Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 orther 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 simultaneousy. 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)

Phone

+98 25 3261 1141

Email address

psy.h.maleki@gmail.com

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 simultaneousy.

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

Ghoum

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.
City
sarpolezahab
Province
Kermanshah
Postal code
6771953163
Phone
+98 83 4223 0636
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
City
Ashtian
Province
Markazi
Postal code
3961813347
Phone
+98 86 3722 2500
Fax
+98 86 3722 2500
Email
aiau.ac@gmail.com
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
Street address
Iran-Qom Province- Boulevard Republic-Alley 42- Teachers Building 1- Unit 145
City
Qom
Province
Ghoum
Postal code
3716749994
Phone
+98 25 3261 1141
Email
psy.h.maleki@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Hossein Maleki
Position
A member of the Young Researchers Club of the Islamic Azad University of Ashtian
Latest degree
Bachelor
Other areas of specialty/work
Psychology
Street address
Iran - Qom - Republic Blvd - Teachers Building 1 - Unit 145
City
qom
Province
Ghoum
Postal code
371679994
Phone
+98 252611141
Email
psy.h.maleki@gmail.com

Person responsible for updating data

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
Street address
Iran - Qom - Republic Blvd - Teachers Building 1 - Unit 145
City
Qom
Province
Ghoum
Postal code
3716749994
Phone
+98 252611141
Fax
Email
psy.h.maleki@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
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