

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Feasibility and Accessibility of Bounce Back Program for Managing Trauma in Pakistani Children: A Pilot Randomized Controlled Trials

Protocol summary

Study aim

To evaluate the feasibility and acceptability of the adapted Bounce Back intervention among school children aged 8-11 years in Pakistan , including recruitment, attendance, retention, and intervention completion rates To assess the fidelity of Bounce Back Program Training according to its standard procedure. To examine early indications of improvement in children's anxiety, depression, resilience, emotional regulation, and behavioral functioning among those receiving the intervention compared to the waitlist group.

Design

Two-arm, parallel-group, assessor-blinded, pilot randomized controlled trial.

Settings and conduct

The study was conducted in a semi government-based school located in Rawalpindi, Pakistan.

Participants/Inclusion and exclusion criteria

Had experienced one or more potentially traumatic events. Obtained a score from 15 to 20 on the Urdu version of the Child and Adolescent Trauma Screen (CATS), indicating clinically significant trauma-related distress. Exclusion Criteria Presented with severe psychological or psychiatric conditions. met the criteria for PTSD or score above 21 on CATS.

Intervention groups

two groups: Intervention Group and Control Group

Main outcome variables

Reduction in Anxiety and Depression Symptoms
Resilience, Emotional regulation, and behavioral functioning.

General information

Reason for update

Acronym

Bounce Back Program Trials

IRCT registration information

IRCT registration number: **IRCT20260716070216N1**

Registration date: **2026-07-21, 1405/04/30**

Registration timing: **retrospective**

Last update: **2026-07-21, 1405/04/30**

Update count: **0**

Registration date

2026-07-21, 1405/04/30

Registrant information

Name

ANDLEEB HAIDER

Name of organization / entity

National university of science and technology,
islamabad

Country

Pakistan

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+92 310 5100867

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-12-15, 1404/09/24

Expected recruitment end date

2025-12-31, 1404/10/10

Actual recruitment start date

2025-12-15, 1404/09/24

Actual recruitment end date

2026-01-05, 1404/10/15

Trial completion date

2026-06-20, 1405/03/30

Scientific title

Feasibility and Accessibility of Bounce Back Program for Managing Trauma in Pakistani Children: A Pilot Randomized Controlled Trials

Public title

Feasibility and Accessibility of Bounce Back Program for Managing Trauma in Pakistani Children: A Pilot Randomized Controlled Trials

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Had experienced one or more potentially traumatic events. Children between 8 and 11 years of age. Children who score 15 to 20 on CATS(Child and Adolescent Trauma Screen) screening scale Children enrolled in Grades 3, 4 and 5 of participating in school.

Exclusion criteria:

any children with neuro-developmental disorder any children with PTSD any children on medication Reported sexual abuse as their primary traumatic experience

Age

From **8 years** old to **11 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **500**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants were randomly allocated to either the intervention group or the wait-list control group in a 1:1 allocation ratio using a computer-generated randomization sequence. The random allocation sequence was generated by an independent statistician who was not involved in participant recruitment, baseline assessment, or intervention delivery. Stratified randomization was performed separately within each participating school based on gender and grade level to ensure balanced allocation across groups. Allocation concealment was maintained until completion of baseline assessments. Following randomization, participants in the intervention group received the culturally adapted Bounce Back Program in a school-based group format, whereas participants in the wait-list control group continued receiving routine school support services and were offered the intervention after completion of the post-intervention assessment.

Blinding (investigator's opinion)

Single blinded

Blinding description

Single-blind (blinded outcome assessment). Two independent outcome assessors, each holding an MS degree in Psychology, remained blinded to participants' group allocation throughout baseline, post-intervention, and follow-up assessments. The assessors were not involved in participant randomization or intervention delivery, thereby minimizing assessment bias

Placebo

Not used

Assignment

Parallel

Other design features

Pilot randomized controlled trial with a pretest-posttest wait-list control design and follow-up assessment.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

NUST Research Ethics Committee

Street address

H12

City

Islamabad

Postal code

44000

Approval date

2026-01-21, 1404/11/01

Ethics committee reference number

0839/Ethics/07/S3H/154/DBS

Health conditions studied**1****Description of health condition studied**

Trauma Symptoms

ICD-10 code

F43.9

ICD-10 code description

Reaction to severe stress, unspecified

Primary outcomes**1****Description**

Anxiety and Depression Symptoms

Timepoint

pre, post and follow-up

Method of measurement

Measured through approved questionnaires in Urdu-Language

Secondary outcomes**1****Description**

Resilience, Behavioral Functioning and Emotional Regulation

Timepoint

Pre, Post and Follow-Up

Method of measurement

all measured through approved questionnaires

sadafgul621@gmail.com

Web page address

Intervention groups

1

Description

Intervention group: The intervention group received the culturally adapted Urdu version of the Bounce Back Program, a trauma-focused cognitive behavioral intervention for children aged 8–11 years experiencing trauma symptoms. The program consisted of 10 structured group sessions and 3 individual sessions delivered over approximately 10 weeks. Each session lasted approximately 45–60 minutes. The intervention was delivered by the principal researcher (clinical psychologist) who was trained in the Bounce Back intervention protocol. Two additional trained clinical psychologists were involved in monitoring treatment fidelity and ensuring adherence to the intervention manual. The intervention included psychoeducation about trauma, relaxation and coping skills, emotion identification and regulation, cognitive restructuring, trauma narrative activities, problem-solving skills, safety planning, and parent psychoeducation/home practice activities.

Category

Behavior

2

Description

Control group: The control group was assigned to the wait-list condition. Participants continued their routine school activities and did not receive the Bounce Back intervention during the study period. They underwent the same assessment procedures as the intervention group at pre-test, post-test, and follow-up stages. After completion of the study assessments, participants in the wait-list control group were offered the intervention.

Category

N/A

Recruitment centers

1

Recruitment center**Name of recruitment center**

Inclusive Education School

Full name of responsible person

Dr. Sadaf Gul

Street address

9

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Rawalpindi

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+92 305 1783621

Email**Sponsors / Funding sources**

1

Sponsor**Name of organization / entity**

National University of Science and Technology,
Islamabad

Full name of responsible person

Dr. Tamkeen Ashraf

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

National University of Science and Technology,
Islamabad

Proportion provided by this source

1

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

NUST, DBS, S3H

Full name of responsible person

Dr. Tamkeen Ashraf

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

Contact

Name of organization / entity
NUST, DBS, S3H
Full name of responsible person
Dr Tamkeen Ashraf
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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No. De-identified individual participant data will not be made publicly available due to ethical considerations, participant confidentiality, and institutional data protection policies.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Feasibility and Accessibility of Bounce Back Program for Managing Trauma in Pakistani Children: A Pilot Randomized Controlled Trials The study protocol, statistical analysis plan, and summary study results will be made available after publication of the primary study findings. De-identified participant-level data will not be shared. The protocol and study documents may be provided upon reasonable request to the corresponding investigator for academic and non-commercial research purposes, subject to institutional approval and ethical requirements.

When the data will become available and for how long

The study protocol and summary study results will be available after publication of the primary study findings and will remain available for five years upon reasonable request to the corresponding investigator

To whom data/document is available

Qualified researchers upon reasonable request and subject to institutional approval and ethical requirements.

Under which criteria data/document could be used

For non-commercial academic and scientific research purposes only, subject to institutional policies and ethical requirements.

From where data/document is obtainable

Available from the corresponding investigator upon reasonable request via email, subject to institutional approval and applicable ethical requirements.

What processes are involved for a request to access data/document

Access requests should be submitted to the corresponding investigator by email. Requests will be reviewed in accordance with institutional policies and ethical requirements before access is granted.

Comments