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

Country
Iran (Islamic Republic of)

Phone
+98 28 3335 3695

Email address
z.zarabadipour@qums.ac.ir

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
Qazvin

Province
Qazvin

Postal code
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
Premenstural 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
IThe first intervention group: received acupressure 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. Acupressure 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
he 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 acupressure 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
Street address
Qazvin University of Medical Sciences. Bahonar Blvd
City
Qazvin
Province
Qazvin
Postal code
15315-34199
Phone
+98 28 3333 8034
Email
z.zarabadipour@qums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Dr. Amir Peymani
Street address
Qazvin University of Medical Sciences,Deputy Minister for Research and Technology, Shahid Beheshti Blvd.
City
Qazvin
Province
Qazvin
Postal code
13911/34156
Phone
+98 28 3333 7006
Email
apeymani@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
Zeinab Zarabadipour
Position
Master student
Latest degree
Bachelor
Other areas of specialty/work

Midwifery
Street address
Qazvin University of Medical Sciences. Bahonar Blvd
City
Qazvin
Province
Qazvin
Postal code
15315-34199
Phone
+98 28 3333 8034
Email
z.zarabadipour@qums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Dr. Zinat Jorabchi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Qazvin University of Medical Sciences. Bahonar Blvd
City
Qazvin
Province
Qazvin
Postal code
15315-34199
Phone
+98 28 3333 8034
Email
zjourabchi@qums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Zeinab Zarabadipour
Position
Masters student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Qazvin University of Medical Sciences. Bahonar Blvd
City
Qazvin
Province
Qazvin
Postal code
ایران
Phone
+98 28 3333 8034
Email
z.zarabadipour@qums.ac.ir

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