ISRCTN16685192 https://doi.org/10.1186/ISRCTN16685192

Virtual reality-assisted cognitive behavioral therapy for conflict-affected adolescents in Gaza: a low-intensity mental health intervention

Submission date
06/08/2025

Recruitment status
Recruiting

Registration date
08/08/2025

Overall study status
Ongoing

Last Edited
08/08/2025

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Adolescents in Gaza face repeated traumatic experiences due to ongoing conflict, displacement, and loss. These experiences can lead to long-term emotional and psychological struggles, especially a condition called Complex PTSD (CPTSD), which affects how children regulate emotions, feel safe, and build healthy relationships.
Most therapies for PTSD are designed for children in safe environments, after the traumatic event has passed. But in Gaza, trauma is still ongoing. This study aims to test a new approach to therapy that uses Virtual Reality (VR) alongside traditional Cognitive Behavioral Therapy (CBT). The goal is to provide children with safe and calming experiences through VR to help them manage stress more effectively, especially in such a difficult and dangerous context.
We will compare two types of therapy:
1. CBT with the addition of a 15-minute VR experience (VR-CBT)
2. Standard CBT without VR
We want to see whether adding VR makes therapy more effective and easier to engage with for children affected by war, and assess the long-term effect of the two types of therapy.

Who can participate?
Children aged 12 to 18 years who live in refugee camps in the south of Gaza and show signs of trauma (based on the War Trauma Exposure Scale – Gaza Version) can take part. Children must be able to attend weekly sessions and have a parent or guardian give consent. Children who are currently receiving other psychological treatment or have conditions that prevent them from participating in VR will not be included.

What does the study involve?
First, we aim to screen 100 children using the war-related trauma questionnaire. From this group, 42 children will be selected for the study. These children will be randomly divided into two groups. One group will receive six weekly CBT sessions plus 15-minute VR experiences designed to help with calming and emotional regulation. The other group will simultaneously receive the same CBT sessions without VR. Children will complete questionnaires at the start of the study, after the final session, and at follow-up, 2 months later, to see how they are doing.

The therapy will be delivered by trained mental health professionals. Children who need more intensive therapy will be referred to other services.

What are the possible benefits and risks of participating?
Benefits include improved stress management and emotional control; VR may enhance engagement. Risks are minimal but include possible discomfort discussing trauma or VR side effects (e.g., dizziness). Support will be available throughout.

Where is the study run from?
The study is run in Gaza across multiple tented refugee camps in the south.

When is the study starting and how long is it expected to run for?
July 2025 to November 2025

Who is funding the study?
The study is funded by The Sameer Project, which supports all logistical aspects of the Techmed Gaza project. This includes funding for personnel (e.g., psychologists), printing, equipment, and the provision of tents used as clinical spaces within the refugee camps where the study is conducted.

Who is the main contact?
1. Co-investigator Rawan Iriqat (University of California, San Diego) oversees design and correspondence: ririqat@health.ucsd.edu
2. Chief Investigator: Dr Basel Elkhodary (Islamic University of Gaza)

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IUG 2025/11

Study information

Scientific Title
A two-arm randomized controlled trial evaluating the effectiveness of virtual reality-assisted cognitive behavioral therapy compared to standard CBT in reducing PTSD symptoms among conflict-affected adolescents in Gaza

Acronym
Gaza VR-CBT

Study objectives
Primary:
Evaluate the effectiveness of virtual reality-assisted cognitive behavioral therapy (VR-CBT) in reducing acute psychological distress symptoms (anxiety, fear, stress).

Secondary:
Assess impact on well-being, emotional regulation, perceived safety, and resilience.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 20/07/2025, Ethical Research Committee at the Islamic University of Gaza (PO Box 108, Rimal Street, Gaza, -, Palestine, State of; +970 (0)8 2644400; public@iugaza.edu.ps), ref: 2025/11

Study design
Two-arm randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Other

Study type(s)
Treatment, Efficacy

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

Post-Traumatic Stress Disorder (PTSD) and Complex PTSD (CPTSD) symptoms, Acute psychological distress (anxiety, fear, stress), emotional dysregulation and impaired well-being in conflict-affected adolescents, mental health impacts of chronic trauma and armed conflict in Gaza

Interventions
Participants will be randomly assigned to the intervention (VR-assisted CBT) or control (CBT-only) group using a computer-generated block randomization scheme, stratified by gender to ensure balanced allocation. Due to the nature of the intervention, psychologists delivering therapy will not be blinded to group allocation. However, outcome assessors responsible for post-intervention psychological evaluations will be blinded to group assignment. Data analysts will also be blinded during primary outcome analysis.

Virtual Reality-Assisted Cognitive Behavioral Therapy (VR-CBT):
CBT sessions enhanced with immersive VR grounding techniques (nature scenes, guided breathing, mindfulness visuals)

Standard Cognitive Behavioral Therapy (CBT):
Traditional CBT sessions without VR components

The program lasts 6 weeks, with one session each week. The researchers will measure their stress and PTSD symptoms before, right after, and 2 months after the therapy to see how well each treatment works in the long run.

Intervention Type
Behavioural

Primary outcome measure
PTSD symptoms measured using the International Trauma Questionnaire (ITQ) at baseline, 6 weeks (post-intervention), and 14 weeks (2-month follow-up)

Secondary outcome measures
1. Psychological distress (depression, anxiety, and stress) measured via the Depression, Anxiety, and Stress Scale (DASS-21, Arabic version) at baseline and post-intervention (6 weeks)
2. Treatment satisfaction assessed with the Treatment Satisfaction Scale at post-intervention only (6 weeks)

Overall study start date
20/07/2025

Completion date
30/11/2025

Eligibility

Key inclusion criteria
1. Adolescents aged 12-18 years
2. Clinical or subclinical PTSD symptoms

3. Residing in the Gaza refugee camps
4. Consent and assent obtained
5. Able to commit to sessions

Participant type(s)
Patient, Other

Age group
Child

Lower age limit
12 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
42

Key exclusion criteria
1. Active psychosis
2. Severe developmental delay
3. Physical impairments affecting VR use
4. Currently undergoing other psychological interventions

Date of first enrolment
06/08/2025

Date of final enrolment
20/08/2025

Locations

Countries of recruitment
Palestine, State of

Study participating centre
Refugee camps in southern Gaza
South Gaza
Gaza Strip
Palestine, State of
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Sponsor information

Organisation
University of California, San Diego

Sponsor details
9500 Gilman Drive
La Jolla
United States of America
92039

Sponsor type
University/education

Website
https://ucsd.edu

ROR
https://ror.org/0168r3w48

Funder(s)

Funder type
Charity

Funder Name
The Sameer Project

Results and Publications

Publication and dissemination plan
Data analysis for the initial phase of the study will begin approximately 2 months after the intervention starts. We will then incorporate outcomes measured at the 2-month follow-up to assess the longer-term effects of the interventions.

Findings from the study will be prepared for publication in peer-reviewed scientific journals and shared with stakeholders, including participating communities, mental health practitioners, and policymakers, to help inform mental health interventions in conflict-affected settings. Additionally, results will be presented at relevant conferences to maximize dissemination within the global health and mental health research communities.

Intention to publish date
20/12/2025

Individual participant data (IPD) sharing plan

Data will be stored securely in drives at the Islamic University of Gaza and only deidentified forms will be shared via encrypted transfer with the University of California, San Diego.
The datasets generated during and/or analysed during the current study will be available upon request from the corresponding author (Rawan Iriqat; ririqat@health.ucsd.edu). De-identified data will become available 6 months after the first manuscript publication and will be shared with qualified researchers for ethically approved secondary analyses related to adolescent mental health, trauma, or intervention outcomes in conflict settings. A data-sharing agreement and ethics approval from the requester's institution will be required. Participants and their guardians will be informed during the consent process that de-identified data may be shared for academic purposes.

IPD sharing plan summary

Available on request