. Protásio Alves, n° 211, Portão 4, Bloco C, 5º andar, Porto Alegre, 90.410-000, Brazil; +55 (51) 3359-6246; cep@hcpa.edu.br), ref: 7.316.886

5. submitted 10/10/2024, Research Ethics Committee of the Universidade Federal de Sergipe (Rua Cláudio Batista s/n B. Sanatório. Prédio do Centro de Pesquisas Biomédicas - HU, Aracajú, 49.060-110, Brazil; +55 (79)3194-7208; cep@academico.ufs.br), ref: 7.375.566

Study design
Feasibility hybrid type III cluster randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Management of depression and anxiety among at-risk low-income university students

Interventions
This is a feasibility hybrid type III cluster randomised controlled trial, taking place in four universities in Brazil. Universities will be considered clusters and will be randomly allocated to one of the four arms: a) digital mental health intervention only, b) digital mental health intervention + engagement strategy 1, c) digital mental health intervention + engagement strategy 2, or d) digital mental health intervention + engagement strategy 1 + engagement strategy 2. Randomisation will be computerised using a computer-based pseudo-random number generator. Each university will engage approximately 8 university students.

The digital mental health intervention consists of 10 weekly group sessions over a period of 10 weeks. Sessions will last 1-1.5 hours. Sessions will be delivered by trained facilitators (PhD

psychology students), all with clinical psychology experience. The intervention will be delivered via Zoom (a secure web-based video conferencing platform).
Intervention content is organised into 5 themes, with each theme spanning 2 workshops:
Theme 1: You feel the way you think
Workshop 1: Emotional triggers and automatic thoughts
How to identify activating events (emotional triggers) and recognise how automatic thoughts contribute to the way you feel
Workshop 2: Challenging automatic thoughts and core beliefs
How to identify and challenge unhelpful core beliefs and automatic thoughts
Theme 2: Planning to succeed
Workshop 1: Getting on top of problems before they get you down
How to recognise stressors and use strategies to solve interpersonal and emotional problems
Workshop 2: Goal setting and planning
How to set goals and plan for behaviour change
Theme 3: Hacks to boost your mood
Workshop 1: Avoiding thinking traps
How to identify and modify dysfunctional patterns of thinking
Workshop 2: Overcoming rumination and guilt
How to use strategies to overcome rumination and guilt
Theme 4: Building mastery
Workshop 1: Behaviour activation
How to identify and increase activities that promote feelings of well-being and reduce stress
Workshop 2: Behaviours that matter
How to identify unhealthy habits and develop health-promoting behaviours
Theme 5: Avoiding meltdowns
Workshop 1: Understanding the body's stress response
Understanding the body's stress response and how to use strategies to regulate physiological arousal
Workshop 2: Managing stress and overcoming avoidance
How to manage stress and overcome avoidance

Participants will receive electronic interactive PDF workbooks, prior to each workshop, that include exercises and concise summaries of the key concepts and skills for each session. They will have the option to maintain anonymity by keeping their web cameras off and/or using pseudonyms, although they will be encouraged to turn on their cameras to show their faces during the workshops. Additionally, participants will be invited to utilise the web-based chat function to share comments, questions, or responses during the sessions if they encounter uneasy speaking up in the group.

Twi engagement strategies will be implemented: strategy 1 and strategy 2. To prevent contamination cross study arms, detailed descriptions of these strategies will not be included in this protocol.

Combined arm: participants will receive the digital mental health intervention, well-being cash transfer and peer support over 10 weeks.

Intervention Type
Behavioural

Primary outcome(s)

The following feasibility outcomes of this pilot study will be measured at 12 weeks, tertiary outcomes measures will be collected at baseline and 12 weeks follow-up and include:
1. Feasibility of data collection will be assessed using the proportion of missing items and distribution of responses on each measure
2. Fidelity of digital mental health intervention delivery by facilitators (all arms) across all sessions (average across intervention arms) based on self-developed instruments designed to assess the implementation of the intervention according to intervention protocols.
3. Reported (severe) adverse events reported during the intervention (average across arms)
4. Safety and feasibility of the two engagement strategies

Key secondary outcome(s))

The following secondary outcomes will be measured at 12 weeks, tertiary outcomes measures will be collected at baseline and 12 weeks follow-up:
Additional implementation measures to help adapt the intervention as needed for a future cRCT will include:
1. Adoption: proportion of students enrolled in the intervention among people who sign up and meet eligibility criteria
2. Acceptability (perceived satisfaction/usefulness of information); Appropriateness (perception that the digital group intervention and implementation strategies are tailored to the needs, culturally appealing and relevant), Utility (perceived benefit of the intervention for improving mental health and well-being), will be assessed using the instrument developed by Weiner et al. (2017).
3. Cost assessment will encompass all expenses associated with implementing i) the intervention, including Zoom platform usage, facilitator training and supervision, time allocated by facilitators to conduct the intervention, including pre-and post-intervention activities (i.e., student contact for enrolment, attendance tracking, and completion of the fidelity questionnaire), and ii) implementation strategies: costs associated with the engagement strategy 1, engagement strategy 2, and combined strategies.

Secondary outcome measures for a future cRCT will be:
Mental health outcomes:
1. Depressive Symptoms: Patient Health Questionnaire - PHQ-9
2. Anxiety Symptoms: Generalised Anxiety Disorder Scale - GAD-7
Additional measures on engagement:
We conceptualise engagement as comprising behavioural, cognitive, and emotional components (Milne-Ives et al., 2024).
1. Behavioural Engagement:
1.1. End of session attendance: Number of sessions attended in the final phase of the programme (i.e., focusing on the last 3 sessions)
1.2. Dropout Rate: Proportion or number of sessions attended before dropout. Dropout will be defined as completing <50% of sessions, missing three consecutive sessions without returning, and without contacting the facilitator
1.3. Facilitators report on how often they actively participated in the group sessions
2. Cognitive Engagement:
2.1. Participants report on how focused they were during the sessions
2.2. Participants report on to what extent they find themselves thinking about the group discussions or materials presented during the intervention
2.3. Participants report on to what extent they applied the skills they learned in the group in between sessions
3. Emotional Engagement:
3.1. Level of enjoyment participants experienced during the sessions

3.2. Motivation to use the learned techniques in their daily life
3.3. Feelings of connectedness with the other group participants
4. Behavioural generalisation linking to real-world behaviour change / Macro engagement:
4.1. Lasting changes in how they manage stress or emotions since completing the intervention
4.2. Frequency of use of techniques they learned during the intervention to manage daily challenges
4.3. Perception of the helpfulness of the techniques they learned for managing challenges

Tertiary outcome measures of the future cRCT will include:
1. Warwick-Edinburgh Mental Wellbeing Scale
2. Alcohol Use Disorders Identification Test - AUDIT-3
3. Alcohol, Smoking and Substance Involvement Screening Test Frequency and Concern Items - ASSIST-FC on marijuana use
4. HiTOP scale
5. EQ-5D-5L
6. UCLA Loneliness Scale – 3-Item Version
7. Yorke Belonging Scale
8. Career Optimism
9. Bespoke adapted version of Client Service Receipt Inventory - CSRI
10. Self-identification of mental illness, SELFI Scale
11. Patient health questionnaire – depression module (PHQ-9)
12. Generalised anxiety disorder assessment (GAD-7)

Completion date
31/07/2025

Eligibility

Key inclusion criteria
The inclusion criteria for the low-income university students recruited in the pilot cluster RCT are as follows:
1. Currently enrolled at one of the four participating universities
2. Aged between 18 and 30 years
3. Receiving a 100% scholarship from the University for All Programme (PROUNI) [private universities] or a scholarship from the National Student Assistance Plan (PNAES) [public universities] or coming from a family that is or has been a beneficiary of the Bolsa Família Programme

Participant type(s)
Learner/student

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit

30 years

Sex
All

Key exclusion criteria
Do not agree to participate in the study by signing the Informed Consent Form

Date of first enrolment
24/02/2027

Date of final enrolment
17/03/2027

Locations

Countries of recruitment
Brazil

Study participating centre
Universidade do Extremo Sul Catarinense
Av. Universitária, 1105 – Cx. P. 3167
Criciúma, Santa Catarina
Brazil
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Study participating centre
Universidade Federal de Santa Maria
Av. Roraima nº 1000, Cidade Universitária, Bairro Camobi
Santa Maria, Rio Grande do Sul
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97105-900

Study participating centre
Universidade Federal do Rio Grande do Sul
Rua Ramiro Barcelos, 2.350, Bairro Santa Cecília
Porto Alegre, Rio Grande do Sul
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90035-903

Study participating centre
Universidade Federal de Sergipe
Av. Marcelo Deda Chagas, s/n, Bairro Rosa Elze São Cristóvão

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Sponsor information

Organisation
London School of Economics and Political Science

ROR
https://ror.org/0090zs177

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

Individual participant data (IPD) sharing plan
All data obtained via questionnaires and interviews will be pseudonymised by use of participant ID numbers. Audio-recordings of interviews, which contain identifiable data, will be destroyed as soon as the transcripts are finalised. Only the consent forms will be stored in an identifiable format. The link file, containing information on participants' names and ID will be kept in a separate location beyond the completion of the research, to allow participants to potentially be part of future research activities linked to the study.

During data collection, pseudonymised data arising from the project may be shared and used among the partner institutions listed within the collaboration agreement. All data arising will be considered confidential and will not be shared with external researchers without prior consent from all institutions. In that case, a data sharing agreement will need to be completed with the external researcher or institution before de-identified data are shared.

Following project completion, the datasets generated during the current study will be stored in a private repository using the UNIFESP RedCap server. The data will include an embargo of two years. The study will generate data that may be of interest for other researchers, policymakers or service users within the study and related sites. In principle we shall make data available to others and will create a system to facilitate use of the data. Interested parties will need to complete a proforma that will ask for the specific research question and data needed. The research team will provide an independent view on the scientific merits of the request. We shall ensure that no reasonable request will be refused and there will not be unnecessary delays in providing access. Our data sharing procedure will be guided by: (1) the need to ensure that the datasets are first used to address the primary aims of the project; (2) every effort will be made to offer unrestricted access thereafter, with the only proviso being the continued protection of the anonymity of participants; and (3) due acknowledgement is given by subsequent users to the original source of the data. We will work to ensure that the data, whenever it is to become available to the public, is understandable. Data would be shared only using the anonymous ID number, without any identifying personal information. Both data and the consent forms will be kept for at least 10 years. After 10 years, the principal investigators will, however, reconsider whether the data should be kept for longer, depending on the usefulness of the data to national or international researchers external to the team at that time, keeping in mind the FAIR principles.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes