ISRCTN11220474 https://doi.org/10.1186/ISRCTN11220474

Evaluating the effectiveness of a school-based stepped care treatment model for adolescent depression in Pakistan

Submission date
04/11/2025

Recruitment status
No longer recruiting

Registration date
06/11/2025

Overall study status
Completed

Last Edited
01/12/2025

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
Depression and anxiety symptoms are common among adolescents in Pakistan, with around one in four young people affected. Many schools lack access to mental health support. This study aims to test a new, school-based "stepped care" model for adolescent depression, where support is matched to each student's level of need. The program combines two evidence-based psychological interventions that can be delivered by trained non-specialists:
1. A universal intervention that promotes socioemotional well-being for all students.
2. A guided self-help app based on Cognitive Behavioural Therapy (CBT) for adolescents who continue to experience distress.
The study will help identify which combination and sequence of interventions work best, for whom, and under what conditions, to guide cost-effective mental health support for adolescents in schools.

Who can participate?
Male and female adolescents aged 13–15 years enrolled in public schools in Gujar Khan sub-district, Rawalpindi, Pakistan, can participate if they report symptoms of psychological distress. Adolescents must provide assent, and their parents or guardians must give written informed consent.

What does the study involve?
The study includes 40 schools, randomly assigned to either receive the universal school-based intervention or continue with usual school activities (treatment-as-usual). After screening, 600 adolescents showing signs of distress will be enrolled.
Stage 1: Students in intervention schools will receive the universal program delivered by trained non-specialist facilitators, while those in comparison schools will continue usual care.
Stage 2: After 3 months, students who still have symptoms will be re-randomized to either continue their initial intervention or receive an additional CBT-based guided self-help app.
Assessments will be conducted at baseline, 3 months, 6 months, and 9 months to track changes in depressive symptoms, emotional well-being, and functioning.

What are the possible benefits and risks of participating?
Participants may benefit from learning coping skills, problem-solving strategies, and ways to manage stress and emotions. Improved well-being may also enhance their school performance and relationships.
Risks are minimal but may include mild emotional distress when discussing personal experiences. Trained facilitators and supervisors will monitor participants, and any adolescents requiring specialist support will be referred to the Institute of Psychiatry, Benazir Bhutto Hospital, Rawalpindi.

Where is the study run from?
The study is coordinated by the Global Institute of Human Development (GIHD), Islamabad, Pakistan. The research is conducted in public schools across the Gujar Khan sub-district in Rawalpindi District, Punjab.

When is the study starting and how long is it expected to run for?
November 2025 to December 2025

Who is funding the study?
National Institute of Mental Health (NIMH) (USA)

Who is the main contact?
Dr Syed Usman Hamdani, director@gihd.onmicrosoft.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Syed Usman Hamdani

ORCID ID
https://orcid.org/0000-0002-5120-3225

Contact details
Building 18, SVC Road C2/C4, Sector H, Phase 5, DHA Islamabad
Islamabad
Pakistan
46000
+92 (0)330 9979750
director@gihd.onmicrosoft.com

Additional identifiers

Study information

Scientific Title
Evaluating the effectiveness of a school-based stepped care intervention model for adolescent depression in Pakistan: a clustered sequential multiple assignment randomized trial (SMARTSTEP)

Acronym
SMART-STEP

Study objectives
Our primary objective is that at 9 months from baseline, adolescents who receive the universal intervention will show improved symptoms of depression, as measured by the self-reported Patient Health Questionnaire-9-A (PHQ-9-A), compared to treatment-as-usual (TAU).

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 16/04/2024, Institutional Review Board of Global Institute of Human Development (Building 18, SVC Road C2/C4, Sector H, Phase 5, DHA Islamabad, Islamabad, 45730, Pakistan; +92 (0)330 9979750; hr@gihd.edu.pk), ref: IRB/1604/2024

Study design
Cluster sequential multiple assignment randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
First stage intervention: universal intervention for intervention & TAU for control arms:
The first-stage intervention involves a universal intervention delivered in the intervention arm, while the control arm receives treatment-as-usual (TAU). In the intervention arm, all adolescents aged 13-15 years receive a structured, school-based program delivered by non-specialists. It is grounded in developmental, behavioural, social, and cognitive theories and aims to provide basic psychological support to adolescents, build their socioemotional life skills, and strengthen collaboration between parents and schools, including referral pathways for those requiring specialist care. Using a structured manual, storybooks, and lesson plans, non-specialists deliver interactive sessions in class.

Mental health services are not available in public schools in Pakistan, so no structured programs will be delivered to adolescents in schools in the control group (TAU).

CBT-based guided self-help application:
The second-stage intervention in both arms is a CBT-based self-help app. At 3 months, adolescents scoring ≥5 on the PHQ-9 in both arms (indicating the presence of depressive symptoms) are individually re-randomized to continue their initial treatment (universal or TAU) or receive a step-up, CBT-based guided self-help app.

Intervention Type
Behavioural

Primary outcome(s)
Symptoms of depression in adolescents are measured using the Patient Health Questionnaire-9 (PHQ-9) at baseline and 3, 6 and 9 months post-intervention.

Key secondary outcome(s))
Measured at baseline and 6 and 9 months post-intervention:
1. Adolescent psychosocial distress measured using the Pediatric Symptoms Checklist (PSC)
2. Adolescent symptoms of anxiety and depression measured using the Revised Children's Anxiety and Depression Scale (RCADS)
3. Adolescent mental health domains measured using DSM-5 Level 1 Cross-Cutting Symptom Measure
4. Adolescent somatic symptoms measured using the Checklist of Somatic Symptoms of Distress
5. Adolescent well-being measures using the Short Warwick-Edinburgh Mental Wellbeing Scale (SWEMWS)
6. Adolescent perceived psychological functioning measured using PSYCHLOPS (Psychological Outcome Profile)
7. Adolescent functioning measures using Children's Global Assessment Scale (CGAS)
8. Adolescent problem solving measured using The Social Problem-Solving Inventory - Revised Short Form
9. Adolescent perceived social and emotional support measured using the Perceived Emotional /Personal Support Scale
10. Adolescent experience of bullying measured using the Bullying Victimization Questionnaire
11. Academic performance measured through the teacher-rated student academic achievement record form
12. Adolescent- and carer-reported school climate measured using Beyound Blue School Climate Questionnaire
13. Caregivers' Wellbeing measured using Self Reporting Questionnaire (SRQ)
14. Parents’ positive involvement using the Alabama Parenting Questionnaire (APQ)
15. Caregivers reported health services utilization measured using Client Service Receipt Inventory (CSRI)

Completion date
01/12/2025

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 from parent 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)
Learner/student

Healthy volunteers allowed

No

Age group
Child

Lower age limit
13 years

Upper age limit
15 years

Sex
All

Total final enrolment
0

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.
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.
3. 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
13/11/2025

Date of final enrolment
01/12/2025

Locations

Countries of recruitment
Pakistan

Study participating centre
Global Institute of Human Development
Gujar Khan Campus
Near Government Rural Health Center Mandra
Rawalpindi
Pakistan
46000

Sponsor information

Organisation
Global Institute of Human Development

Funder(s)

Funder type
Government

Funder Name
National Institute of Mental Health

Alternative Name(s)
Mental Health NIMH, NIH National Institute of Mental Health, Instituto Nacional de la Salud Mental, NIMH

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
In compliance with the data sharing agreement, the unidentifiable dataset will be periodically submitted to the online NIMH data repository National Database for Clinical Trials Related to Mental Illness (NDCT).

IPD sharing plan summary
Stored in publicly available repository