Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

The effect of Eye Movement Desensitization and Reprocessing (EMDR) on pain intensity in cancer patients: a randomized controlled trial within a 2-month follow-up.

Protocol summary

Study aim
Effectiveness of eye movement desensitization and reprocessing (EMDR) on pain intensity in cancer patients

Design
Trial has a control and an intervention group with parallel group and unblinded

Settings and conduct
We want patients to visualize the worst picture of pain that is related to cancer and then follow the finger of researcher that is in front of patient face in 30 centimeter distance. Each move, going and getting back, lasts 1 sec. This is called one cycle. 12 to 24 cycles are called a collection. After any collection, we stop the procedure and want patient to take a deep breath. Then patients fill the questionnaires again. This procedure proceed according to the demand and motivation of each patient.

Participants/Inclusion and exclusion criteria
Patient with cancer disease according to diagnosis of doctor that at least pass over six months. Intermediate to severe pain according to pain scale Do not collaborate during the intervention Do not tolerate the route of EMDR

Intervention groups
Intervention: for each patient personally the route of EMDR will take place in 7 sessions. Before and after intervention both scales(SUD and Pain scales) will filled by patients.The number of patients in this group is 30. Control: In first session all of questionnaires will filled and then without any intervention questionnaires will filled again.The number of patients in this group is 30.

Main outcome variables
Pain intensity; Distress intensity

General information

Reason for update
Recorrect the title of study and minimum of patients age as a inclusion critria

Acronym

IRCT registration information
IRCT registration number: **IRCT20190822044581N1**
Registration date: **2019-09-21, 1398/06/30**
Registration timing: **prospective**

Last update: **2020-02-08, 1398/11/19**
Update count: **2**

Registration date
2019-09-21, 1398/06/30

Registrant information

Name
Naeem Abdi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 74 3222 3853

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-09-23, 1398/07/01

Expected recruitment end date
2019-11-22, 1398/09/01

Actual recruitment start date
2019-09-23, 1398/07/01

Actual recruitment end date
2019-12-06, 1398/09/15

Trial completion date
2020-02-04, 1398/11/15

Scientific title
The effect of Eye Movement Desensitization and Reprocessing (EMDR) on pain intensity in cancer patients: a randomized controlled trial within a 2-month follow-up.

Public title
The effect of Eye Movement Desensitization and Reprocessing (EMDR) on pain intensity in cancer patients: a randomized controlled trial within a 2-month follow-up

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Patient with cancer disease according to diagnosis of doctor that at least pass over six months. Stabilization of hemodynamic condition Do not use of relaxation drugs Intermediate to severe pain according to pain scale Consciousness and trainable literacy Have not any visual disorders Do not use of narcotics Do not have any systemic disorders Age of patients is between 30-60

Exclusion criteria:
Do not collaborate during the intervention Do not tolerate the route of EMDR

Age
From **30 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**
Actual sample size reached: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Samples will be allocated randomly by block assignment between the two groups.considering the highest sample size needed for each of the study groups and a possible attrition of 20%, a total of 60 people was estimated as the sample size with 30 people for each group. During random block assignment, the order of the participants in the intervention and control groups was determined as follows: By multiplying the number of study groups (two groups) by 2, the number of samples per block was calculated as 4; then, by calculating the factorial of each block sample size (4!=4×3×2×1=24), the number of blocks generated from all possible orders was obtained as 24; since the number of people in each block was 4 and the estimated sample size was 60 based on the following description, by matching 13 random numbers generated by Sample Randomizer with the mentioned block numbers, the order of 60 research subjects was determined, numbers one to sixty were allocated to the subject and control groups, and the random allocation list was edited.

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 Yasuj University of Medical Sciences.

Street address
Alley.4, East Modaress Ave, Gachsaran town.

City
Yasuj

Province
Kohgilouyeh-va-Boyrahmad

Postal code
7581698999

Approval date
2019-08-14, 1398/05/23

Ethics committee reference number
IR.YUMS.REC.1398.074

Health conditions studied

1

Description of health condition studied
Investigation the pain severity in patients with cancer

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Pain intensity according to pain scale

Timepoint
Evaluation before the intervention and immediately after intervention and follow-up two months after the end of the intervention

Method of measurement
Pain intensity scale

2

Description
Distress intensity according to Subjective units of Distress

Timepoint
Evaluation before the intervention and immediately after intervention and follow-up two months after the end of the intervention

Method of measurement
Subjective Units of Distress (SUD)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:The number of patients in this group is 30.Intervention: for each patient personally the route of EMDR took place in 7 sessions. Before and after intervention both scales(SUD,PAIN SCALE) were filled by patients. After two months of follow-up, the above measures will be completed by the patients again
Category
Treatment - Other

2

Description
Control group: In first session all of questionnaires(demographic, sud and pain scale) filled and then without any intervention questionnaires were filled by patients again. The control group received no intervention from the beginning of the intervention until the end of the follow-up and received only routine care. In the first session, the demographic characteristics questionnaire, pain rating scale and mental distress scale will be completed in the first session, then the questionnaires will be completed two months later without any intervention.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Jalil hospital of Yasuj city
Full name of responsible person
Naeem Abdi
Street address
Bagherhkan Ave. Yasuj
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Mohammad Malekzadeh
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Montazeri Street, Yasuj
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yasouj 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
Yasouj University of Medical Sciences
Full name of responsible person
Naeem Abdi
Position
Faculty member
Latest degree
Master
Other areas of specialty/work
Nursery
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Person responsible for scientific inquiries

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Position

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available