Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Nov 2026

Investigating the effect of eye movement desensitization and reprocessing (EMDR) on pain intensity of primary dysmenorrhea

Protocol summary

Study aim
Investigating the effect of eye movement desensitization and reprocessing therapy on pain intensity 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. Pain intensity 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
Pain intensity of primary dysmenorrhea

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180823040851N1**
Registration date: **2018-10-06, 1397/07/14**
Registration timing: **prospective**

Last update: **2018-10-06, 1397/07/14**
Update count: **0**

Registration date
2018-10-06, 1397/07/14

Registrant information

Name
Sahar Valedi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 28 3377 0328

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s.valedi@qums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-10-23, 1397/08/01

Expected recruitment end date
2019-03-21, 1398/01/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of eye movement desensitization and reprocessing (EMDR) on pain intensity of primary dysmenorrhea

Public title

EMDR & Primary dysmenorrhea

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Moderate to severe primary dysmenorrhea Single Reproductive age (18 to 45 years) Resident of dormitory 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, sub acute endometriosis, pelvic inflammatory disease, copper intrauterine devices, ovarian cysts, congenital pelvic abnormality and cervical stenosis The history of known mental illnesses Drug Addiction History of seizure Strabismus and vision problems 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

Sampling will be done through a convenience method. The researcher will refer to the dormitories of Qazvin University of Medical Sciences, and eligible people will be enrolled to the study. A random allocation of the participants into two groups will be done by the simple random blocking method with 4 blocks. In the block randomization method, the assignment sequence will be 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: EMDR group; B: control group). All possible modes for the 4 blocks will be written and numbered as fillows: 1.AABB 2.ABAB 3.BBAA 4.BABA 5.ABBA 6.BAAB Next, using a simple random method and the table of random numbers, a number of blocks will be selected from the blocks of numbers, and by writing the contents of the blocks for those numbers (as long as the sample size is determined), the sequence of random allocation is determined. For example, if the numbers obtained are 1,2,2,3 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 in 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

Parallel

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

2018-08-16, 1397/05/25

Ethics committee reference number

IR.QUMS.REC.1397.100

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

Pain intensity of primary dysmenorrhea

Timepoint

1 and 2 months before intervention & 1 and 2 months

after intervention

Method of measurement

Visual Analogue Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

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

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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

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Research vice chancellor of Qazvin university of Medical Sciences, Valie Asr Street, Qazvin, Iran

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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

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

Master

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