# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

19 Sep 2026

## Investigating the effect of eye sensitization and re-processing on anxiety of primary dysmenorrhea

## Protocol summary

**Study aim**
Investigating the effect of eye movement desensitization and reprocessing therapy on Anxiety of primary dysmenorrhea

**Design**
Randomized controlled clinical trial with parallel control group

**Settings and conduct**
The research will be carried out in the girls' dormitory of Qazvin University of Medical Sciences. eligible individuals will be assigned randomly for intervention and control group. Eye movement desensitization and reprocessing therapy will be performed for intervention group. control group would not receive any intervention. Due to the nature of the study, blinding is not possible. Anxiety of dysmenorrhea will be assessed 1 and 2 months before intervention and 1 and 2 months after intervention for both groups.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: the presence of moderate to severe dysmenorrhea in most menstrual cycles, being bachelor, the fertility age (18-45 years), residence in the dormitories of Qazvin University of Medical Sciences, and willingness to participate in the study. Exclusion criteria are secondary dysmenorrhea and its underlying causes including the history of endometriosis, adenomyosis, sub-acute endometritis, pelvic inflammatory diseases, copper intrauterine devices, ovarian cysts, congenital anomalies of the pelvis and cervix, history of known psychological illnesses, addiction to drugs, history of seizure, having strabismus and vision problems, history of pelvic or abdominal surgery, cardiovascular and pulmonary respiratory disease, and the graduation during the follow-up period.

**Intervention groups**
Intervention group: eye movement desensitization and reprocessing therapy will be implemented through 6 sessions, which will be held twice a week. The duration of the treatment sessions is 30 to 90 minutes. Control group: no intervention will be implemented.

**Main outcome variables**
Anxiety of primary dysmenorrhea

## General information

**Reason for update**

**Acronym**
EMDR

**IRCT registration information**
IRCT registration number: **IRCT20180823040851N2**
Registration date: **2019-02-09, 1397/11/20**
Registration timing: **registered_while_recruiting**

Last update: **2019-02-09, 1397/11/20**
Update count: **0**

**Registration date**
2019-02-09, 1397/11/20

**Registrant information**

**Name**
Sahar Valedi

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 28 3377 0328

**Email address**
s.valedi@qums.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2019-02-03, 1397/11/14

**Expected recruitment end date**
2019-05-04, 1398/02/14

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Investigating the effect of eye sensitization and re-processing on anxiety of primary dysmenorrhea

**Public title**
Investigating the effect of eye sensitization and re-processing on anxiety of primary dysmenorrhea
**Purpose**
Supportive
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Moderate to severe primary dysmenorrhea (score above 4 on the pain ruler) Single At the age of fertility (18 to 45 years) Resident of Qazvin University of Medical Sciences The desire to participate in the study
**Exclusion criteria:**
The presence of secondary dysmenorrhea and its underlying causes, such as the history of endometriosis, adenomyosis, subacute endometritis, pelvic inflammatory disease, copper intrauterine devices, ovarian cysts, congenital pelvic abnormality and cervical spine. History of known mental illnesses Drug addiction History of seizure History of pelvic or abdominal surgery The probability of graduation during the follow-up period Cardiovascular and pulmonary respiratory disease
**Age**
From **18 years** old to **45 years** old
**Gender**
Female

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **88**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Will be made available first. Referring to the University of Medical Sciences girls' dormitory, eligible people will be willing to participate in the enrollment study. Then random allocation of participants in the two groups will be done by simple random blocking method with 4 blocks. Block randomization method is that the assignment sequence is written before the beginning of the research. Given that the two groups will be studied, four blocks will be used and each letter will be assigned to one group (A: intervention group by EMDR method: B control group). All possible modes for the 4th block are written and numbered, such as: 1.AABB 2.ABAB 3.BBAA 4.BABA 5.ABBA 6.BAAB 7.---- Then, by random method (using a random number table), the number of blocks is selected by number of numbers and by writing the contents of the blocks for those numbers (as long as the sample size is determined) Sequence of random allocation is determined. For example, if the numbers obtained are 3,2,2,1 and ..., the assignment sequence will be as follows: AABB ABAB ABAB BBAA Then, inside the envelopes in the matte packet, the type of intervention is written based on the assignment sequence and encoded on the envelope. In this case, a questionnaire with the same code will be completed for the person receiving the code 1 intervention. Due to the nature of the study, there is no possibility of blindness.
**Blinding (investigator's opinion)**
Not blinded
**Blinding description**
**Placebo**
Not used
**Assignment**
Other
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics Committee of Qazvin University of Medical Sciences
**Street address**
Qazvin university of Medical Sciences, Shahid Bahonar Boulevard, Qazvin, Iran
**City**
Qazvin
**Province**
Qazvin
**Postal code**
3419759811
**Approval date**
2018-11-02, 1397/08/11
**Ethics committee reference number**
۱۴۰۰۳۴۳۷

## Health conditions studied

### 1

**Description of health condition studied**
Primary dysmenorrhea
**ICD-10 code**
N94.4
**ICD-10 code description**
Primary dysmenorrhea

## Primary outcomes

### 1

**Description**
Anxiety of Primary dysmenorrhea
**Timepoint**
Before intervention, after intervention and two months after intervention

**Method of measurement**
Adjunctive Anxiety Inventory-Spielberge State, Scale of anxiety or mental discomfort units, Validity Scale or Test of Semantic Difference in Cognition

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: The intervention group will receive eye movement desensitization and reprocessing therapy for 6 therapeutic session, twice a week. The duration of the treatment sessions is 30 to 90 minutes.
**Category**
Treatment - Other

### 2

**Description**
Control group: no intervention will be implemented.
**Category**
N/A

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
girls' campus of Qazvin university of Medical Sciences
**Full name of responsible person**
Sahar Valedi
**Street address**
School of Nursing & Midwifery, Qazvin university of Medical Science,، SHahid Bahonar boulevard, Qazvin, Iran
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Qazvin University of Medical Sciences
**Full name of responsible person**
Dr peymani
**Street address**
Research vice chancellor of Qazvin university of Medical Sciences, Valie Asr Street, Qazvin, Iran
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research.dpt@qums.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Qazvin 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**
Qazvin University of Medical Sciences
**Full name of responsible person**
sahar valedi
**Position**
MSc. student
**Latest degree**
Bachelor
**Other areas of specialty/work**
Midwifery
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## Person responsible for scientific inquiries

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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**
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**
Not applicable
**Title and more details about the data/document**
Data set and questionniares
**When the data will become available and for how long**
After publishing the results
**To whom data/document is available**
According to request it will be available
**Under which criteria data/document could be used**
All researchers in this field
**From where data/document is obtainable**
The supplementary file will be published at the time of publication
**What processes are involved for a request to access data/document**
Email to corresponding author
**Comments**