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

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
06/08/2025	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
08/08/2025	Completed	☐ Results
Last Edited	Condition category	Individual participant data
08/08/2025	Mental and Behavioural Disorders	[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

#### Contact name

Ms Rawan Iriqat

#### Contact details

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# Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

# 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

#### Study type(s)

Treatment, Efficacy

#### 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(s)

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

#### Key secondary outcome(s))

- 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)

#### 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

#### Healthy volunteers allowed

No

#### Age group

Child

#### Lower age limit

12 years

#### Upper age limit

18 years

#### Sex

All

#### 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

# Sponsor information

#### Organisation

University of California, San Diego

#### **ROR**

https://ror.org/0168r3w48

# Funder(s)

#### Funder type

Charity

#### **Funder Name**

## **Results and Publications**

#### 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 Irigat; ririgat@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

#### **Study outputs**

Output type **Details** Date created Date added Peer reviewed? Patient-facing? Participant information sheet 11/11/2025 No

Participant information sheet

Yes