ISRCTN16803509 https://doi.org/10.1186/ISRCTN16803509

Testing the feasibility and acceptability of the co-adapted Early Adolescent Skills for Emotions (EASE-SA) intervention among young adolescents showing symptoms of depression and anxiety and their caregivers in South African school settings

Submission date
09/12/2024

Recruitment status
No longer recruiting

Registration date
12/12/2024

Overall study status
Completed

Last Edited
12/12/2024

Condition category
Mental and Behavioural Disorders

[ ] 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
Adolescence is a critical developmental stage, often marked by heightened vulnerability to mental health challenges, particularly depression and anxiety. In low-resource settings such as South African schools, effective, scalable interventions addressing these issues remain limited. This study assesses the feasibility and acceptability of a co-adapted version of the Early Adolescent Skills for Emotions (EASE) intervention, designed to reduce symptoms of depression and anxiety among adolescents and their caregivers in South African school settings.

Who can participate?
Adolescents aged between 10 and 14 years old who are at risk of depression or anxiety

What does the study involve?
Adolescent and caregiver participants complete the baseline assessment, which is a self-administered tablet-based survey. The EASE-SA intervention will be initiated in person for a duration of 8 weeks. An 8-week post-intervention follow-up and a 3-month follow-up assessment, including interviews, are conducted.

What are the possible benefits and risks of participating?
Participants may find the programme helpful to better understand and deal with their emotions, be able to solve problems and build relationships with their families. The feedback will also help the researchers make the EASE programme better, which could help other children and caregivers. Participants will provide vital feedback that will aid in the future implementation of the EASE program in school settings, improving the mental health of children and their caregivers.

Participating in this study will cause no harm. If participants feel sad or upset after completing the questionnaire, the research team will be there to support them. They will also provide a list of social service and support organisations available in the local community that can be contacted if help or support of any kind is needed.

Where is the study run from?
University of Cape Town (South Africa)

When is the study starting and how long is it expected to run for?
October 2021 to July 2024

Who is funding the study?
The Sue Struengmann Initiative (SSI), University of Cape Town (South Africa)

Who is the main contact?
Ms Mirriam Mkhize, Mkhmir003@myuct.ac.za

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Ms Mirriam Mkhize

ORCID ID
https://orcid.org/0000-0002-6416-5395

Contact details
46 Sawkins Road
Rondebosch
Cape Town
South Africa
7700
+27 (0)216506061
mkhmir003@myuct.ac.za

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
A non-randomized pre-post feasibility study to assess the Early Adolescent Skills for Emotions (EASE-SA) intervention for reducing depression and anxiety among adolescents and improving parenting skills among their caregivers in South African school settings

Acronym
EASE-SA intervention

Study objectives
The rationale of this non-randomized study is to assess the feasibility and acceptability of the co-adapted World Health Organization's Early Adolescent Skills for Emotions (EASE-SA) intervention to reduce symptoms of depression and anxiety in young adolescents and improve the parenting skills of their caregivers in school settings in South Africa.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 21/10/2021, University of Cape Town Human Research Ethics Committee (HREC: 565 /2021) (Faculty Office: Barnard Fuller Building Anzio Road Observatory Cape Town, Cape Town, 7925, South Africa; +27 (0)21 650 6346; hrec-enquiries@uct.ac.za), ref: HREC 565/2021

2. Approved 21/10/2021, Western Cape Education Department (Private Bag x9114, Cape Town, 8000, Cape Town, 8000, South Africa; +27 (0)21 467 2350; meshack.kanzi@westerncape.gov.za), ref: 20211018-6776

Study design
Pre-post single-group non-randomized study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
School

Study type(s)
Prevention

Participant information sheet
Not available in web format

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

Interventions

The feasibility and acceptability of the co-adapted EASE-SA intervention were assessed using a pre-post single-group design. This combined a non-randomized approach with an embedded mixed-methods research design that included quantitative assessments and qualitative structured interviews. The study included (1) adolescent verbal screening using PHQ-A for depression symptoms and GAD-7 for anxiety symptoms; (2) informed consent/assent and recruitment; (3) EASE intervention initiated; and (4) 8-week and 3-month follow-up assessments.

The EASE intervention is a World Health Organization group-based intervention for young adolescents aged 10 to 14 years who experience anxiety or depression symptoms in low-income settings. EASE is delivered by trained non-specialist facilitators to groups of adolescents over seven sessions and caregivers over three sessions.

Intervention Type
Behavioural

Primary outcome measure
The feasibility of study procedures and intervention delivery (assessed on predetermined progression criteria):
1. Facilitator competencies were measured using the Therapeutic Attributes and Competencies for Teen Groups in South Africa (TACT-SA) tool, adapted from the Group Facilitation Assessment of Competencies (GroupACT), rating the facilitator's competency during the intervention implementation
2. Acceptability of study procedures and intervention was assessed using the Child Evaluation Inventory (CEI) at the 3-month follow-up assessment

Secondary outcome measures
1. Depression measured using the Patient Health Questionnaire for Adolescents (PHQ-A) and Patient Health Questionnaire (PHQ-9), for caregivers at baseline, 8-week and 3-month follow-up
2. Anxiety measured using the Generalized Anxiety Disorder Screen 7(GAD-7), at baseline, 8-week and 3-month follow-up.
3. Emotional regulation measured using the Difficulties in Emotion Regulation Scale -16 item version (DERS-16) for adolescents at baseline, 8-week and 3-month follow-up
4. Emotional regulation measured using the Difficulties in Emotion Regulation Scale item version (DERS-30) for caregivers at baseline, 8-week and 3-month follow-up

Overall study start date
12/10/2021

Completion date
08/07/2024

Eligibility

Key inclusion criteria
Adolescents:
1. Aged between 10 and 14 years old
2. Screen at risk for depression using the Patient Health Questionnaire for Adolescents (PHQ-A) with a score of 10 or above
3. Screen at risk for anxiety using the 7-item Generalized Anxiety Disorder (GAD-7) screening tool with a score of 10 or above
4. Provide written assent to participate in the study and also have written informed consent

from their caregivers. In this study, adolescents were permitted to participate even if their caregivers did not wish to participate, provided that consent from caregivers had been obtained for the adolescents' participation.

Caregivers:
1. Providing written informed consent for their own participation
2. Willing to attend the EASE-SA intervention

Participant type(s)
Carer, Learner/student

Age group
Mixed

Lower age limit
10 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
113

Total final enrolment
111

Key exclusion criteria
1. At high risk of suicide
2. Severely impaired
3. Unable to provide informed consent or assent
4. Individuals who demonstrated a high level of psychological distress were referred for mental health support and counselling through our partner organization's referral pathways

Date of first enrolment
18/07/2023

Date of final enrolment
01/02/2024

Locations

Countries of recruitment
South Africa

Study participating centre

Alan J Flisher Center for Public Mental Heath
46 Sawkins Road
Rondebosch
Cape Town
South Africa
7700

Sponsor information

Organisation
University of Cape Town

Sponsor details
46 Sawkins Road
Rondebosch
Cape Town
South Africa
7700
+27 (0)214066663
gillian.hanslo@uct.ac.za

Sponsor type
University/education

Website
https://cpmh.org.za/

ROR
https://ror.org/03p74gp79

Funder(s)

Funder type
Charity

Funder Name
Sue Struengmann Initiative (SSI)

Results and Publications

Publication and dissemination plan

The researcher is currently analysing the data and preparing the manuscript for publication by February 2025.

Intention to publish date
15/02/2025

Individual participant data (IPD) sharing plan
The datasets generated during and or analysed during the current study will be stored in a non-publicly available repository. The Centre for Public Mental Health (CPMH) is in the process of applying for ethical approval for a data registry for quantitative postgraduate student data where all quantitative study data will be deposited and stored with restricted access only to the researchers in this study until 2 years after the thesis being made available on OpenUCT. Thereafter data will be available on request, on signature of a data-sharing agreement approved by the Research Contracts Office at UCT and according to the CPMH data registry standard operating procedures.

Data cannot be shared publicly because all data will be stored in the Centre for Public Mental Health (CPMH) a data registry for quantitative postgraduate student data where all quantitative study data will be deposited and stored with restricted access only to the researchers in this study until 2 years after after the thesis being made available on OpenUCT. Thereafter data will be available on request, on signature of a data-sharing agreement approved by the Research Contracts Office at UCT and according to the CPMH data registry standard operating procedures.

IPD sharing plan summary
Stored in non-publicly available repository