Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of acupressure on improving quality of sleep and fatigue in female students with Premenstrual Syndrome (PMS)

Protocol summary

Summary

This is a randomized controlled trial which the primary outcomes measure include reducing fatigue and increasing quality of sleep in female students with Premenstrual Syndrome (PMS). Census sampling method will be used to screen PMS in the students of Islamic Azad University and Payam e Noor University in Bandar Genaveh, Bushehr Province. Then, 140 students with PMS and the inclusion criteria will be selected consecutively and randomly assigned to two groups of experiment (intervention) and control (with Blocking Randomization Method). The inclusion criteria include: students with fatigue and sleep quality score of 31 and 5, respectively; regular menstruation of 24-35 days; age of 18-35 years old; not married; no physical and mental diseases; no medication or traditional treatment for controlling PMS; The exclusion criteria consist no interest for participation in the trial anymore; performing incomplete acupressure for less than 6 consecutive days for any reason; irregular menses; get married during the trial; pharmacological or non-pharmacological treatments for PMS during the trial. For data collection, a self report questionnaire will be used for Premenstrual Syndrome diagnosis. Fatigue Severity Scale (FSS) and Pittsburg Sleep Quality Index (PSQI) will be used to measure the main dependent variables in the study. The independent variable will be acupressure on the points of ST36 – below the knee, in the anterior boarder of tibia and HT7 in the hands, at the wrist crease, on the radial side of the flexor carpi ulna is tendon, between the ulna and the pisiform bones. The intervention (acupressure) will be applied for 5 minutes on each points of the body. In other words, the total duration of intervention will be 20 minutes per day for 5-10 days premenstrual period in two consecutive cycles. The procedure of acupressure will be confirmed if subjects felt sore, numb, heavy, distended, and/or warm as a result of acupressure massage.

General information

Acronym

PMS

IRCT registration information

IRCT registration number: **IRCT201206126247N6**
Registration date: **2012-10-11, 1391/07/20**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-10-11, 1391/07/20

Registrant information

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Farideh Bastani

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Tehran University of Medical Sciences

Expected recruitment start date

2012-06-20, 1391/03/31

Expected recruitment end date

2012-09-20, 1391/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of acupressure on improving quality of sleep and fatigue in female students with Premenstrual Syndrome (PMS)

Public title
Acupressure, sleep and fatigue in students with Premenstrual Syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: students with fatigue and sleep quality score of 31 and 5, respectively; regular menstruation of 24-35 days; age between 18-35 years old; not married; no physical and mental diseases; no medication or traditional treatment for controlling Premenstrual Syndrome (PMS); Exclusion criteria: Unwillingness to continue participation in the trial; performing incomplete acupressure for less than 6 consecutive days for any reason; irregular menstruation; get married during the trial; pharmacological or non-pharmacological treatments for Premenstrual Syndrome during the trial.

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

Gender
Female

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: **140**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
This is an experimental study.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
The Ethics Committee of Tehran University of Medical Sciences

Street address
Keshavarz Boulevard, Ghods St.

City
Tehran

Postal code

Approval date
2012-06-20, 1391/03/31

Ethics committee reference number
91/N/130/154

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
Sleep Quality and Fatigue

Timepoint
pre and post intervention (before and after acupressure)

Method of measurement
Fatigue Severity Scale (FSS) and Pittsburg Sleep Quality Index (PSQI)

Secondary outcomes

empty

Intervention groups

1

Description
In this study, the intervention would be acupressure which will be applied for control of the PMS symptoms of fatigue and quality of sleep on the experiment group.

Category
Other

2

Description
The control group will be students who not exposed to acupressure or any interventions for the control of the PMS symptoms (fatigue and sleep quality).

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Islamic Azad University and Payam e Noor University of Bandar Genaveh

Full name of responsible person
Bahare Mohammad Salehi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Tehran University of Medical Sciences
Full name of responsible person
Dr. Akbar Fotoohi, Vice Chancellor for Research, Tehran University of Medical Sciences
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Keshavarz, Boulevard, Ghods St.
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Tehran
Grant name
Grant code / Reference number
91-02-28-17955
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research, Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty