

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jul 2026

### The effect of Eye Movement Desensitization and Reprocessing (EMDR) on kinesiophobia and ADL in elderly with musculoskeletal pain referring to outpatient clinic in Rafsanjan city in 2023.

#### Protocol summary

##### Study aim

Determining the effect of desensitization through eye movements and reprocessing on movement phobia (kinesiophobia) and performing daily activities in the elderly with musculoskeletal pain.

##### Design

44 eligible elderly people will be divided into two equal groups by simple randomization method and the intervention will be done on one of the groups based on random selection.

##### Settings and conduct

In the elderly have a kinesiophobia with musculoskeletal pain referring to the outpatient clinic of Dr. Abbasi in Rafsanjan, the EMDR intervention group is performed by the researcher individually.

##### Participants/Inclusion and exclusion criteria

Entry requirements include: being over 60 years old. Not having severe hearing and vision problems. Obtaining a score higher than 18 from the TSK questionnaire. No addiction and use of neuropsychiatric drugs. Having musculoskeletal pain for 6 months. Obtain informed consent. Not having diseases like Parkinson's and Korea. No bereavement and acute mental problems in the last 6 months. Exit criteria include: unwillingness to continue cooperation. Conducting other psychotherapeutic interventions such as CBT on kinesiophobia. The use of psychotherapeutic drugs is effective against kinesiophobia (such as antidepressants and anti-anxiety drugs).

##### Intervention groups

First, the participants will complete the questionnaires of fear of movement and daily activities of life, for the intervention group EMDR sessions will be conducted individually for 8 weeks and 3 sessions of 45 to 60 minutes each week (up to a maximum of 90 minutes) by the researcher for each elderly person. and there will be no intervention for the control group. Then, at the end

and one month after the end of the intervention, the aforementioned questionnaires will be completed again by the participants.

##### Main outcome variables

kinesiophobia, Activities of Daily Living

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150519022320N31**

Registration date: **2023-08-09, 1402/05/18**

Registration timing: **prospective**

Last update: **2023-08-09, 1402/05/18**

Update count: **0**

##### Registration date

2023-08-09, 1402/05/18

##### Registrant information

##### Name

Tayebeh Mirzaei

##### Name of organization / entity

Rafsanjan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3425 5900

##### Email address

t.mirzaei@rums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-09-22, 1402/06/31

##### Expected recruitment end date

|                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2023-10-22, 1402/07/30                                                                                                                                                                                                                                                                                                                                                                                                                                  | Not used                                                                                                                                                         |
| <b>Actual recruitment start date</b>                                                                                                                                                                                                                                                                                                                                                                                                                    | <b>Assignment</b>                                                                                                                                                |
| empty                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Parallel                                                                                                                                                         |
| <b>Actual recruitment end date</b>                                                                                                                                                                                                                                                                                                                                                                                                                      | <b>Other design features</b>                                                                                                                                     |
| empty                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                  |
| <b>Trial completion date</b>                                                                                                                                                                                                                                                                                                                                                                                                                            | <b>Secondary Ids</b>                                                                                                                                             |
| empty                                                                                                                                                                                                                                                                                                                                                                                                                                                   | empty                                                                                                                                                            |
| <b>Scientific title</b>                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>Ethics committees</b>                                                                                                                                         |
| The effect of Eye Movement Desensitization and Reprocessing (EMDR) on kinesiophobia and ADL in elderly with musculoskeletal pain referring to outpatient clinic in Rafsanjan city in 2023.                                                                                                                                                                                                                                                              | <b>1</b>                                                                                                                                                         |
| <b>Public title</b>                                                                                                                                                                                                                                                                                                                                                                                                                                     | <b>Ethics committee</b>                                                                                                                                          |
| The effect of Eye Movement Desensitization and Reprocessing (EMDR) on kinesiophobia and ADL in elderly with musculoskeletal pain referring to outpatient clinic in Rafsanjan city in 2023.                                                                                                                                                                                                                                                              | <b>Name of ethics committee</b>                                                                                                                                  |
| <b>Purpose</b>                                                                                                                                                                                                                                                                                                                                                                                                                                          | Research Ethics Committee of Rafsanjan University of Medical Sciences                                                                                            |
| Supportive                                                                                                                                                                                                                                                                                                                                                                                                                                              | <b>Street address</b>                                                                                                                                            |
| <b>Inclusion/Exclusion criteria</b>                                                                                                                                                                                                                                                                                                                                                                                                                     | School of Nursing and Midwifery, Nurse avenue, Rafsanjan                                                                                                         |
| <b>Inclusion criteria:</b>                                                                                                                                                                                                                                                                                                                                                                                                                              | <b>City</b>                                                                                                                                                      |
| Being over 60 years old Not having severe hearing and vision problems Obtaining a score higher than 18 from the TSK questionnaire No addiction and use of neuropsychiatric drugs Having musculoskeletal pain for 6 months Obtain informed consent Not having diseases like Parkinson's and Korea No bereavement and acute mental problems in the last 6 months                                                                                          | Rafsanjan                                                                                                                                                        |
| <b>Exclusion criteria:</b>                                                                                                                                                                                                                                                                                                                                                                                                                              | <b>Province</b>                                                                                                                                                  |
| Lack of informed consent Non-cooperation based on the programs taught Taking psychotherapeutic drugs effective on kinesiophobia (such as antidepressants and anti-anxiety drugs) Conducting other psychotherapeutic interventions such as CBT on kinesiophobia                                                                                                                                                                                          | Kerman                                                                                                                                                           |
| <b>Age</b>                                                                                                                                                                                                                                                                                                                                                                                                                                              | <b>Postal code</b>                                                                                                                                               |
| From <b>60 years</b> old to <b>75 years</b> old                                                                                                                                                                                                                                                                                                                                                                                                         | 7718796755                                                                                                                                                       |
| <b>Gender</b>                                                                                                                                                                                                                                                                                                                                                                                                                                           | <b>Approval date</b>                                                                                                                                             |
| Both                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 2023-08-07, 1402/05/16                                                                                                                                           |
| <b>Phase</b>                                                                                                                                                                                                                                                                                                                                                                                                                                            | <b>Ethics committee reference number</b>                                                                                                                         |
| N/A                                                                                                                                                                                                                                                                                                                                                                                                                                                     | IR.RUMS.REC.1402.063                                                                                                                                             |
| <b>Groups that have been masked</b>                                                                                                                                                                                                                                                                                                                                                                                                                     | <b>Health conditions studied</b>                                                                                                                                 |
| No information                                                                                                                                                                                                                                                                                                                                                                                                                                          | <b>1</b>                                                                                                                                                         |
| <b>Sample size</b>                                                                                                                                                                                                                                                                                                                                                                                                                                      | <b>Description of health condition studied</b>                                                                                                                   |
| Target sample size: <b>44</b>                                                                                                                                                                                                                                                                                                                                                                                                                           | kinesiophobia                                                                                                                                                    |
| <b>Randomization (investigator's opinion)</b>                                                                                                                                                                                                                                                                                                                                                                                                           | <b>ICD-10 code</b>                                                                                                                                               |
| Randomized                                                                                                                                                                                                                                                                                                                                                                                                                                              | <b>ICD-10 code description</b>                                                                                                                                   |
| <b>Randomization description</b>                                                                                                                                                                                                                                                                                                                                                                                                                        | <b>2</b>                                                                                                                                                         |
| After identifying the elderly who meet the inclusion criteria and listing them, they will be divided into 2 groups of 22 people, the intervention group and the control group, using a simple random division method using a random number table. People will be divided into two groups based on the random number table. 22 people A and B will be divided and finally two groups A and B will be placed in test and control groups based on lottery. | <b>Description of health condition studied</b>                                                                                                                   |
| <b>Blinding (investigator's opinion)</b>                                                                                                                                                                                                                                                                                                                                                                                                                | Activities of Daily Living                                                                                                                                       |
| Not blinded                                                                                                                                                                                                                                                                                                                                                                                                                                             | <b>ICD-10 code</b>                                                                                                                                               |
| <b>Blinding description</b>                                                                                                                                                                                                                                                                                                                                                                                                                             | <b>ICD-10 code description</b>                                                                                                                                   |
| <b>Placebo</b>                                                                                                                                                                                                                                                                                                                                                                                                                                          | <b>Primary outcomes</b>                                                                                                                                          |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>1</b>                                                                                                                                                         |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>Description</b>                                                                                                                                               |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Kinesiophobia of the elderly with musculoskeletal pain                                                                                                           |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>Timepoint</b>                                                                                                                                                 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                         | All participants will complete the Tampa Fear of Movement Questionnaire (TSK) before and after the intervention and one month after the end of the intervention. |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>Method of measurement</b>                                                                                                                                     |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Fear of Movement Tampa Questionnaire (TSK)                                                                                                                       |

## 2

### Description

Activities of Daily Living in the elderly with musculoskeletal pain

### Timepoint

All participants will complete ADL and IADL questionnaires before and after the intervention and one month after the end of the intervention.

### Method of measurement

ADL and IADL questionnaires

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

The researcher will start the work after stating the goals and method of the study and obtaining the consent of the people to participate in the study. Participants will complete questionnaires of fear of movement and activities of daily living, for the eye movement desensitization and reprocessing (EMDR) intervention group in eight steps; (1. history taking and treatment design 2. preparation 3. examination and evaluation 4. desensitization 5. operation 6. physical examination 7. termination or closure 8. re-evaluation) is done. EMDR sessions will be conducted individually and face-to-face for 8 weeks and 3 sessions of 45 to 60 minutes each week (up to a maximum of 90 minutes) by the researcher (the first session by the therapist and under his supervision) for each elderly person. In this intervention, the patient creates scenes of fear of movement in his mind, and during EMDR movements, he follows the researcher's finger with eye movements to finally get rid of the confusion caused by movement phobia. Each finger movement takes approximately one to two seconds. Each finger movement cycle is 20 seconds or more. Then, at the end and one month after the end of the intervention, the aforementioned questionnaires will be completed again by the participants.

### Category

Treatment - Other

## 2

### Description

Control group: During the study period, there will be no intervention in the control group and the questionnaires will be completed by the participants.

### Category

Other

## Recruitment centers

## 1

### Recruitment center

### Name of recruitment center

Outpatient rheumatology clinic of Rafsanjan city

### Full name of responsible person

Dr. Ali Ravari

### Street address

Faculty of Nursing, Nurse Blvd., Jomhury street, Rafsanjan

### City

Rafsanjan

### Province

Kerman

### Postal code

7718174715

### Phone

+98 34 3428 0038

### Email

ravary4776@yahoo.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Rafsanjan University of Medical Sciences

#### Full name of responsible person

Dr.Reza Vazirinejad

#### Street address

Emam Ali Blvd

#### City

Rafsanjan

#### Province

Kerman

#### Postal code

7718174715

#### Phone

+98 34 3131 5075

#### Email

rvazirinejad@yahoo.com

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Rafsanjan 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

Rafsanjan University of Medical Sciences

**Full name of responsible person**

Dr. Ali Ravari

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Faculty of Nursing, Nurse Blvd., Jomhury street,  
Rafsanjan

**City**

Rafsanjan

**Province**

Kerman

**Postal code**

7718174715

**Phone**

+98 34 3428 0038

**Email**

ravary4776@yahoo.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Rafsanjan University of Medical Sciences

**Full name of responsible person**

Dr. Ali Ravari

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Faculty of Nursing, Nurse Blvd., Jomhury street,  
Rafsanjan

**City**

Rafsanjan

**Province**

Kerman

**Postal code**

7718174715

**Phone**

+98 34 3428 0038

**Email**

ravary4776@yahoo.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Rafsanjan University of Medical Sciences

**Full name of responsible person**

Dr. Ali Ravari

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Faculty of Nursing, Nurse Blvd., Jomhury street,  
Rafsanjan

**City**

Rafsanjan

**Province**

Kerman

**Postal code**

7718174715

**Phone**

+98 34 3428 0038

**Email**

ravary4776@yahoo.com

**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