Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Aug 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)

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+98 28 3377 0328

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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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s.valedi@qums.ac.ir

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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3419759811
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+98 28 3333 6003
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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 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