Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

The effect of distraction techniques on the physical and mood symptoms of premenstrual syndrome (PMS)

Protocol summary

Study aim
The effect of distraction technique on physical and mood symptoms of premenstrual syndrome (PMS)

Design
Randomized controlled clinical trial with parallel groups

Settings and conduct
The research population includes young women and girls of reproductive age and age range of 14-35 years who referred to health centers in Isfahan city in 1401. People will be randomly divided into two intervention and control groups. Distraction technique training for the intervention group is held in 4 sessions of 45 minutes each week. and PMS symptoms are recorded daily by the participant using a PMS tool. After the training, the questionnaires are filled again by the participants.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Women and girls in reproductive age and age range (14-35) Obtaining the necessary points (17 to 33) using the PMS tool Absence and intolerance to Gelofen Exclusion criteria: Reluctance to continue Pregnancy during the study The presence of ovarian disorders (due to abnormal menstruation and resulting mood disorders)

Intervention groups
Intervention group: teaching different distraction techniques and their effectiveness, which includes watching TV, listening to music, writing about their favorite topic, counting numbers .For the control group, routine care includes providing information about how premenstrual syndrome occurs and how to deal with it according to previous studies.

Main outcome variables
Physical and mood symptoms of premenstrual syndrome

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20151211025477N5**
Registration date: **2022-12-11, 1401/09/20**
Registration timing: **prospective**

Last update: **2022-12-11, 1401/09/20**
Update count: **0**

Registration date
2022-12-11, 1401/09/20

Registrant information

Name
Elahe Ahmadnia

Name of organization / entity
Social determinants of health center

Country
Iran (Islamic Republic of)

Phone
+98 24 3344 9192

Email address
ahmad@zums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-16, 1401/09/25

Expected recruitment end date
2023-03-20, 1401/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of distraction techniques on the physical and mood symptoms of premenstrual syndrome (PMS)

Public title

The effect of distraction techniques on premenstrual syndrome

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Women and girls in the age range of 14-35 At least six months have passed since their menarche not taking medicine for reduce PMS symptoms not participating in the same classes have minimum reading and writing literacy Absence of pregnancy obtaining score 17-33 using the PMS tool Absence to physical and mental illness as known Absence sensitivity to Gelophen

Exclusion criteria:

Unwillingness to continue study participation Pregnancy during the study The presence of ovarian disorders (due to irregular menstruation and mood disorders caused by it)

Age

From **14 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

The sample selection method will be easy and available among fertile women and girls, and then the participants will be divided into two intervention and control groups using the random block method. Four-dimensional blocks will be created, and in each block, half of the participants will be in the intervention group and the other half will be in the control group. Selection of blocks will continue to achieve the sample size (21 in the intervention group and 21 in the control group). Eleven blocks will be selected based on the table of random numbers and grouped according to the modes determined in the previous step.

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

The ethics committee of Zanjan University of Medical Sciences

Street address

The ethics committee of Zanjan University of Medical Sciences, First floor, Northside Azadi, Zanjan

City

Zanjan

Province

Zanjan

Postal code

4515613113

Approval date

2022-10-11, 1401/07/19

Ethics committee reference number

IR.ZUMS.REC.1401.208

Health conditions studied

1

Description of health condition studied

Premenstrual syndrome

ICD-10 code

N94.3

ICD-10 code description

Premenstrual tension syndrome

Primary outcomes

1

Description

the physical symptoms of premenstrual syndrome

Timepoint

Before the intervention, 3 months after the intervention

Method of measurement

Premenstrual Symptoms Tool (Rossignol & Bonlander)

Secondary outcomes

1

Description

Mood symptoms of premenstrual syndrome

Timepoint

Before the intervention three months after the last counseling

Method of measurement

Premenstrual Symptoms Tool (Rossignol & Bonlander)

Intervention groups

1

Description

Intervention group: Distraction techniques are taught in 4 items including watching movies, listening to music, visualizing about a topic of interest, and counting down numbers to reduce temporary physical and emotional premenstrual symptoms. The trainings are 4 sessions and each session is 45 minutes, which is held weekly.

The intervention group will start their training sessions from the fifth to the seventh day of the menstruation and the effects of the intervention will be evaluated three months later.

Category

Lifestyle

2

Description

Control group: The control group will receive training in the field of menstrual process and occurrence and intensity of pain and control of PMS symptoms through laboratory methods in previous studies such as caffeine-limited diet and daily activity.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Health Center No. 2

Full name of responsible person

Behzad heydarian

Street address

Isfahan, Faiz Street, Sheikh Mofid Crossroad Corner, Isfahan Health Center No. 2

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Isfehan

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81649-69459

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beh2-farhangi@phc.mui.ac.ir

2

Recruitment center

Name of recruitment center

Isfahan health center number one

Full name of responsible person

Mohammad hasan baradaran esfahani

Street address

Isfahan, Faiz street, corner of Sheikh Mofid intersection, Isfahan health center number one

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Samad Nadri

Street address

Chancellor for Research and Technology of Zanjan University of Medical Sciences, First floor, Northside Boulevard Azadi, zanjan

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Grant name

Thesis

Grant code / Reference number

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

Yes

Title of funding source

Zanjan University of Medical Sciences

Proportion provided by this source

10

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

Zanjan University of Medical Sciences

Full name of responsible person

Shima movaffagh

Position

Msc student of counseling in midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Zanjan University of Medical Sciences

Full name of responsible person
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Ph.D of Reproductive Health

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Person responsible for updating data

Contact

Name of organization / entity
Zanjan University of Medical Sciences

Full name of responsible person
Shima movaffagh

Position
Msc student of counseling in midwifery

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
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Province
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Phone
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Email
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is 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
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
After completion of the study, information on the main outcome will be shared

When the data will become available and for how long
Starting the access period from 2023-2024

To whom data/document is available
Data and documentation will be available to medical researchers

Under which criteria data/document could be used
The data can be used to study, give a citation, create new ideas, and practically apply in medical centers.

From where data/document is obtainable
Email to: shimasalt69@gmail.com

What processes are involved for a request to access data/document
The data will be provided to the applicant within one month after reviewing and confirming the request.

Comments