

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### The effect of foot reflexology on premenstrual syndrome among students in the dormitory of jahrom university 1390

#### Protocol summary

##### Summary

This study determined the effects of foot reflexology on symptoms of premenstrual syndrome on students living in dormitories are Jahrom University, and the prevalence of disease, and selection of samples based on inclusion criteria: age 35-18 years, normal BMI, lack of drug addiction, smoking and alcohol, regular menstrual periods, lack of physical and mental illness and exclusion criteria included shock and misadventure and drug use that affect the PMS, as patients with premenstrual syndrome randomized into two groups. In the intervention group were treated by the researcher with foot reflexology, foot reflexology for 15 minutes on each leg (total 30 minutes) once a day, 10-5 days prior to the time period (monthly bleeding cycle) is , and it is before the onset of symptoms, and be continued until the period (total 10-5 days). Just a gentle massage and foot controls are ineffective. Independent variable and the dependent variable in this study, foot reflexology is the study of premenstrual syndrome.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138811103226N1**

Registration date: **2012-08-07, 1391/05/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-08-07, 1391/05/17

##### Registrant information

###### Name

Mahrokh Dolatian

###### Name of organization / entity

Shahid Beheshti University of Medical Scenices

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8820 2512

###### Email address

m\_dolatian@sbmu.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Shahid Beheshti University of Medical Scineces

###### Expected recruitment start date

2011-12-21, 1390/09/30

###### Expected recruitment end date

2012-03-19, 1390/12/29

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

The effect of foot reflexology on premenstrual syndrome among students in the dormitory of jahrom university 1390

###### Public title

The effect of reflexology on premenstrual syndrome

###### Purpose

Treatment

###### Inclusion/Exclusion criteria

Inclusion criteria: Iranian race; 18 – 35 year age; normal BMI (19.8 – 26); not addicted to drugs, cigarette and alcohol; regular menstruation (Period between 21 – 35 days); gained score 0 – 9 in Depression Test. By virtue of their own statements they should not have known mental disease such as bipolar and personality disorders, drugs misuse and other mental diseases and depression. Also they should have the syndrome according to the

table registering daily signs for two months. They should not use vitamins ( B6, E , sulfate zinc , multivitamin ), contraceptives , medroxyprogesterone, diderogestrone, spironolactone , fluoxetine , alperazolam , calcium , anticonvulsive , antidepressive and herbal medications in recent three months or any drugs influencing on the premenstrual syndrome( PMS). They should not have had any deplorable event such as near relatives' death or surgical operation in recent six months. Exclusion criteria: known physical disease; suffering from cardiac diseases; coagulation disorders; deep vein thrombosis; vein phlebitis, infection; feet burn or wound and severe infections; diabetes; heartbeat regulation apparatus and varicose vein and If the patients do not cooperate.

#### **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: **90**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Single blinded

#### **Blinding description**

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

The International Branch of Shahid Beheshti university of medical sciences & health sciences

###### **Street address**

Shahid Abbaspour avenue, Tavanir avenue, nabshe pol hemmat, the international branch of shahid beheshti university of medical sciences & health sciences

###### **City**

Tehran

###### **Postal code**

##### **Approval date**

2011-11-29, 1390/09/08

##### **Ethics committee reference number**

116/3540

### **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**

Foot Reflexology

##### **Timepoint**

5-10 days before menstruation period

##### **Method of measurement**

Check List

### **Secondary outcomes**

#### **1**

##### **Description**

Premenstrual Syndrome

##### **Timepoint**

Premenstrual Syndrome forms have been completed by sampel of this study for 2 months

##### **Method of measurement**

Premenstrual Syndrome Questinnare daily, DSM4

### **Intervention groups**

#### **1**

##### **Description**

Foot reflexology for 15 minutes on each leg (total 30 minutes) once a day, 10-5 days prior to the time period (monthly bleeding cycle) is, and it is before the onset of symptoms, and the time period be continued (total 10-5 days (

##### **Category**

Treatment - Other

#### **2**

##### **Description**

In the control group (without doing foot reflexology techniques) in those days, ie 5-10 days before menstruation and gentle massage to the feet may be ineffective.

##### **Category**

Treatment - Other

### **Recruitment centers**

## 1

### Recruitment center

**Name of recruitment center**

The Girls Students Dormitory of Jahrom University

**Full name of responsible person**

Sareh Abdollahy fard

**Street address**

the dormitory of jahrom university(number 1-11),sepah avenue,jahrom city,fars state

**City**

Jahrom

## Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

The Intrnational Branch of Medical Science & Health medicine Shahid Beheshti University

**Full name of responsible person**

Mrs Dr Ghanati

**Street address**

The intrnational branch of medical science & health medicine Shahid Beheshti university,Tehran

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

The Intrnational Branch of Medical Science & Health medicine Shahid Beheshti University

**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

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences, International-Branch, Iran.

**Full name of responsible person**

Sareh Abdollahifard

**Position**

M.Sc Student of Midwifery

**Other areas of specialty/work****Street address**

Vali Asr niayesh avenue,Nursing & Midwifery college of Shahid Beheshti University of Medical

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**Web page address**

## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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**Name of organization / entity**

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**Position**

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**Fax****Email**

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**Web page address**

*empty*

## **Sharing plan**

**Informed Consent Form**

*empty*

**Deidentified Individual Participant Data Set (IPD)**

**Clinical Study Report**

*empty*

*empty*

**Study Protocol**

**Analytic Code**

*empty*

*empty*

**Data Dictionary**

**Statistical Analysis Plan**

*empty*