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Use of implementation strategies to improve engagement with digital group mental health interventions among low-income university students in Brazil

Submission date
12/08/2025

Recruitment status
Recruiting

Registration date
13/08/2025

Overall study status
Ongoing

Last Edited
29/08/2025

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
Low engagement remains a critical barrier to the effectiveness of guided digital mental health interventions, particularly in low-resource settings. This study involves low-income university students aged 18–30 from 20 universities across Brazil. The study tests two strategies designed to encourage participation in a 10-week digital group cognitive behavioural therapy (CBT) intervention. The primary outcome is engagement, defined by attendance at digital CBT sessions at 3 months. Secondary outcomes include depression and anxiety symptoms, adoption of the intervention, cognitive, emotional and sustained engagement, career optimism, educational outcomes (including e.g., dropout), and cost-effectiveness, assessed at baseline, 3 and 9 months. Tertiary outcomes include sleep quality and insomnia, disinhibition, substance use, daily functioning, mental wellbeing, perceived social support, and social connectedness.

Who can participate?
Low-income university students aged between 18 and 30 from participating universities in Brazil. These universities include 16 public (tuition-free) and 4 private (with tuition fees) institutions from different states. Participants must be receiving a scholarship targeting low-income students or come from a family that has benefited from the Bolsa Família cash transfer programme.

What does the study involve?
The study is a four-arm study in which universities are randomly assigned using a computer to one of four groups with a 1:1:1:1 ratio:
a) Digital group CBT intervention only (control),
b) Digital group CBT intervention + engagement strategy 1,
c) Digital group CBT intervention + engagement strategy 2, or
d) Digital group CBT intervention + engagement strategy 1 + engagement strategy 2.

The randomisation will be performed by the data manager. Randomisation will be stratified by university type (public vs private) and blocking to ensure that each of the four private universities is allocated to one of the four arms.

Participants will be recruited through university email lists (including via contacts from university scholarship administrators and student representatives such as leaders of academic centers, student unions and athletic associations), targeted social media advertisements, student WhatsApp groups, university website announcements, pop-up events and flyers.
The digital group CBT intervention consists of 10 weekly group sessions, each lasting 1 hour, delivered via Zoom by recently qualified psychologists with training in CBT. This study evaluates two implementation strategies designed to promote both initial and sustained engagement (i.e., application of skills) with the digital group CBT intervention.

Facilitators will record attendance and rate behavioural engagement. Participants will complete standardised assessments at three time points: prior to the intervention, immediately following its conclusion (3 months) and six months post-intervention (9 months after the beginning of the intervention). Qualitative interviews will also be carried out, via Zoom, with six to eight participants from each trial arm, purposively sampled according to sex and level of engagement, to explore experiences with the intervention and implementation strategies.

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. The study will provide valuable insights into the effectiveness of the intervention and its implementation strategies, contributing to their improvement 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 participants who indicate moderate to high risk will receive assessment by an experienced clinician and, where indicated, referral to specialised mental health services, consistent with the study's risk management plan. A pilot study was conducted across four universities to evaluate the feasibility, acceptability, and cost of the digital group CBT intervention and associated implementation strategies and to test trial procedures and measures in preparation for the full-scale multi-site trial. Participating students completed surveys and took part in qualitative interviews. The pilot study demonstrated that the intervention components —including structured intervention sessions, and engagement strategies— were acceptable and feasible, with no adverse events reported during this phase.

Where is the study run from?
1. Care Policy and Evaluation Centre (CPEC) at the London School of Economics and Political Science (LSE) (UK)
2. Universidade Federal de São Paulo, Universidade Presbiteriana Mackenzie, and Universidade Federal do Rio Grande do Sul in Brazil,
3. King's College London (UK)
4. Unisanté - University of Lausanne (Switzerland)
5. South African Medical Research Council
6. New York University (USA)
7. Duke University (USA)
8. UNICEF
9. Universidade Federal Rural de Pernambuco (Brazil)

When is the study starting and how long is it expected to run for?
The overall study start date was October 2024. Recruitment for the trial will begin in August 2025. All data collection, including follow-up, is anticipated to be completed by September 2027.

Who is funding the study?
UK Research and Innovation, Medical Research Council, UK

Who is the main contact?
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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 hybrid type III cluster randomised controlled trial

Study objectives
The study tests two strategies designed to encourage participation in a 10-week digital group cognitive behavioural therapy (CBT) intervention: Strategy 1 and Strategy 2. To prevent contamination across study arms, detailed descriptions of these strategies will not be included in this protocol. The primary outcome is engagement, defined by attendance at digital CBT sessions at 3 months. Secondary outcomes include symptoms of depression and anxiety, adoption of the intervention, cognitive, emotional, and sustained engagement, career optimism, educational outcomes (e.g., dropout rates), and cost-effectiveness, assessed at baseline, 3, and 9 months. Tertiary outcomes include sleep quality and insomnia, disinhibition, substance use, daily functioning, mental wellbeing, perceived social support, and social connectedness.

Study hypotheses

The primary hypothesis (H1) is that participants in the combined arm (receiving both the engagement strategies) will demonstrate significantly greater behavioural engagement (number of sessions attended at 3 months) compared to those receiving the digital group CBT intervention alone.

H2: It is hypothesised that there will be greater behavioural engagement in arms receiving digital group CBT combined with either engagement strategies compared to the control condition receiving digital group CBT only.

H3: The combined arm (digital group CBT plus both engagement strategies) will demonstrate superior behavioural engagement relative to the arms receiving either engagement strategy individually.

Secondary Outcomes

H4: Participants who receive Strategy 2 (or combined arm) are more likely to adopt the digital group CBT intervention (proportion of eligible participants who confirm intention to participate in the intervention prior to session commencement) than those in the CBT-only or Strategy 1-only arms.

H5: Participants who receive digital group CBT plus either engagement strategies will report greater cognitive and emotional engagement scores compared to participants receiving digital group CBT alone.

H6: Participants in the combined arm will report the highest cognitive and emotional engagement scores

H7: Participants who receive either engagement strategies alongside digital group CBT will report significantly greater sustained behavioural, cognitive and emotional engagement (at 9 months compared to participants receiving digital group CBT alone.

H8: The combined arm will report the highest sustained engagement (i.e., ongoing application and relevance of intervention-related skills, behaviours, and concepts in participants' daily lives beyond the active program) at 9 months

H9: Participants who receive either engagement strategies alongside digital group CBT will report fewer symptoms of depression (PHQ-9) and anxiety (GAD-7) at 3 and 9 months compared to participants receiving digital group CBT alone.

H10: The combined implementation arm will report the lowest scores for symptoms of depression (PHQ-9) and anxiety (GAD-7) at 3 and 9 months

H11: Participants who receive either engagement strategies alongside digital group CBT will have lower university dropout rates and higher career optimism compared to participants receiving digital group CBT alone. The combined arm will report the greatest improvements in education outcomes at 3 and 9 months

H12: The incremental cost per unit improvement in behavioural engagement (defined as the number of sessions received) associated with receiving Strategy 2 and/or Strategy 1 in addition to digital group CBT will be considered cost-effective compared to the digital group CBT alone.

H13: The combined strategy may have the most favourable incremental cost per Quality-Adjusted Life Year – QALY (measured using the EQ-5D) gained ratios at 3 and 9 month follow-ups.

Tertiary outcomes

Participants who receive either engagement strategies alongside digital group CBT will demonstrate greater improvements in sleep quality and insomnia (HiTOP) (H14), hyperactivity and disorganisation (HiTOP) (H15), substance use (AUDIT-3, ASSIST-FC) (H16), daily functioning (H17), mental wellbeing (Warwick-Edinburgh Mental Wellbeing Scale) (H18), perceived social support (H19) and social connectedness (H20) compared to participants receiving digital group CBT alone. Participants in the combined arm will demonstrate the greatest improvements at 3 and 9 months

Hypothesis on mechanisms

The engagement Strategy 2 is hypothesised to influence mental health outcomes through both indirect and direct pathways.

H21: Participants in the Strategy 2 arms will report higher behavioural engagement (session attendance), emotional and cognitive engagement and greater use of CBT skills outside of

sessions (compared to participants receiving digital group CBT alone. These engagement-related indicators will mediate reductions in depression (PHQ-9) and anxiety (GAD-7) symptoms at 3 and 9 months.

H22: Participants receiving Strategy 2 will report lower perceived financial stress (Flourish index) at follow-up compared to participants receiving digital group CBT alone.

H23: Participants receiving Strategy 2 will report higher mental wellbeing, as measured by the WEMWBS, compared to participants receiving digital group CBT alone, independent of session attendance.

Strategy 1 is also hypothesised to influence mental health outcomes (PHQ-9 and GAD-7) through both indirect and direct pathways:

H24: Participants in Strategy 1 arms will report higher behavioural engagement (session attendance), emotional and cognitive engagement and greater use of CBT skills outside of sessions (compared to participants receiving digital group CBT alone. These engagement-related indicators will mediate reductions in depression (PHQ-9) and anxiety (GAD-7) symptoms at 3 and 9 months.

H25: Participants receiving Strategy 1 will report higher perceived social connectedness (HRS three-item loneliness scale) and university belonging (Yorke Sense of Belonging in Higher Education Scale) at follow-up compared to participants receiving digital group CBT alone.

H26: Exploratory analyses will assess whether Strategy 1 is associated with changes in perceived social status (MacArthur Scale)

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 02/10/2024, 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; cep@unifesp.br), ref: 6.888.335

2. approved 13/06/2025, 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: 7.625.891

3. approved 22/06/2025, Comitê de Ética em Pesquisa da Universidade Federal do Amazonas (CEP – UFAM) (Rua Teresina, 4950, Adrianópolis, 69.057-070, Brazil; +55 (92)3305-4000; cep@ufam.edu.br), ref: 7.656.343

4. approved 23/06/2025, Comitê de Ética em Pesquisa da Universidade do Estado do Rio de Janeiro (CEP – UERJ) (Rua São Francisco Xavier 524, BL E 3oand. Sl 3018, Rio de Janeiro, 20550-900, Brazil; +55 (21)2334-2180; coep@sr2.uerj.br), ref: 7.657.739

5. approved 01/07/2025, Comitê de Ética em Pesquisa do Centro de Ciências da Saúde da Universidade Federal da Paraíba (CEP/CCS– UFPB) (Campus I / Prédio do CCS UFPB - 1o Andar, Bairro Cidade Universitária, João Pessoa, 58.051-900, Brazil; 55 (83)3216-7791; comitedeetica@ccs.ufpb.br), ref: 7.679.930

6. approved 01/07/2025, Comitê de Ética em Pesquisa da Universidade Federal Rural de Pernambuco (CEP-UFRPE) (Rua Dom Manuel de Medeiros, s/n Dois Irmãos, 1o andar do Prédio Central da Reitoria da UFRPE, Recife, 52171-900, Brazil; +55 (81)3320-6638; cep@ufrpe.br), ref: 7.682.084

7. approved 02/07/2025, Comitê de Ética em Pesquisa da Universidade Federal da Grande Dourados (CEP – UFGD) (Rua João Rosa Góes, 1761, Dourados, 79825-070, Brazil; +55 (67)3410-2853; cep@ufgd.edu.br), ref: 7.684.440

8. approved 03/07/2025, Comitê de Ética em Pesquisa da Escola de Enfermagem de Ribeirão Preto da Universidade de São Paulo (CEP-EERP/USP) (Avenida dos Bandeirantes, 3900, Campus Universitário Bairro Monte Alegre, Riberão Preto, 14.049-900, Brazil; +55 (16)3315-9197; cep@eerp.usp.br), ref: 7.688.196

9. approved 09/07/2025, Comitê de Ética em Pesquisa da Universidade do Vale do Itajaí (CEP-UNIVALI) (Rua Uruguai, 458. Bloco B6 - Sala 107, Itajaí, 88302-901, Brazil; +55 (47)3341-7738; etica@univali.br), ref: 7.698.249

10. approved 13/07/2025, Câmara de Ética em Pesquisa da Pontificia Universidade do Rio de Janeiro – CEPq / PUC-Rio (Rua Marqués de São Vicente 225, Rio de Janeiro, 22451-045, Brazil; +55 (21)3527-1612; vrac@puc-rio.br), ref: 33-2025

11. approved 17/07/2025, Comitê de ética em pesquisa com Seres Humanos da Universidade Federal de Santa Catarina (CEPSH/UFSC) (Rua Desembargador Vitor Lima, nº222, sala 701, 7º andar, Trindade, Florianópolis, 88040-400, Brazil; +55 (48)3721-6094; cep.propesq@contato.ufsc.br), ref: 7.712.542

12. approved 30/07/2025, Comitê de ética em pesquisa Universidade Federal de Alagoas CEP /UFAL (Av. Longitudinal UFAL 1, n°1444, Maceió, 57072-900, Brazil; +55 (82)3214-1041; cep@ufal.br), ref: 7.733.712

13. approved 31/07/2025, Comitê de ética em pesquisa Universidade Estadual do Piauí CEP /UESPI (Rua Olavo Bilac, 2335, Teresina, 64001280, Brazil; +55 (86)99939-2981; comitedeeticauespi@uespi.br), ref: 7.737.666

14. approved 31/07/2025, Comitê de ética em pesquisa da Pontifícia Universidade Católica de São Paulo CEP-PUC/SP (Rua Ministro Godoi, 969 - sala 63C, São Paulo, 05014-001, Brazil; +55 (11) 3670-8466; cometica@pucsp.br), ref: 7.737.923

15. approved 05/08/2025, Comitê de ética em pesquisa da Universidade Federal do Sul da Bahía CEP-UFSB (Avenida Getúlio Vargas, nº 1732 A, Teixeira de Freitas, 45996-108, Brazil; +55 (73) 2103-8358; cep@ufsb.edu.br), ref: 7.746.722

16. approved 11/08/2025, Comitê de ética em pesquisa Universidade Presbiteriana Mackenzie CEP/UPM (Rua da Consolação nº 896 - Ed João Calvino 4º andar sala 400, São Paulo, 01302-907, Brazil; +55 (11)2766-7615; cep@mackenzie.br), ref: 7.758.484

17. submitted 13/06/2025, Comitê de ética em Pesquisa Universidade Federal do Rio Grande do Norte (CEP-UFRN) (Av. Sen. Salgado Filho, 3000, Natal, 59066-800, Brazil; +55 (84)99193-6266; cepufrn@propesq.ufrn.br), ref: 81165724.7.3008.5537

18. submitted 13/06/2025, Comitê de Ética em Pesquisa Universidade Federal de Goiás (CEP-UFG) (Rodovia R2, n. 3.061, Parque Tecnológico Samambaia, Edifício K2,sala 110, piso 1, Goiânia, 74.690-631, Brazil; +55 (62)3521-1215; cep.prpi@ufg.br), ref: 81165724.7.3004.5083

19. submitted 13/06/2025, Comitê de Ética em Pesquisa do Centro de Ciências da Saúde da Universidade Federal do Pará (CEP CCS UFPA) (Rua Augusto Corrêa nº 01- Campus do Guamá , UFPA- Faculdade de Enfermagem do ICS - sala 13 - 2º and, Belém, 66.075.110, Brazil; +55(91) 3201-7735; cepccs@ufpa.br), ref: 81165724.7.3018.0018

20. submitted 13/06/2025, Comitê de Ética em Pesquisa da Universidade Federal de Uberlândia - CEP UFU (Av. João Naves de Ávila 2121- Bloco "1A", sala 224 - Campus Sta. Mônica, Uberlândia, 38408-100, Brazil; (34)3239-4131; cep@propp.ufu.br), ref: 81165724.7.3005.5152

21. submitted 13/06/2025, Comitê de Ética em Pesquisa da Faculdade de Ciências da Saúde da Universidade de Brasília (Campus Universitário Darcy Ribeiro Asa Norte, Brasília, 70.910-900, Brazil; +55 61 3107-1947; cepfs@unb.br), ref: 7.625.891

Study design
Four arm 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 symptoms among at-risk low-income university students

Interventions
This is a hybrid type III effectiveness-implementation cluster randomised controlled trial, taking place in 20 universities in Brazil. Universities will be considered as 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 + strategy 1 + strategy 2. Randomisation will be computerised using a computer-based pseudo-random number generator. Each university will engage approximately 100 university students.
The digital mental health intervention consists of 10 weekly group sessions delivered over 10-12 weeks. Sessions will last 1 hour. The intervention will be facilitated by recently qualified psychologists with training in CBT. All psychologists recruited as facilitators will receive training on the protocol and also weekly group supervision throughout the intervention period. Supervision will be conducted by two experienced psychologists who have previous experience of facilitating the intervention. The intervention will be delivered synchronously 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 wellbeing 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 intervention, 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 sessions. Additionally, participants will be invited to utilise the audio and web-based chat function to share comments, questions or responses during the sessions.

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

Combined arm: participants will receive the digital mental health intervention over 10 weeks, strategies 1 and 2 over 9 months (including the intervention period and six months after the intervention).

Intervention Type
Behavioural

Primary outcome(s)
Behavioural Engagement measured using study data capturing the number of digital group CBT intervention sessions attended, recoded by Zoom and confirmed by facilitators via REDCap form at one timepoint

Key secondary outcome(s))

Secondary adoption and engagement outcomes
Adoption: Proportion of eligible students who confirm participation before commencement of the first session. Captured via REDCap form at baseline.

Cognitive engagement measured using the following:
1. Three-item scale adapted from the Digital Behavior Change Intervention Engagement Scale (DBCI-ES), specifically tailored for this trial, assessing attention and interest with the intervention content adapted from the Digital Behavior Change Engagement Scale, at 3 months
2. Two-item scale assessing sustained cognitive engagement with the intervention, adapted from the DBCI-ES, at 9 months

Emotional engagement measured using the following:
1. Three-item scale adapted from the DBCI-ES, specifically tailored for this trial, assessing emotional and experiential responses, such as enjoyment, motivation to apply learned techniques, and sense of connection with the group, at 3 months
2. Three-item scale assessing continued emotional engagement and sustained personal significance of the intervention over time, adapted from the DBCI-ES, at 9 months

Behavioural generalisation linking to real-world behaviour change:
Three-item scale assessing ongoing application and relevance of intervention-related skills, behaviours, and concepts in participants' daily lives beyond the active program, adapted from the DBCI-ES, at 3 and 9 months

Secondary implementation outcomes assessed at 3 and 9 months:
1. Acceptability, appropriateness and feasibility implementation outcomes measured using the Feasibility of Intervention Measure (FIM)
2. Perceived utility of the intervention measured using a two-item scale about learning helpful strategies in the intervention and their intention to continue using them

Secondary mental health outcomes assessed at baseline, 3- and 9-month follow-ups:
1. Depressive symptoms measured using the Patient Health Questionnaire - PHQ-9
2. Anxiety symptoms measured using the Generalised Anxiety Disorder Scale - GAD-7

Secondary educational outcomes assessed at baseline, 3- and 9-month follow-ups:
1. Dropout from university: Self-reported dropout from university
2. Career Optimism: Assessment of perceptions of ability to advance in professional life

Secondary economic outcomes assessed at baseline, 3- and 9-month follow-ups:
1. Quality of life: EuroQol 5-Dimension 5-level (EQ-5D-5L) questionnaire
2. Mental health–related service use: Adapted version of the Service Assessment for Children and Adolescents (SACA) - questionnaire
3. Indirect economic impact of mental health problems: Client Service Receipt Inventory - CSRI

Sociodemographic characteristics: Participants will report their ZIP code, ethnicity (White, Black, Mixed-Race, Indigenous, Asian, other, or prefer not to answer), and whether they identify as part of a Quilombola community. Additional items will assess gender identity and sexual orientation. Information on marital and parental status, living arrangements (e.g., alone, with family, partner, or in shared/student housing), and disability status (physical, visual, hearing, intellectual, or none) will also be collected. Data on parental education attainment (from incomplete elementary to postgraduate) will also be collected. All will only be collected at baseline, except by ZIP code and living arrangement.

Academic and employment status assessed at baseline, 3- and 9-month follow-ups:
1. Scholarship benefit: Self-reported participation in PROUNI or PNAES, and specific PNAES support programs (e.g., student housing, transportation, food).
2. Academic Information: Participants will provide details on their current year of study, academic program, university, and mode of course delivery (in-person, online, hybrid).
3. Employment: Employment status will be assessed, distinguishing between formal/informal work, internships, and exclusive study. For those employed, work hours, number of days worked in the past week, and gross monthly income will be recorded. Unemployed participants will report their willingness to work and weekly availability.

Potential Mechanisms assessed at baseline, 3- and 9-month follow-ups:
1. Mental Wellbeing measured using the Warwick-Edinburgh Mental Wellbeing Scale
2. Financial Stress measured using one item from the Flourish Index on frequency, the participant was worried about being able to cover their usual monthly expenses in the last 2 months
3. Sense of Belonging measured using the Yorke Sense of Belonging in Higher Education Scale
4. Loneliness measured using the HRS three-item loneliness scale

Tertiary mental health outcomes assessed at baseline, 3- and 9-month follow-ups:
1. Alcohol abuse measured using the Alcohol Use Disorders Identification Test - AUDIT-3
2. Marijuana abuse measured using the Alcohol, Smoking and Substance Involvement Screening Test Frequency and Concern Items - ASSIST-FC on marijuana use
3. Sleep problems measured using the Item of Hierarchical Taxonomy Of Psychopathology (HiTOP) scale
4. Disinhibition measured using the Personality Inventory for DSM-5 (PID-5)
5. Symptom severity measured using the Work and Social Adjustment Scale (WSAS)
6. Stigma towards people with mental illness measured using the Reported and Intended Behaviour Scale (RIBS)
7. Self-identification of mental illness measured using the Self-Identification as Having a Mental Illness Scale - SELF-I

Tertiary socioeconomic outcomes assessed at baseline, 3- and 9-month follow-ups:
1. Perceived social status measured using the MacArthur Scale of Subjective Social Status
2. Expenditures measured using the Personal wellbeing related expenditures over the past month on items such as entertainment, food, clothing, personal care, digital devices, and transportation (yes or no).

Tertiary educational outcomes assessed at baseline, 3- and 9-month follow-ups:
Study Habits measured using the reported number of hours spent studying per week, number of hours spent attending classes in a typical week, and the frequency of missing or skipping classes.

Academic Performance:
1. Number of subjects failed in the previous academic term due to not meeting the required passing grade
2. Subject withdrawal during the previous semester, including reasons
3. Whether they have ever suspended or dropped out of an entire academic semester
4. Average grade at the end of the previous semester

Completion date
30/09/2027

Eligibility

Key inclusion criteria
1. Currently enrolled at one of the 20 participating universities
2. Aged between 18 and 30 years
3. Receiving a 100% scholarship from the University for All Programme (PROUNI) or Universidade Gratuita Programme [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
1. Do not agree to participate in the study by signing the Informed Consent Form
2. No clinical or behavioral criteria will be applied to exclude participants once enrolled

Date of first enrolment
15/08/2025

Date of final enrolment
01/12/2026

Locations

Countries of recruitment
Brazil

Study participating centre
Universidade Federal de Alagoas
Av. Lourival Melo Mota, s/n, Tabuleiro do Martins

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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.

After 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 (https://redcap.epm.br/). 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 the 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 becomes 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
Stored in non-publicly available repository

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