

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Comparison of Effectiveness of Intervention with the Methods of Trembling Blanket and EMDR, on PTSD

Protocol summary

Study aim

Comparison of the efficacy of the intervention with Puttolazan method and the method of sensitization with eye movements and its rehabilitation on post traumatic stress disorder in children in the stricken cities of Kermanshah.

Design

15 patients were randomly assigned to the experimental group, the intervention with trembling blanket, and 15 subjects received the intervention in the other experimental group, who received eye drops and retardation, and 15 were assigned. All study samples randomly assigned to three groups are blind.

Settings and conduct

The research site is Kermanshah. The study samples were divided into two experimental groups, one receiving petulsarine intervention group and the other experimental group with EMDR and one control group receiving no intervention. All samples in this study, randomly assigned to three equal groups, are blind study groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age range 7 to 10 years. Being male. Acquiring a score from the post traumatic stress disorder check-list based on the fifth edition of the diagnostic and statistical manual disorder (PCL-5) The consent of the subject to participate in the research. (written consent) The subject has the ability to follow eye movements. Lack of intervention, psychotherapy and medication simultaneous. Exclusion criteria: Dissatisfaction and cooperation The research sample. Get treatment at the same time. Family history of earthquakes. There is a disorder at the same time.

Intervention groups

* The intervention group (1) consists of 15 subjects who receive interventional eye sensitization and retardation.
* The intervention group 2 consists of 15 subjects who receive the intervention by the petuleran method. * The control group includes 15 subjects who do not receive

any interventions.

Main outcome variables

The percentage of people who have a PTSD score list is above 33.

General information

Reason for update

Acronym

PTSD & EMDR

IRCT registration information

IRCT registration number: **IRCT20181217042027N1**

Registration date: **2019-08-14, 1398/05/23**

Registration timing: **prospective**

Last update: **2019-08-14, 1398/05/23**

Update count: **0**

Registration date

2019-08-14, 1398/05/23

Registrant information

Name

Hossein Maleki

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 25 3261 1141

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-18, 1398/05/27

Expected recruitment end date

2019-09-01, 1398/06/10

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of Effectiveness of Intervention with the Methods of Trembling Blanket and EMDR, on PTSD

Public title
The effect of trembling blankets and eye movements desensitization on post-traumatic stress

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age range 7 to 10 years. Being male. Acquiring a score from the post traumatic stress disorder check-list based on the fifth edition of the diagnostic and statistical manual disorder (PCL-5). The consent of the subject to participate in the research. (written consent) The subject has the ability to follow eye movements. Lack of intervention, psychotherapy and medication simultaneously.

Exclusion criteria:
Dissatisfaction and cooperation The research sample. Get treatment at the same time. Family history of earthquakes. There is a disorder at the same time.

Age
From **7 years** old to **10 years** old

Gender
Male

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
A simple randomization will be used using the lottery.

Blinding (investigator's opinion)
Triple blinded

Blinding description
It is explained to the participants that they participate in a pilot study, but they do not describe how the implementation of them will be different from the method of implementation on the other group, nor will they be aware of the information of other groups. Relationship between groups is controlled by the end of the experiment.

Placebo
Not used

Assignment
Parallel

Other design features
One of the treatments used in the research is trembling blanket exposure treatment, which is a researcher's innovative technique, and is the first to be scientifically

examined

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Biomedical Sciences of Islamic Azad University of Qom

Street address

15th Khordad Avenue, Islamic Azad University of Qom

City

Qom

Province

Ghous

Postal code

۳۷۱۴۹۶۳۷۴۴

Approval date

2019-07-08, 1398/04/17

Ethics committee reference number

IR.IAU.QOM.REC.1398.008

Health conditions studied

1

Description of health condition studied

Post traumatic stress disorder

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The percentage of people who have a post-traumatic stress disorder score list is above 33.

Timepoint

Measuring the rate of post-traumatic stress disorder before intervention and 7, 14 and 21 days after intervention.

Method of measurement

Structured diagnostic interview based on the fifth Diagnostic and Statistical Manual of Psychiatric Disorders and the Post Traumatic Stress Disorder Checklist questionnaire are based on the fifth edition of the Diagnostic and Statistical Manual of Psychiatric Disorders (PCL-5).

Secondary outcomes

1

Description

Score of post traumatic stress disorder

Timepoint

Measurement of post-traumatic stress disorder before intervention, 7, 14 and 21 days after intervention.

Method of measurement

The Post Traumatic Stress Disorder Checklist is also based on the fifth edition of the PCL-5 Diagnostic and Statistical Manual of Mental Disorders.

Intervention groups

1

Description

The first intervention group: intervention using eye degradation and retardation; the intervention group's interventional group with sensory degeneration with eye movements and rehabilitation included: 1- Acquiring the necessary information 2- Preparing the therapist 3- Evaluation 4. Sensitization 5. Brokerage 6- Checking Physical 7. Closing 8. Re-evaluation.

Category

Treatment - Other

2

Description

Intervention group: the intervention by the trembling blanket method; the intervention stages include: 1) an effective and intimate relationship between the therapist (therapeutic communication) and the therapist; 2) the logic of this technique is explained, so that the treatment acquaints with the treatment model 3. Creating mutual trust between the therapist and the therapist in order to facilitate the process of treatment; 4- Preparing a therapist for participation in treatment; and Finally, arranging for a blanket and treatment.

Category

Treatment - Other

3

Description

Control group: no interventions are performed.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Relief Committee

Full name of responsible person

Heydar Bahrami

Street address

sarpolezahab, next to the governorate.

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sarpolezahab

Province

Kermanshah

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Email

Emdad_sarpolezahab@chaparmail.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Ali Forghaniha

Street address

Iran - Markazi Province - Ashtian - Imam Khomeini Blvd (RA) - Islamic Azad University, Ashtian Branch

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Province

Markazi

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Web page address

<http://www.aiau.ac.ir/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

1

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

UN agencies and international organizations

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Hossein Maleki

Position

Member of Young and Elite Research Club of Islamic Azad University, Ashtian

Latest degree

Bachelor
Other areas of specialty/work
Psychology
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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

Yes - There is 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

Part of the data, such as information on the main
implications and effectiveness, and the comparison of
the two interventions, are published.

When the data will become available and for how long

Three months after printing results.

To whom data/document is available

Researchers and therapists in the field of health, medical
sciences universities, the Welfare Organization, the
Committee for Psychosocial Interventions of Academic
Societies and the Red Crescent Society.

Under which criteria data/document could be used

Observing professional and ethical principles in research.
Like mentioning the source.

From where data/document is obtainable

Email the researcher to: psy.h.maleki@gmail.com

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

In an email, let us know about the scope and use of the
results. After review, a maximum of two weeks will be
answered.

Comments