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Online group cognitive behavioural therapy for South African university students with depression and anxiety

Submission date
16/08/2022

Recruitment status
No longer recruiting

Registration date
11/10/2023

Overall study status
Completed

Last Edited
01/11/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
The aim of this study is to find out whether undergraduate university students with mild-to-moderate symptoms of depression and/or anxiety who receive an online group cognitive behavioural therapy (GCBT) intervention report lower rates of symptoms of depression and/or anxiety than control groups who receive self-guided digital interventions. The online GCBT intervention has been developed with content that is drawn from common elements identified from GCBT interventions shown to be effective for university students.

Who can participate?
Undergraduate students aged 18 years or older from a selection of five universities across South Africa with mild-to-moderate symptoms of depression and/or anxiety

What does the study involve?
After baseline data collection, students who indicate mild-to-moderate symptoms of depression and/or anxiety will be randomly allocated into the intervention or control group. The intervention will be delivered via Microsoft Teams (a secure web-based video conferencing platform) in 10 weekly workshops of 60-75 minutes. The participants will be provided with electronic interactive pdf workbooks consisting of exercises and brief summaries of the main ideas and skills for each session before each workshop. Sessions will be facilitated by mental health practitioners under the supervision of a registered PhD psychologist. The control groups will be assigned to make use of either a mood monitoring smartphone application called MoodFlow, or a smartphone-based self-help tool called SuperBetter, both of which are freely available digital interventions. Follow-up data collection will occur 3, 6 and 12 months after the end of the intervention (counted from the last day of intervention delivery).

What are the possible benefits and risks of participating?
Due to the nature of psychotherapeutic interventions, there is a risk of participants experiencing emotional distress during the GCBT programme. Participants will be provided with contact details for additional mental health services. Participants within the control group may also experience distress during the study and will be provided with the same list of mental health

resources as the intervention participants. Benefits of participation include potential therapeutic effects of the interventions (both control and interventions), namely a decrease in symptoms of depression and anxiety.

Where is the study run from?
Stellenbosch University (South Africa)

When is the study starting and how long is it expected to run for?
May 2022 to May 2024

Who is funding the study?
National Research Foundation (South Africa)

Who is the main contact?
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2. Prof. Jason Bantjes, Jason.Bantjes@mrc.ac.za

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
Nil known

Study information

Scientific Title
A randomised controlled trial of an online group cognitive behavioural therapy intervention for South African students with depression and anxiety

Study objectives
Undergraduate university students with mild-to-moderate symptoms of depression and/or anxiety who receive an online group cognitive behavioural therapy (GCBT) intervention will report significantly lower rates of symptoms of depression and/or anxiety than control groups who receive self-guided digital interventions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/06/2022, Health Research Ethics Committee of Stellenbosch University (Education Building, Tygerberg Campus, Faculty of Medicine and Health Sciences, Francie van Zijl Drive, Tygerberg 7505, Netherlands; +27 (0)21 938 9075; blanchep@sun.ac.za), ref: N22/04/047

Study design
Multi-site parallel-group randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Mild-to-moderate symptoms of depression and anxiety

Interventions
The trial will take place across between three and five of the following universities: Stellenbosch University (SU), the University of the Free State (UFS), the University of Cape Town (UCT), the University of the Western Cape (UWC), Rhodes University (RU), and the University of the Witwatersrand (Wits).

In participating universities, the email addresses of all undergraduate students will be obtained via institutional permission processes. An email invitation will be sent to randomized batches of students, who, after completing a baseline assessment meet the inclusion criteria, will be randomized using block randomization, into either the intervention or control conditions. Intervention group recipients will receive a 10-week online GCBT intervention. Control groups will be assigned to self-guided digital interventions. Follow-up will occur 3, 6 and 12 months after the end of the intervention (counted from the last day of intervention delivery).

The intervention targets undergraduate university students who have mild-to-moderate symptoms of depression and anxiety. These mood disorders are associated with academic failure, severe role impairment and suicide. Self-guided and guided digital interventions have been touted as scalable and cost-effective treatments for university students. However, they have been shown to have high rates of attrition and low rates of engagement. The active condition is digital GCBT which includes a) online group-based sessions facilitated by a mental health practitioner, and b) materials for intervention which are implemented during sessions and can be referenced after the group intervention is completed. The intervention consists of 10 sessions over a 10-week period. Control groups will be assigned to self-guided digital interventions, both of which are mental health apps including Moodflow (https://www.moodflow.co/) and Superbetter (https://www.superbetter.com/). These students will also have access to a list of mental health resources if further support is required.

Intervention Type
Behavioural

Primary outcome measure
Self-reported depression and anxiety symptoms measured using the Patient Health Questionnaire-9 (PHQ-9) and the Generalised Anxiety Disorder Assessment (GAD-7) at baseline, 3, 6 and 12 months

Secondary outcome measures
1. Attention and concentration: Standardised survey instrument to measure attention and concentration from The Composite International Diagnostic Interview Screening Scales (CIDISC) at baseline, 3, 6 and 12 months
2. Substance use: Standardised survey instrument to measure substance use from The

Composite International Diagnostic Interview Screening Scales (CIDISC) at baseline, 3, 6 and 12 months
3. Panic attacks: Standardised survey instrument to measure symptoms of panic from The Composite International Diagnostic Interview Screening Scales (CIDISC) at baseline, 3, 6 and 12 months
4. Social anxiety: Standardised survey instrument to measure symptoms of social anxiety from The Composite International Diagnostic Interview Screening Scales (CIDISC) at baseline, 3, 6 and 12 months
5. High mood: Standardised survey instrument to measure symptoms of high mood (or 'mania') from The Composite International Diagnostic Interview Screening Scales (CIDISC) at baseline, 3, 6 and 12 months
6. Obsessive-compulsive disorder: Standardised survey instrument to measure symptoms of obsessive-compulsive disorder from The Composite International Diagnostic Interview Screening Scales (CIDISC) at baseline, 3, 6 and 12 months
7. Stressful experiences: Standardised survey instrument to measure symptoms of PTSD and exposure to stressful life events from The Composite International Diagnostic Interview Screening Scales (CIDISC) at baseline, 3, 6 and 12 months
8. Other behavioural health problems: Standardised survey instrument to measure symptoms of disordered eating and dissociation from The Composite International Diagnostic Interview Screening Scales (CIDISC) at baseline, 3, 6 and 12 months
9. Self-harm: Standardised survey instrument to assess the presence of self-harm behaviours and suicidality from The Composite International Diagnostic Interview Screening Scales (CIDISC) at baseline, 3, 6 and 12 months

Overall study start date
01/05/2022

Completion date
01/05/2024

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Enrolled as an undergraduate student at one of the target institutions
3. Provide Informed Consent
4. Access to the internet to join the online group
5. Report mild-to-moderate symptoms of depression and/or anxiety (taken as a symptom threshold of 10 or above on both scales)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
210

Key exclusion criteria
1. No internet availability
2. Students who report active suicidality with intent will be referred to appropriate campus-based crises services, national suicide helplines, and any additional referral sites specified by the local administration
3. Students who do not have at least mild-to-moderate symptoms of depression and/or anxiety will also be excluded but given advice about how to access informational resources about mental health, and will not be followed up

Date of first enrolment
17/08/2022

Date of final enrolment
31/08/2022

Locations

Countries of recruitment
South Africa

Study participating centre
Stellenbosch University
Faculty of Medicine and Health Sciences
Francie van Zyl Drive
Cape Town
South Africa
7505

Study participating centre
University of the Free State
205 Nelson Mandela Drive
Park West
Bloemfontein
South Africa
9301

Study participating centre
University of the Western Cape
Modderdam Road

Cape Town
South Africa
7535

Study participating centre
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Woolsack Drive
Cape Town
South Africa
7701

Study participating centre
Rhodes University
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Grahamstown
South Africa
6139

Study participating centre
University of the Witwatersrand
1 Jan Smuts Avenue
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Sponsor type
University/education

Website
http://www.sun.ac.za/english

ROR
https://ror.org/05bk57929

Funder(s)

Funder type
Research organisation

Funder Name
National Research Foundation

Alternative Name(s)
South Africa’s National Research Foundation, National Research Foundation (South Africa), NRF

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
South Africa

Results and Publications

Publication and dissemination plan
Planned publications include a protocol paper, as well as description of the results of the trial in high-impact peer-reviewed journals and conferences; further, feedback to university counselling centres in South Africa about the outcomes, including the sharing of the intervention materials and assisting staff to implement the intervention (if found to be effective).

Intention to publish date
01/10/2024

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