

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/03/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 19/06/2025	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Cluster randomised trial

Study setting(s)

School

Study type(s)

Treatment

Participant information sheet

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

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 measure

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

Secondary outcome measures

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

Overall study start date

30/09/2024

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

Age group

Mixed

Lower age limit

13 Years

Sex

Both

Target number of participants

(i) Adolescents: 768, across 24 clusters and 2 arms (24X2X16) (ii) Caregivers: 768 (iii) IPT facilitators and supervisors: 16 (iv) School staff (school principals, teachers): 24

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

Sponsor details

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Sponsor type

University/education

Website

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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, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Planned dissemination through symposia, talks and poster presentations at conferences and publication in a high-impact peer-reviewed journal.

Intention to publish date

01/04/2028

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-clark@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