ISRCTN17755448 https://doi.org/10.1186/ISRCTN17755448

Early adolescent skills for emotions (EASE) program trial for young adolescents studying in public schools of rural Pakistan

Submission date
15/10/2021

Recruitment status
No longer recruiting

Registration date
22/10/2021

Overall study status
Completed

Last Edited
19/07/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Emotional conditions in children and adolescents such as symptoms of depression and anxiety are the leading contributors to health burden among adolescents worldwide. There is an urgent need for evidence-based psychological interventions for young people, especially those living in adversity. WHO guidelines for the treatment of emotional disorders in children and adolescents recommend the use of psychological interventions. WHO has developed Early Adolescent Skills for Emotions (EASE), a brief group psychological intervention delivered by non-specialist providers for young adolescents impaired by anxiety and depression and exposed to adversity. We aim to investigate the effectiveness of EASE, compared to treatment-as-usual to reduce symptoms of anxiety and depression in young adolescents, studying in public schools of rural Rawalpindi, Pakistan using a cluster randomized controlled trial design.

Who can participate?
All adolescents, aged 13-15 years, who might be experiencing symptoms of psychosocial distress, studying in public schools of rural sub-district of Gujar Khan, Rawalpindi, Pakistan, and their caregivers can take part in this study.

What does the study involve?
After being enrolled in the study, all these adolescents and their parents will attend group sessions of the EASE program where they will be trained to better cope with emotional and practical problems of adolescents and improve parent-child relationships. However, the program will be delivered in 2-groups. Schools in group 1 will receive the program immediately after being enrolled in the study, the schools in group 2 will receive the program after 3-months post-program implementation to group 1 (on the basis that the evaluation with the adolescents and parents/primary caregivers in the 1st group demonstrates positive findings). The allocation of schools to group 1 and group 2 will be randomly decided based on chance, like a flip of a coin. All schools will have an equal chance of being in either group. We will evaluate the impact of this program on these selected adolescents so that the effectiveness of the program can be measured.

What are the possible benefits and risks of participating?
Potential benefits
All participating adolescents and their caregivers will receive direct benefits including learning to better manage emotional and practical problems that adolescents might be facing, working on improving parent-child interaction, which may lead to better academic performance and wellbeing of these adolescents. This study aims to gather essential information to design a program that will address the emotional and practical problems experienced by adolescents. What we learn from this study will be used to inform the roll-out of the WHO EASE program to address symptoms of anxiety and depression in adolescents, living in low resource settings, globally.
Potential risks
There is a small risk that some people may find talking about or addressing the emotional problems of adolescents difficult or distressing. If any child or parent, gets upset or finds that they would like to talk to someone in more depth, a referral for additional support will be arranged. All aspects of this study are being carried out by trained non-specialist counselors from WHO Institute of Psychiatry, Benazir Bhutto Hospital, Rawalpindi, Pakistan, all of whom are skilled in responding to distress. Moreover, the program does not 'diagnose' the adolescents with problems and hence avoids the risk of labeling an adolescent. However, there is a risk of stigma posed to children who might be identified as experiencing emotional and behavioral problems through our research study. The risk of stigmatization of children will be minimized by ensuring the confidentiality of the results of the research study. Only the research team will have access to the results of the research study. Anonymized, aggregated results of the research study will be shared with the school administration. This will ensure that no individual child is identified as possibly having emotional problems.

Where is the study run from?
The study being conducted by Human Development Research Foundation (HDRF) (Pakistan)

When is the study starting and how long is it expected to run for?
September 2021 to August 2022

Who is funding the study?
The study is funded by Medical Research Council, UK.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRB/001/2020

Study information

Scientific Title
Randomized evaluation of WHO Early Adolescent Skills for Emotions (EASE) for young adolescents studying in public schools of rural Pakistan: a cluster randomized controlled trial

Acronym
EASE cRCT

Study objectives
Our primary hypothesis is that Easrly Adolescent Skills for Emotions (EASE) program plus Treatment as Usual (TAU will be superior compared to TAU alone, in reducing the symptoms of psychosocial distress in adolescents, measured with the self-rated Paediatric Symptoms Checklist (PSC) in 13-15 years old adolescents at 3-months' post-intervention follow-up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/09/2021, Ethics committee of World Health Organization (WHO, 20 Avenue Appia, Geneva, Switzerland; no telephone number provided; no email provided), ref: ERC.0003251

Study design
Single center cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
School

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Adolescents experiencing symptoms of psychosocial distress.

Interventions
Intervention:
The Early Adolescent Skills for Emotions (EASE) intervention program is a new, brief, group psychological intervention program (Dawson et al., 2019) based on Cognitive Behavioural Therapy (CBT) techniques that are empirically supported and formally recommended by the WHO (WHO, 2016). The intervention is comprised of 7 group sessions lasting 90 minutes for the young adolescents and is accompanied by 3 group sessions for their caregivers, each lasting approximately 90 minutes. The young adolescent sessions involve the following empirically supported components: psychoeducation, problem solving, stress management (slow breathing), behavioural activation, and relapse prevention. The caregiver sessions involve psychoeducation, active listening, quality time, praise, caregiver self-care and relapse prevention. The adolescent sessions will be delivered on weekly basis, and the three caregiver sessions will be embedded across the seven-week period.

Wait-list control:
Evidence based health practices are not available in schools to manage the mental health problems of children. No structured programs are being implemented in school settings for adolescents experiencing the symptoms of anxiety and depression, studying in 8 and 9 grades. During the study, participants in both arms will be able to seek specialists (psychologist /psychiatrist) support from the child psychiatry department at the Institute of Psychiatry (IoP)-the tertiary mental health care facility of the region. We will maintain the record of health care services sought by study participants in both study arms using Client Service Receipt Inventory (CSRI) at baseline and 3-months follow-up.
40 eligible schools, stratified by gender, will be randomized into intervention and control arms with a 1:1 allocation ratio. Following informed consent and assent procedures, adolescents will be screened for symptoms of psychosocial distress using self-Reported-Paediatric Symptoms Checklist (PSC). 550 adolescents scoring ≥28 on the self-rated PSC will be recruited and equally randomized into intervention and control arms (225 in each arm).

Intervention Type
Behavioural

Primary outcome measure

Symptoms of psychosocial distress in adolescents are measured using the self-reported Paediatric Symptoms Checklist (PSC) at baseline, immediate post-intervention, and 3-months post-intervention.

Secondary outcome measures
Measured at baseline, immediate post-intervention, and 3-months post-intervention:
1. Internalzing symptoms measured using Revised Children Anxiety and Depression Scale
2. Adolescent wellbeing measured by the Short Warwick Edinburgh Wellbeing Scale (SWEWS)
3. Adolescent quality of life measured by the Paediatric Quality of Life (PedsQL)-child version
4. Adolescent problem solving skills measured by Social Problem-Solving Inventory-Revised Short Form
5. Adolescent somatic complaints measured by somatic symptoms checklist
6. Adolescent perceived emotional support measured by Perceived Emotional/Personal Support Scale
7. Adolescent symptoms of depression measured by Patient Health Questionnaire- Adolescent version (PHQ-A)
8. Academic performance measured through teacher-rated student academic achievement record form
9. Child dropouts measured through school administration record
10. Parent-child relationship measured by Alabama parenting scale
11. Parent's wellbeing measured by PedsQL-family impact module

Overall study start date
02/09/2021

Completion date
30/08/2022

Eligibility

Key inclusion criteria
1. Adolescents aged 13-15 years
2. Living with parents/primary caregivers, attending high public schools in the study area.
3. Written parent/primary caregiver informed consent or witnessed consent (in case the parent /primary caregiver is unable to read and write, the informed consent will be obtained parent /primary caregiver in presence of a witness) and adolescent assent for participation in the study.
4. Screened positive on self-reported PSC (cut- off score ≥ 28).
5. Where there is more than one eligible child in a family unit, we will include the youngest eligible child.

Participant type(s)
Other

Age group
Child

Lower age limit
13 Years

Upper age limit

15 Years

Sex
Both

Target number of participants
40 clusters (14 participants in each cluster)

Total final enrolment
566

Key exclusion criteria
1. Adolescents at high risk of imminent suicide as reported by the students themselves, or parents/primary caregivers, or identified by the trained assessment team during screening. The suicide risk will be assessed by administering the screening item for suicide from the PHQ-9-Adolescents version. This will be supplemented by assessing suicidal thoughts based on WHO mhGAP guidelines for assessing current or historical suicidal (within one month) thoughts, plans, and attempts.
2. Adolescents with acute medical conditions who require immediate or on-going in-patient medical or psychiatric care, as reported by student themselves or parents/primary caregivers or identified by the trained assessment team during screening.
4. Adolescents with deafness, blindness and speech difficulties or with a severe mental, neurological or substance use disorders (e.g. psychosis, mutism, intellectual disability, autism, or drug dependence) identified by the trained assessment team during screening.

Date of first enrolment
02/11/2021

Date of final enrolment
30/11/2021

Locations

Countries of recruitment
Pakistan

Study participating centre
Institute of Psychiatry, Benazir Bhutto Hospital, Rawalpindi and Human Development Research Foundation (HDRF)
Global Institute of Human Development
Shifa Tameer-e-Millat University
Gujar Khan Campus
Near Government Rural Health Center Mandra
Rawalpindi
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46000

Sponsor information

Organisation
Benazir Bhutto Hospital

Sponsor details
Near Chandni Chowk
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/052afx753

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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/03/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Syed Usman Hamdani (Site-Principal Investigator) by contacting him at usman.hamdani@hdrfoundation.org; usman.hamdani@stmu.edu.pk; syedusmanhamdani@gmail.com
The Anonymized Personal data, which means information and/or data about one or more living person who is the subject of personal data ("Data Subject") and who can be identified from that information, including but not limited to surname, initials, date of birth, address and postal address, will be provided.
The data will be available after the publication of primary trial results to researchers who will be interested to do the secondary analysis of the trial data. The data-sharing agreement will be signed between the investigators and second party to outline the ownership and usage of the data, confidentiality, publication, protection, and security of the research data, and termination of the agreement. Permission from the data subject has been obtained to use the data for any subsequent secondary analysis and research purposes.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		23/09/2022	29/09/2022	Yes	No
Results article		17/07/2024	19/07/2024	Yes	No