

Outcome study on the classroom/camp /community-based intervention for children exposed to armed conflict in Nepal

Submission date 06/12/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 10/01/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 14/01/2021	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mr Mark Jordans

Contact details

Lazimpat
Kathmandu
Nepal
PO 8974 CPC 612
+977 (0)1 4428439
mjordans@healthnettpo.org

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Outcome study on the classroom/camp/community-based intervention for children exposed to armed conflict in Nepal

Study objectives

Classroom/Camp/Community-Based Intervention (CBI) will improve daily functioning and reduce psychological distress.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Research design has been reviewed and approved by the Ethical Review Committee of the Vrije Universiteit Amsterdam (Free University) and is currently under review at the Nepal Health Research Council.

Study design

Randomised Controlled Trial (cluster randomisation)

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

Healthy children who have been exposed to extreme stressors

Interventions

The intervention on which research takes place is the Classroom Based (or Community-Based or Camp-Based) Intervention (CBI) as developed by the Centre for Trauma Psychology in Boston. This is a highly structured community-based intervention, which aims at increasing childrens capacity to deal with the psychosocial problems that having been/being exposed to extreme stressors can cause, and aims to include components that enhance existing resources to deal with these consequences (individual coping methods, play, social support, existing rituals, etc.).

It entails a five-week long, 15-session intervention implemented with groups of children in a class-room, refugee-camp or orphanage setting. It includes mainly group activities (including games, music, art, and drama). Structure is present between sessions and within sessions. Between sessions there is a build-up of activities; in the first two weeks activities are aimed at

stabilising traumatic stress reactions, securing a safe place and building internal resources. In the third week and fourth week activities are aimed at exposure to the possible difficult reactions and memories associated with the conflict, through non-verbal means and in the final, fifth week activities are aimed at identifying and installing external and internal resources and coping strategies.

Within sessions the following format is use:

1. Sessions start with a get together around a circular coloured object representing unity and safety (parachute), while simple hand/body movements and dancing are done
2. The second part of the sessions focuses on what is the central topic for today, e.g. drawing your own body with the places where you feel strength
3. The third part of the session is a cooperative game (games with special rules about inclusion, competition, safety and working together), and the session ends with
4. A final get together around the parachute to say goodbye.

The control group will be a waitlist condition. After T2 measurement the control group will receive the same treatment as the Study Group; i.e. the 15-session Classroom Based Psychosocial Intervention (CBI).

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Reduction in psychological symptoms
2. Post Traumatic Stress Disorder (PTSD) symptoms
3. Depression symptoms
4. Anxiety symptoms
5. Agression symptoms

Secondary outcome measures

Measuring change in resilience outcomes, such as:

1. Coping
2. Pro-social behaviour
3. Self-efficacy

as well as change in Daily Functioning.

Overall study start date

01/01/2007

Completion date

01/05/2007

Eligibility

Key inclusion criteria

1. Aged between 11 and 14
2. Score above cut-off point on Nepal-specific screener for general psychosocial well-being (a screening tool currently in clinical use)

Participant type(s)

Patient

Age group

Child

Lower age limit

11 Years

Upper age limit

14 Years

Sex

Not Specified

Target number of participants

140 Study group; 140 Control Group (Wait list)

Total final enrolment

325

Key exclusion criteria

1. Children scoring under cut-off score
2. Children in need of individual/specialised service

Date of first enrolment

01/01/2007

Date of final enrolment

01/05/2007

Locations**Countries of recruitment**

Nepal

Study participating centre

Lazimpat

Kathmandu

Nepal

PO 8974 CPC 612

Sponsor information

Organisation

Save the Children USA (Nepal office)

Sponsor details

Maharajgunj

Kathmandu

Nepal

PO Box 2218

+977 (0)1 4412598

tclawson@savechildren.org.np

Sponsor type

Charity

Website

<http://www.savethechildren.org/countries/asia/nepal.html>

ROR

<https://ror.org/036jr6x18>

Funder(s)

Funder type

Charity

Funder Name

Save the Children USA (Nepal office)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2010	14/01/2021	Yes	No