

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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 Gelofo 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 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

City

Esfahan

Province

Isfahan

Postal code

81649-69459

Phone

+98 31 3661 7371

Email

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

City

Esfahan

Province

Isfahan

Postal code

81649-69358

Phone

+98 31 3661 8234

Email

isfahani20@gmail.com

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

City

Zanjan

Province

Zanjan

Postal code

4515613191

Phone

+98 24 3314 8300

Fax

+98 24 3314 8300

Email

shoghli@zums.ac.ir

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

Kaveh Street, Aburihan Street, East Madi Shahpasand, Unit 13, Marvarid Building

City

Esfahan
Province
Isfahan
Postal code
8193754485
Phone
+98 31 3458 1561
Email
shimasalt69@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
DR elahe ahmadnia
Position
Ph.D of Reproductive Health
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Zanjan University of Medical Sciences, Gavazang Road
City
Zanjan
Province
Zanjan
Postal code
4515613191
Phone
+98 24 3314 8300
Email
ahmad@zums.ac.ir

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
Kaveh Street, Aburihan Street, East Madi Shahpasand, Unit 13, Marvarid Building
City
Esfahan
Province
Isfahan
Postal code
8193754485
Phone
+98 31 3458 1561
Email
shimasalt69@gmail.com

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