

# 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

<b>Submission date</b> 09/12/2024	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 12/12/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 12/12/2024	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

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

## **Study type(s)**

Prevention

## **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(s)**

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

## **Key secondary outcome(s)**

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

## **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

### **Healthy volunteers allowed**

No

### **Age group**

Mixed

**Lower age limit**

10 years

**Upper age limit**

60 years

**Sex**

All

**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 Health**

46 Sawkins Road

Rondebosch

Cape Town

South Africa

7700

## **Sponsor information**

**Organisation**

University of Cape Town

ROR

<https://ror.org/03p74gp79>

## Funder(s)

### Funder type

Charity

### Funder Name

Sue Struengmann Initiative (SSI)

## Results and Publications

### 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