Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

comparing the of modified version of unified protocol versus dyadic-developmental psychotherapy in reduction of post-traumatic stress symptoms, dissociation, and self-harm in individuals with developmental/post traumatic stress disorder among survivors of the 12-day war

Protocol summary

Study aim
evaluate the effectiveness of unified protocol and dyadic-developmental psychotherapy among individuals with developmental trauma disorder or Post-traumatic stress disorder

Design
clinical trial among participants in two intervention groups and two blinded designs that psychotherapists and assessors will be blind in 3 phases: baseline-intervention and 12-month follow-ups. Participants will randomly assign to each treatment condition by using https://www.sealedenvelope

Settings and conduct
This study will be conducted at the clinical psychology office in Taleghani Hospital, which is located in Velenjak rejoin, Tehran, Iran. Participants will be allocated randomly to two intervention groups. therapists, assessors, and data analyst will not be aware of the treatment conditions. The first group will be received the unified protocol and each main modules will be applied for them through at least 12 sessions. Next one, will be treated by Dyadic-developmental psychotherapy through at least 16 sessions.

Participants/Inclusion and exclusion criteria
Inclusion:(1) met Diagnostic statistic mental disorder -5 diagnostic criteria for developmental trauma disorder or Post-traumatic stress disorder, and 2) were at least 18-years old. Excluded if they: 1) intellectual disability, 2) change in dosage and type of psychiatric medicine 3 months before the study, 3) met criteria for a psychotic disorder, bipolar disorder and brain diseases,4) required specialized treatment for high risk of suicide, 5) received 8 or more sessions of cognitive behavior therapy within last 5 years

Intervention groups
Intervention group 1: UP consisted of maximum of 12 sessions, 60-minute individual treatment sessions. intervention group 2: dyadic-developmental psychotherapy maximum of 16 sessions that applied in individual (1 hours/week)

Main outcome variables
severity of traumatic stress disorder or PTSDsymptoms

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231106059970N4**
Registration date: **2026-01-28, 1404/11/08**
Registration timing: **prospective**

Last update: **2026-01-28, 1404/11/08**
Update count: **0**

Registration date
2026-01-28, 1404/11/08

Registrant information

Name
Banafsheh Mohajerin

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 912 578 6918

Email address
bmohajerin@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-01-30, 1404/11/10
Expected recruitment end date
2026-04-30, 1405/02/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
comparing the of modified version of unified protocol versus dyadic-developmental psychotherapy in reduction of post-traumatic stress symptoms, dissociation, and self-harm in individuals with developmental/post traumatic stress disorder among survivors of the 12-day war

Public title
unified protocol versus dyadic-developmental psychotherapy for children and adolescent with PTSD
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Meet the diagnostic criteria of Developmental trauma disorder / or Post-traumatic stress disorder Aged between 6 and 65 Be able to speak and read Farsi
Exclusion criteria:
met criteria for a psychotic disorder met criteria for Bipolar mood disorder intellectual disability Required specialized treatment for high risk of suicide Missing at least three treatment sessions continuously Primary care giver refuse for participation in this study
Age
From **6 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Investigator
- Outcome assessor

Sample size
Target sample size: **62**
More than 1 sample in each individual
Number of samples in each individual: **31**
31
Randomization (investigator's opinion)
Randomized
Randomization description
Study will employ block randomization at the individual level. Allocation method: true randomization via 4 and 6 variable block size. Random sequence will be generate by random allocation software. Allocation ratio will be 1:1 in each group. Independent researcher will generated the random sequence. Allocation concealment will be ensured using sequentially numbered, opaque, sealed envelopes
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the therapist delivering the interventions, assessors and and data analyzers will be blinded to group allocation. Participants will be aware that there will be two treatment conditions. blinding will be occur after study will be finished.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Shahid Behehshti University of Medical Sciences
Street address
Arabi St, Yaman St, Velenjak, Tehran
City
Tehran
Province
Tehran
Postal code
1983963113
Approval date
2025-10-12, 1404/07/20
Ethics committee reference number
IR.SBMU.RETECH.REC.1404.579

Health conditions studied

1

Description of health condition studied
Post-traumatic stress disorder
ICD-10 code
F43.1
ICD-10 code description
Post-traumatic stress disorder (PTSD)

2

Description of health condition studied
unspecified Post-traumatic stress disorder
ICD-10 code
F43.10
ICD-10 code description
Post-traumatic stress disorder, unspecified

Primary outcomes

1

Description
Post-traumatic stress symptoms severity
Timepoint
baseline, after intervention, 6, and 12 months after intervention as a follow-up phas
Method of measurement
by using PTSD Checklist (PCL-5; Blevins et al., 2015)

Secondary outcomes

1

Description
anger severity
Timepoint
baseline, after intervention, 6, and 12 months after intervention as a follow-up phase
Method of measurement
by using self-report the State–Trait Anger Expression Inventory–2 questionnaire

2

Description
dissociative symptoms severity
Timepoint
baseline, after intervention, 6, and 12 months after intervention as a follow-up phase
Method of measurement
by using self-report the dissociative Experiences Scale questionnaire

Intervention groups

1

Description
Intervention group 1: The Unified Protocol (UP), is emotion-focused cognitive-behavioral therapy. It consists 5 core treatment modules: (1) mindful emotion awareness, (2) cognitive flexibility, (3) identifying and preventing patterns of emotion avoidance, (4) increasing awareness and tolerance of emotion-related physical sensations, and (5) interoceptive and situational emotion-focused exposures. Its 5 core modules are preceded by a module focused on enhancing motivation and an introductory module on the adaptive nature of emotions that provides a framework for understanding emotional experiences. Participants will receive at least 36 individual sessions weekly (1 hour).The sessions will follow these modules and will be changed based on individuals' needs and conditions: Psychoeducation and treatment rationale ; Motivation and goal setting; Mindful emotion awareness; Cognitive reappraisal ; Countering emotional avoidance; Awareness of physical sensations; and Imaginal and situational emotional exposures
Category
Treatment - Other

2

Description
Intervention 2: Intervention 2: Dyadic-developmental psychotherapy is a form of psychotherapy that can help form and repair connections and attachment between children, young people and their parent/carers. It tries to create a "playful, accepting, curious, and empathic" environment in which the therapist attunes to the child's "subjective experiences" and reflects this back to the child by means of eye contact, facial expressions, gestures and movements, voice tone, timing. The child and parents working together with the therapist. The child gains relationship experience which helps her to grow and heal emotionally. Family members develop healthy patterns of relating and communicating. It consists five steps: 1: Relationship Building; 2: Problem Assessment; 3: Goal Setting; 4: Counselling Intervention, and 5: Evaluation, Termination. It will be applied through 16 weekly session (60-90 minutes).
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani hospital
Full name of responsible person
Banafsheh Mohajerin
Street address
Talegani Hospital-Arabi St. Yaman St. Velenjak
City
Tehran
Province
Tehran
Postal code
1985711151
Phone
+98 21 2303 1548
Email
banafshehmohajerin@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Arabi St, Yaman St, Velenjak
City
Tehran
Province
Tehran
Postal code
1983969411

Phone
+98 21 2243 9788
Email
urm@sbmu.ac.ir

Grant name

Grant code / Reference number
43015124

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shahid Beheshti University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Banafsheh Mohajerin
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
Taleghani Hoispital, Arabi St, Yaman St, Velenjak
City
Tehran
Province
Tehran
Postal code
1985711151
Phone
+98 21 2303 1548
Email
banafshehmohajerin@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Banafsheh Mohajerin
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
Taleghani Hospital,Arabi St, Yaman St, Velenjak
City
Tehran
Province
Tehran
Postal code
1985711151
Phone
+98 21 2303 1548
Email
banafshehmohajerin@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Banafsheh Mohajerin
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
Psychology Department, Taleghani Hospitan, Arabai St, Yaman St, Velenjak
City
Tehran
Province
Tehran
Postal code
1985711151
Phone
+98 21 2303 1548
Email
banafshehmohajerin@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
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
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be 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
Demographic information and the results of measures will be available after deidentifying process

When the data will become available and for how long

When the results will be published, researchers could have access to data due to reasonable requests

To whom data/document is available

Data will be available for the mental health researchers

Under which criteria data/document could be used

Data will be available for systematic review

From where data/document is obtainable

Please contact Dr. Banafsheh Mohajerin Address: Psychology Department, Taleghani Hospital, Arabi St, Yaman St, velenjak. Tehran Tel: 982123031548 Banafshehmohajerin@gmail.com

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

After data will be published, data will be available within one week

Comments