Sports coaching and clubs to promote adolescent wellbeing in rural Nepal

Submission date 04/08/2022	Recruitment status No longer recruiting Overall study status Completed	[X] Prospectively registered [X] Protocol	
Registration date 06/09/2022		 Statistical analysis plan 	
		[_] Results	
Last Edited 25/08/2023	Condition category Mental and Behavioural Disorders	 Individual participant data Record updated in last year 	
25/00/2025			

Plain English summary of protocol

Background and study aims

Each year, one in five adolescents aged 10-19 experiences a mental disorder like depression or anxiety, and the rate is rising. In Nepal, there is a large population of adolescents at risk of mental disorders but a lack of mental health care. An intervention is needed that can protect adolescents from mental disorders, is accessible, cheap and easy to sustain. One such intervention is mental health promotion, which focuses on improving positive behaviours and characteristics that protect mental health.

This study aims to pilot a mental health promotion intervention that uses sport to engage and improve the mental health of adolescents in Nepal. The focus is on sports because there is evidence that sports activities improve mental health, adolescent participation in sports is supported by national and global adolescent policy, and adolescents across Nepal are already playing sports through a national network of sports clubs.

Who can participate?

Adolescents aged between 12-19 years old who are living in the study area

What does the study involve?

The intervention will be implemented over about 10 months in rural Nepal. It involves sports coaching and adolescent clubs and will be open to all adolescents in the study area. The intervention was informed by qualitative research with key stakeholders, the global literature, and the mapping of local resources and interventions. Data on wellbeing and mental health will be collected from adolescents aged 12-19 living in the study clusters whether or not they chose to participate in the intervention. Data will mainly be collected through surveys before and after the intervention and will be used to assess the feasibility and acceptability of the intervention. Data will also give an initial indication of whether the intervention improves adolescents' wellbeing and mental health.

What are the possible benefits and risks of participating?

Adolescents living in the intervention clusters will benefit from access to sports coaching. There are few risks associated with taking part. Survey participants will be asked questions about their mental health which they may find uncomfortable or upsetting. Some minor injuries may happen

during the sports activities so coaches will be trained in first aid and familiar with local services to refer adolescents if needed.

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? November 2021 to December 2023

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

Who is the main contact? 1. Dr Nagendra Luitel, npluitel@tponepal.org.np (Nepal) 2. Dr Kelly Rose-Clarke, kelly.rose-clarke@kcl.ac.uk (United Kingdom)

Contact information

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Additional identifiers

EudraCT/CTIS number Nil known

IRAS number

ClinicalTrials.gov number NCT05394311

Secondary identifying numbers MR/T040181/1

Study information

Scientific Title

Sports coaching and clubs to promote adolescent mental wellbeing in rural Nepal: A pilot clusterrandomised controlled trial - Sports-based Mental heAlth pRomotion for adolescenTs in Nepal (SMART)

Acronym SMART

Study objectives

Sports coaching and adolescent clubs will improve mental wellbeing among adolescents aged 12-19 in rural Nepal

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Approved 17/05/2022, Nepal Health Research Council (Ramshah Path, PO Box 7626, Kathmandu, Nepal; +977 1 4254220; nhrc@nhrc.gov.np), ref: 3088 2. Approved 22/04/2022, King's College London Research Ethics Committee (Franklin Wilkins Building, 5.9 Waterloo Bridge Wing, Waterloo Road, London, SE1 9NH, United Kingdom; +44 (0) 20 7848 4020; rec@kcl.ac.uk), ref: HR/DP-21/22-27152

Study design Community-based pilot cluster-randomized controlled trial

Primary study design Interventional

Secondary study design Cluster randomised trial

Study setting(s)

Community

Study type(s)

Quality of life

Participant information sheet

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

Health condition(s) or problem(s) studied

Mental wellbeing

Interventions

Randomisation and allocation to the intervention Four communities of approximately 1000 population (~160 adolescents aged 12-19) will be randomised to the intervention or control arm.

Intervention clusters

The intervention aims to improve adolescent mental wellbeing through:

- 1. Sports coaching
- 2. Adolescent clubs

Sports coaching: This will involve weekly sessions for around 90 min, facilitated by a sports coach, teacher, and a youth community mobiliser. Sessions will take place in schools or community sports facilities. Adolescents will be offered coaching in different sports such as football, dance and martial arts/self-defence. Each session will begin with an activity focused on promoting adolescents' mental wellbeing by building self-esteem, self-efficacy and skills including team building, communication, and interpersonal skills. The activities will include games, role-play, discussions, and relaxation exercises. The remainder of the session will focus on practising sport through drills, training and friendly competitions/matches. Coaching will be open to any adolescent wishing to participate but will target adolescents aged 12-19 living in the study clusters.

Adolescent clubs: These will run in the community and be facilitated by youth community mobilisers (i.e. locally recruited individuals aged 15-24 who are able to mobilise and lead adolescents in the community). Clubs will organise sports tournaments which will engage parents and the wider community and provide opportunities for adolescents to learn livelihood and wellbeing skills. Clubs will be open to all adolescents in the study clusters aged 12-19. Adolescents can attend as many or as few club meetings as they wish.

In control and intervention clusters we will provide mental health training for local health workers including psychoeducation and information about services for referral. We will also distribute sports equipment at the municipality level.

Intervention Type

Behavioural

Primary outcome measure

Mental wellbeing measured using the Warwick Edinburgh Mental Wellbeing Scale at baseline and endpoint at 10 months

Secondary outcome measures

All mental health wellbeing outcomes will be measured pre-intervention at baseline and postintervention at the 10-month endpoint

1. Self-efficacy measured using the Generalized Self-Efficacy Scale

2. Self-esteem measured using the Rosenberg Self Esteem Scale

3. Emotion regulation measured using the Emotion Regulation Questionnaire for Children and Adolescents

4. Social support measured using the Multidimensional Scale of Perceived Social Support

5. Support and empowerment of youth and attachment to the neighbourhood, measured using subscales of the Adolescents' Developmental Assets in the Neighborhood Scale

6. Depressive symptoms measured using the Depression Self-Rating Scale

7. Anxiety symptoms measured using the Generalised Anxiety Disorder Assessment

Overall study start date

01/11/2021

Completion date

31/12/2023

Eligibility

Key inclusion criteria

Any adolescent aged between 12-19 years old, in or out of school, married or unmarried living in the study clusters

Participant type(s)

Healthy volunteer

Age group Mixed

Lower age limit 12 Years

Upper age limit 19 Years Both

Target number of participants 640

Key exclusion criteria

Adolescents who do not live in the study clusters (e.g. adolescents who live outside the clusters but are visiting friends/family in the study area at the time of the survey)

Date of first enrolment 15/09/2022

Date of final enrolment 31/10/2023

Locations

Countries of recruitment Nepal

Study participating centre Transcultural Psychosocial Organization Nepal Baluwatar Kathmandu Nepal G.P.O Box 8974/C.P.C. Box 612

Sponsor information

Organisation King's College London

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Sponsor type University/education Website https://www.kcl.ac.uk/index.aspx

ROR https://ror.org/0220mzb33

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 publication in a high-impact peer-reviewed journal

Intention to publish date 30/11/2024

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Protocol article</u>		24/08/2023	25/08/2023	Yes	No