ISRCTN14652885 https://doi.org/10.1186/ISRCTN14652885

# Study to adapt and assess the feasibility of group interpersonal therapy in Nepal

**Submission date**
13/10/2023

**Recruitment status**
No longer recruiting

**Registration date**
09/11/2023

**Overall study status**
Completed

**Last Edited**
21/05/2025

**Condition category**
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[X] 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.

Who can participate?
Adolescents aged 13 to 19 with depression, studying in Class 8, 9 or 11 in government schools.

What does the study involve?
This is a pilot study to test the feasibility and acceptability of group IPT and trial procedures ahead of a larger study. The larger study will compare whether adolescents 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 eight to ten weeks after IPT has finished using a patient questionnaire modified for adolescents.

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. King's College London (United Kingdom)

When is the study starting and how long is it expected to run for?
May 2023 to April 2024

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

Who is the main contact?
1. Dr Kelly Rose-Clarke, kelly.rose-clarke@kcl.ac.uk (United Kingdom)

# Contact information

### Type(s)
Public, Scientific, Principal Investigator

### Contact name
Dr Kelly Rose-Clarke

### ORCID ID
http://orcid.org/0000-0001-8959-9184

### Contact details
Bush House North East Wing
30 Aldwych
London
United Kingdom
WC2B 4BG
+44 (0)20 7848 2885
kelly.rose-clarke@kcl.ac.uk

# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
NCT06017700

### Secondary identifying numbers
MR/W00285X/1

# Study information

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

### Acronym
SAATHI

### Study objectives

Group interpersonal therapy delivered in schools reduces symptoms of depression among adolescents

## Ethics approval required
Ethics approval required

## Ethics approval(s)
1. Approved 28/07/2023, King's College London Research Ethics Committee (Franklin Wilkins Building, 5.9 Waterloo Bridge Wing, Waterloo Road, London, SE19NH, United Kingdom; +44 (0) 20 7848 4020; rec@kcl.ac.uk), ref: 37705

2. Submitted 23/07/2023, Nepal Health Research Council (Ramshah Path, PO Box 7626, Kathmandu, PO Box 7626, Nepal; +977 1 4254220; nhrc@nhrc.gov.np), ref: 4722023

## Study design
Parallel pilot cluster randomized controlled trial with 1:1 allocation to control and intervention arms

## 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
Depression

## Interventions
Intervention
Participants in the intervention arm will receive group interpersonal therapy in schools facilitated by trained laypersons. Groups are gender specific and comprise 6-8 adolescents. There are ten group sessions (approximately 90 minutes each, delivered weekly): in the first session the facilitator will focus on encouraging participants to review and share their interpersonal problems and instilling hope for recovery. In the middle sessions (2–9) participants will learn and practice interpersonal skills and offer and receive support from group members to resolve their problems. In the last session, they will review and celebrate progress and make plans to tackle future problems.

There are also two pre-group sessions. First the facilitator will meet the participant at school to characterise their interpersonal problem, help the participant to 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.

Control
Participants in the control cluster reporting a current suicide plan or a suicide attempt in the past three months at baseline or in subsequent surveys will be assessed by a psychosocial counsellor employed through the project and offered one-to-one counselling as needed.

Assessment/follow-up
Participants in the control and intervention arm will be assessed at baseline, endline (13-14 weeks post-baseline) and follow-up (13-14 weeks after the last group session corresponding to 25-26 weeks post-baseline in the intervention arm). There will also be two midline assessments after group session 2 (M1) and after group session 6 (M2).

Randomisation
This is a cluster-randomised control arm. The unit of clustering is the school. Schools will be randomised after the baseline survey.

### Intervention Type
Behavioural

### Primary outcome measure
Depressive symptoms measured using the Patient Health Questionnaire modified for adolescents (PHQ-A) at follow-up

### 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 three-week period (excluding school closures) at one timepoint

### Overall study start date
15/05/2023

### Completion date
01/04/2024

## Eligibility

### Key inclusion criteria
Current participant inclusion criteria as of 06/12/2023:
1. Adolescents aged between 13-19 years old
2. Attending a participating school
3. Enrolled in Class 8, 9 or 11
4. Depressed (i.e. scoring 11 or more on the PHQ-A)
5. Functionally impaired (i.e. scoring 4 or more on the functional impairment tool)

Previous participant inclusion criteria:
1. Adolescents aged between 13-19 years old

2. Attending a participating school
3. Enrolled in Class 8, 9 or 11
4. Depressed (i.e. scoring 10 or more on the PHQ-A)
5. Functionally impaired (i.e. scoring 4 or more on the functional impairment tool)

### Participant type(s)
Learner/student

### Age group
Mixed

### Lower age limit
13 Years

### Upper age limit
19 Years

### Sex
Both

### Target number of participants
192

### Total final enrolment
161

### Key exclusion criteria
1. In Class 10 and 12 because these students will be busy preparing for School Education and Plus 2 exams
2. In Class 7 because they may be too young to benefit from IPT
3. Current suicide plan or attempted suicide in the past three months because these adolescents require more acute, intensive treatment
4. Conversion disorder (“chhopne”) in the past three months because group-based treatments may not be appropriate
5. Adolescents who are unable to participate in group therapy due to severe neurological, developmental or physical illness

### Date of first enrolment
30/10/2023

### Date of final enrolment
31/12/2023

## Locations

### Countries of recruitment
Nepal

### Study participating centre

**Transcultural Psychosocial Organization Nepal (TPO Nepal)**
Baluwatar
Kathmandu
Chitwan
Nepal
G.P.O Box 8974

# Sponsor information

**Organisation**
UK Research and Innovation

**Sponsor details**
UK Research and Innovation
Polaris House
Swindon
England
United Kingdom
SN2 1FL
+44 (0)300 321 4357
communications@ukri.org

**Sponsor type**
Government

**Website**
https://www.ukri.org/

**ROR**
https://ror.org/001aqnf71

# Funder(s)

**Funder type**
Government

**Funder Name**
UK Research and Innovation

**Alternative Name(s)**
UKRI

**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
01/04/2025

### 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@kcl.ac.uk). Consent will be obtained from participants to share anonymised data. 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 KCL ethics requirements, data will only be shared after there is an appropriate agreement in place.

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Statistical Analysis Plan | version 0.9 | | 10/01/2025 | No | No |
| Protocol file | version 2.3.1 | | 21/05/2025 | No | No |