Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The Effectiveness of Eye Movement Desensitization and Reprocessing Therapy on Anxiety and Pain Levels Experienced by Hospitalized Children After Undergoing Surgery

Protocol summary

Study aim
Determining the Effect of Eye Movement Desensitization and Reprocessing on Hospitalized Children's Anxiety and Pain Levels

Design
Two-group clinical trial by random assignment.

Settings and conduct
This study will be conducted at The Imam Hussein Pediatric Hospital and at The Alzahra Medical Center for Children. The experimental group will undergo Eye Movement Desensitization and Reprocessing Therapy for one session, spanning in length from at least 30 to up to 60 minutes. Afterwards to evaluate the levels of anxiety and pain within the participants of the experimental group, Spielberg's State-Trait Anxiety Inventory and a basic numeric scale for pain will be administered. The control group will receive no special intervention other than being provided a training booklet. The control group will also be evaluated for pain and anxiety using a basic numeric scale for pain and Spielberg's State-Trait Anxiety Inventory. Measures for pain and anxiety will be recorded before intervention, immediately after the intervention and one hour post intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: being between the ages of 12 to 16 years, having experienced hospital admission and surgery for the first time, having mental health and alertness. Non-entry criteria: undergoing other pharmacological interventions, having a history of major psychiatric illnesses, being under severe stress, taking pain and anxiety-reducing medications.

Intervention groups
The experimental/intervention group will undergo Eye Movement Desensitization and Reprocessing therapy, the control group will not receive an intervention.

Main outcome variables
Pain and anxiety

General information

Reason for update

Acronym
EMDR

IRCT registration information
IRCT registration number: **IRCT20190925044880N1**
Registration date: **2020-05-08, 1399/02/19**
Registration timing: **retrospective**

Last update: **2020-05-08, 1399/02/19**
Update count: **0**

Registration date
2020-05-08, 1399/02/19

Registrant information

Name
Afarin Ghanavatpoor
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-12-22, 1398/10/01

Expected recruitment end date
2020-02-20, 1398/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The Effectiveness of Eye Movement Desensitization and Reprocessing Therapy on Anxiety and Pain Levels Experienced by Hospitalized Children After Undergoing Surgery

Public title
The Effectiveness of Eye Movement Desensitization and Reprocessing Therapy on Anxiety and Pain

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Being between the ages of 12 to 16 years old Experiencing hospital admission and surgery for the first time Being of sound mental health

Exclusion criteria:
No other non-pharmacological intervention to control pain and anxiety during research stages. The subjects have not undergone eye surgery, maxillofacial surgery, and neurosurgery. Absence of facial and facial nerves in a way that prevents eye movements. history of hyperactivity, depression, severe anxiety disorders, psychosis, and other major psychiatric illnesses- history of known chronic diseases such as disability, diabetes, heart disease, cancer Lack of speech abnormalities in a way that prevents the child from providing information and communication.- history of surgery Being under severe stress due to education, parental loss, divorce, etc taking anxiolytic and antidepressant drugs

Age
From **12 years** old to **16 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **56**

Randomization (investigator's opinion)
Randomized

Randomization description
For random allocation of the samples, participants names are written on paper cards and then put in a box. The names of participants are then randomly selected by the researcher. The first name drawn is assigned to the experimental group and the second name is assigned to the control group, and so on until all of the cards are selected. In this way, participants do not know whether they are in the experimental or control group.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Building No.4, Isfahan University of Medical Science, Hezarjirib Ave, Isfahan

City
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2019-09-22, 1398/06/31

Ethics committee reference number
IR.MUI.RESEARCH.REC.1398.372

Health conditions studied

1

Description of health condition studied
Children's Surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Anxiety

Timepoint
Before Surgury,Before intervention, immediately and then one hour later.

Method of measurement
Spielberger's State-Trait Anxiety

2

Description
Pain

Timepoint
Before intervention, immediately and then one hour later. In the control group

Method of measurement
and numerical pain rating scale

Secondary outcomes

empty

Intervention groups

1

Description

The Spielberger State-Trait Anxiety Inventory(STAI) is administered to subjects before and after surgery, in both the experimental and control groups. Along with the STAI used for anxiety measures, a numerical pain rating scale is utilized to evaluate levels of pain. In this experiment the patient will undergo EMDR therapy for one session, spanning from at least 30 minutes to up to 60 minutes. The patient will be asked to talk about his/her experiences with their illness and surgery; discussing their memories, worries and negative feelings related to these experiences. Subsequently, scores are obtained through two common methods of variable measurement associated with the practice of EDMR therapy. These methods include the Subjective Units of Disturbance (SUD) Scale, a numerical scale running from 1 through 10, commonly used in the practice of EDMR. The second mode of variable measurement is conducted through the Validity of Cognition (VOC) Scale, a numerical scale running from 1 through 7. These tests are administered to the patients via the researchers and the results are recorded. In the next phase of the experiment, the children are asked to imagine and describe somewhere they consider a safe place and that makes them feel most calm; this could include for example a beach, forest, their room, etc. The child is also asked to keep in mind his/her painful memories associated with all the unpleasant emotions regarding surgery and hospitalization that cause him or her distressing thoughts. At the same time, his/her eyes should be focused on the researcher's finger movements, this should result in them experiencing rapid eye movements synchronized with the movement of the researcher's finger. The treatment then switches focus to the child's positive beliefs and emotions, the child is encouraged through this therapy to replace their positive emotions with the negative beliefs they are harboring with them. This time, while visualizing and keeping the painful memory in mind, we ask the child to trust his/her positive beliefs, while simultaneously following the researcher's hand movements with his/her eyes. At the end of the treatment, we ask of the children to imagine themselves in that safe place they discussed at the beginning of the session. Following the completion of EDMR therapy, the VOC and SUD scores are once again recorded from the participants. The researchers then work with the children to navigate through their emotions, to relieve negative emotions they have been harboring, that are causing feelings of distress and helplessness. In addition, Spielberger Inventory and the numerical pain rating scale are also once again administered and recorded, both immediately after treatment and one-hour post-treatment.

Category

Treatment - Other

2

Description

Control group: In the control group the Spielberger State-Trait Anxiety Inventory(STAI) is initially administered to subjects at the beginning of the trial. The control group receives no intervention, other than being given a copy of the training booklet designed for them. The STAI is then administered and recorded two more times, the first and second hours post experiment.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hussein pediatric hospital

Full name of responsible person

Mehrdad Memarzadeh

Street address

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2

Recruitment center

Name of recruitment center

Alzahra Medical Cente

Full name of responsible person

Majid Rezvani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Web page address

Grant name

Grant code / Reference number

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

Title of funding source
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Afarin Ghanavatpoor

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available