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Study to assess the effectiveness and mechanism of change of group interpersonal therapy for depressed adolescents in Nepal

Submission date
21/03/2025

Recruitment status
Recruiting

Registration date
21/03/2025

Overall study status
Ongoing

Last Edited
19/06/2025

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
Globally a third of adolescents are at risk of depression with negative consequences for their health and development. Most of the world's adolescents live in low- and middle-income countries (LMICs) where access to treatment for depression is limited. Psychological interventions are treatments that seek to change behaviours, cognitions and feelings to improve mental health but few have been tested with adolescents in LMICs. This study will use an approach where schools are randomly assigned to interpersonal therapy (IPT) for adolescents in the Chitwan district of Nepal. We are aiming to explore the effectiveness of IPT and taking a "realist" evaluation approach to explore IPT's mechanisms of change and contextual factors that moderate its effects. This involves using formative research to develop an intervention theory of change from which we have formulated hypotheses about how intervention mechanisms might interact with context to produce outcomes
(context-mechanism-outcome configurations, CMOCs).

Who can participate?
Adolescents aged 13 to 19 with depression, studying in Class 7, 8, 9 in government schools.

What does the study involve?
This is a randomized controlled study to test whether adolescents aged 13-19 years with depression who receive group IPT improve more than adolescents who receive information about local mental health services but no active intervention (enhanced usual care). Adolescents' depressive symptoms will be assessed at endline (week 17 post-randomization) using the Patient Health Questionnaire modified for adolescents (PHQ-A).

What are the possible benefits and risks of participating?
Adolescents who receive IPT may have improved mental health. Possible risks of participating include distress due to talking about mental health problems and breach of confidentiality if group members disclose sensitive information to non-group members.

Where is the study run from?
1. Transcultural Psychosocial Organization Nepal (Nepal)
2. University College London (United Kingdom)

When is the study starting and how long is it expected to run for?
April 2025 to October 2029

Who is funding the study?
UK Research and Innovation (UKRI) (United Kingdom)

Who is the main contact?
Dr Kelly Rose-Clarke, kelly.rose-clarke@ucl.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Kelly Rose-Clarke

Contact details
30 Guilford Street
London
United Kingdom
WC1N 1EH
+44 (0) 20 7679 2000
kelly.rose-clarke@ucl.ac.uk

Additional identifiers

Protocol serial number
MR/W00285X/1

Study information

Scientific Title
School-based group interpersonal therapy for adolescents with depression in Nepal: A phase III realist cluster-randomised controlled trial

Acronym
SAATHI

Study objectives
Group interpersonal therapy delivered in schools reduces symptoms of depression among adolescents compared to enhanced usual care in Nepal

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 10/03/2025, University College London Research Ethics Committee (University College London 2 Taviton St, London, WC1E 6BT, United Kingdom; +44 20 7679 8717; ethics@ucl.ac.uk), ref: LMS REC - 2025-0351-209

2. submitted 20/03/2025, Nepal Health Research Council (Ramshah Path, Kathmandu, PO Box 7626, Nepal; +977 1 4254220; nhrc@nhrc.gov.np), ref: -

Study design
Realist cluster-randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Treatment of depressive symptoms among school-going adolescents in Nepal

Interventions
Participants in the intervention arm will receive group interpersonal therapy in schools facilitated by trained laypersons. Groups are gender specific and comprise 5-8 adolescents. There are two pre-group sessions with each participant, followed by ten group sessions (approximately 90 minutes each, delivered weekly). In the first pre-group session, the facilitator will meet the participant to characterise their interpersonal problem, help link their depressive symptoms to the problem area, and gather information about their interpersonal relationships and history of depression. In the second pre-group session the facilitator will meet the adolescent and their caregiver together to mobilise support and build rapport. In the initial phase of the group, the facilitator will focus on encouraging participants to review and share their interpersonal problems and instilling hope for recovery. In the middle phase (2–9) participants will learn and practice interpersonal skills and offer and receive support from group members to resolve their problems. In the termination phase of the group, they will review and celebrate progress and make plans to tackle future problems.

Participants in the control group will receive written information about local mental health services including services where we have trained providers using the WHO Mental Health Treatment Gap materials. In addition, participants in the control group who report a suicide plan, a suicide attempt in the past three months, or a lifetime attempt with current ideation will be assessed by a psychosocial counsellor employed through the project and offered one-to-one counselling as needed.

Intervention Type
Behavioural

Primary outcome(s)
Depressive symptoms measured using the Patient Health Questionnaire modified for adolescents (PHQ-A) at endline

Key secondary outcome(s))

1. Functional impairment measured using a tool developed for the study setting at endline
2. Anxiety symptoms measured using the Generalised Anxiety Disorder Assessment (GAD-7) at endline
3. Post-traumatic stress disorder symptoms measured using the PCL-5 8-items at endline
4. School attendance calculated as the percentage of days attended in a standardised four-week period (excluding school closures) at endline
5. Academic performance in a standardised exam at follow-up

Completion date
31/12/2029

Eligibility

Key inclusion criteria
Adolescents:
1. 13-19 years old
2. Attending a participating school
3. Going to grades 7, 8, or 9
4. With depression assessed using a standardised tool (≥10 for the PHQ-A)

Caregivers:
1. 18 years old and above
2. Being a caregiver (e.g, parent, grandparent, family member) of an adolescent who takes part in the study

IPT facilitators and supervisors:
1. 18 years old and above
2. Being an IPT facilitator or supervisor in this trial

School staff:
1. 18 years old and above
2. Working at schools that participated in the trial or working in a school within the same municipality

Participant type(s)
Health professional, Carer, Employee, Learner/student

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
13 years

Sex
All

Key exclusion criteria

Adolescents:
We will exclude participants who are currently at risk for suicide. High risk for suicide includes a) suicide ideation with a plan in the past 2
weeks, b) suicide attempt in the past three months and c) lifetime suicide attempt with suicidal ideation in the past 2 weeks.

Caregivers:
No exclusion criteria

IPT facilitators and supervisors:
No exclusion criteria

School staff:
No exclusion criteria

Date of first enrolment
01/04/2025

Date of final enrolment
21/04/2027

Locations

Countries of recruitment
Nepal

Study participating centre
Transcultural Psychosocial Organization Nepal (TPO Nepal)
Baluwatar
Chitwan
Nepal
Box 8974

Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type

Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The quantitative datasets generated during and/or analysed during the current study will be available upon request from Dr Kelly Rose-Clarke (kelly.rose-clarke@ucl.ac.uk). This will be made available subject to a data-sharing agreement. Quantitative data collected from trial-participating adolescents and their caregivers will be shared after our data collection and analysis is complete. Data will be anonymised prior to sharing. As per our UCL ethics requirements, data will only be shared after there is an appropriate agreement in place. Consent will be obtained from participants to share anonymised data.

IPD sharing plan summary
Available on request