Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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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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

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Dr Tamkeen Ashraf
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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