

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Compare the effect of acupressure therapy and Fluoxetine on the symptoms of premenstrual syndrome: A randomized clinical trial

Protocol summary

Study aim

Comparison of the effect of acupressure and fluoxetine on physical and psychological symptoms of premenstrual syndrome

Design

Randomized controlled clinical trial, with parallel group

Settings and conduct

Research population: All female students of Islamic Azad University of Qazvin who have entered the study. For the first diagnosis of syndrome from set temporary premenstrual syndrome used. Beck Depression Inventory is provided to affected people, and depressed people are excluded from the study based on the score. Then, for the definitive diagnosis, the selected individuals are asked to complete the DRSP for 2 cycles. Subjects were then randomly divided into two groups of intervention (acupressure and fluoxetine) and control group. The acupressure group receives acupressure for 18 consecutive sessions in three cycles. And the fluoxetine group received 10 mg of fluoxetine in the luteal phase every 12 hours in three successive cycles. The subjects are asked to complete the DRSP during the intervention and again three months after the end of the intervention.

Participants/Inclusion and exclusion criteria

Entry requirements: Regular menstruation, normalization of bleeding length and volume, range from 18 to 35 years Having normal body mass, having symptoms of premenstrual syndrome in two cycles before intervention

Intervention groups

Acupressure group: Acupressure is given by using aTENS machine for 15 minutes in the second half of the menstrual cycle for 12 days in a one-day interval, namely 6 sessions in three consecutive cycles. Fluoxetine group: In the luteal phase, fluoxetine capsules receive 10 mg every 12 hours Control group: There is no intervention and only they will be asked to complete the sixth month of the DRSP questionnaire every month until the third month and again.

Main outcome variables

Physical and psychosomatic symptoms of premenstrual syndrome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190430043433N1**

Registration date: **2019-05-11, 1398/02/21**

Registration timing: **prospective**

Last update: **2019-05-20, 1398/02/30**

Update count: **1**

Registration date

2019-05-11, 1398/02/21

Registrant information

Name

Zeinab Zarabadipour

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare the effect of acupressure therapy and Fluoxetine on the symptoms of premenstrual syndrome: A randomized clinical trial

Public title

Acupressure therapy in premenstrual syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The desire to participate in the study Regular menstruation from 24 to 35 days The normalization of the length and volume of menstrual bleeding is 3-10 days Age range 18 to 35 years Having a Body Mass (25 -5/18) . Having symptoms of premenstrual syndrome in two cycles before starting the intervention Non-Depression Based on the Beck Questionnaire Having a phone number to follow

Exclusion criteria:

Having known psychological illnesses (according to the person) Use of any drug for the treatment of premenstrual syndrome Tobacco use, narcotics and psychotropic drugs (according to the person) Having regular exercise Use of antidepressants, sedation and hormones and vitamin supplements There are skin lesions in acupressure points A stressful incident in the past six months, such as: separation of parents, death of first-degree family members, and Use of any drug that has fluoxetine interactions

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling takes place in two stages: the first stage, the selection of eligible samples is available and the second stage of random allocation will be divided into three groups by blocking method. For placement of the samples in three groups (two intervention and one control group) using the PSSA software, a randomly blocked block size of 6, 12 and 12 with a 1: 1: 1 ratio is used

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

Dept of research Qazvin University of Medical Sciences Shahid Beheshti, Ave' 3415613911 Qazvin' IRAN

City

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13911/34156

Approval date

2019-04-29, 1398/02/09

Ethics committee reference number

IR.QUMS.REC.1398.014

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**

Physical symptoms of premenstrual syndrome

Timepoint

Two months before the intervention, during the intervention, three months after the end of the intervention

Method of measurement

Daily Record of Severity of Problems chart

2**Description**

Psychosomatic symptoms of premenstrual syndrome

Timepoint

Two months before the intervention, during the intervention, three months after the end of the intervention

Method of measurement

Daily Record of Severity of Problems chart

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group: received acupuncture completely free of charge for 15 minutes in the second half of the menstrual cycle for 12 days in a one day interval, namely 6 sessions in three consecutive cycles. Acupuncture by a researcher at points LIV3, SP9, LI 11, LI 4 is performed using a TENS with a pulse width of 4-200 Hz. Each session will be used as one side of the limb of one side (left or right)

Category

Treatment - Other

2

Description

The second intervention group: the fluoxetine group. Firstly, the necessary training will be given to fluoxetine and the possible side effects of the onset of the drug, and in the event of a problem, the physician will be provided with the samples. Samples are taken for three consecutive cycles every 12 hours under the supervision of a specialist physician to reduce the complications in the luteal phase. 10 mg of fluoxetine capsule (Sobhan Pharmaceutical Company)

Category

Treatment - Drugs

3

Description

Control group: There is no intervention and only they will be asked to complete the sixth month of the DRSP questionnaire every month until the third month and again. Calling will be made every month to remind the samples. To follow ethical principles after the completion of the research, a training session on the treatment of premenstrual syndrome and an acupuncture session will be conducted in accordance with the study protocol for applicants.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad University of Qazvin

Full name of responsible person

Zeinab Zarabadipour

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

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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

Zeinab Zarabadipour

Position

Master student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available