

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### Foot reflexology effect on the severity of premenstrual symptoms (Reflex zone therapy) among female university students living in dormitories of Tehran university of medical sciences

#### Protocol summary

##### Summary

The objective of this study was to investigate the foot reflexology effect (Reflex zone therapy) on the severity of premenstrual symptoms among female university students living in dormitories of Tehran University of Medical Sciences. In this single blind randomized clinical trial, 120 female university students, whose PMS were diagnosed by DICKERSON PMS daily record questionnaire for 2 menstrual, were randomly assigned into one of the two study group. One group received a real reflex zone therapy for 8 weeks (once a week for half an hour). The control group received placebo reflex zone therapy using a similar protocol. Physical and mood symptoms were recorded before and after the intervention and the changes were compared between groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201012223027N3**

Registration date: **2011-02-18, 1389/11/29**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2011-02-18, 1389/11/29

##### Registrant information

###### Name

Fahimeh Sehhatie Shafaie

###### Name of organization / entity

Tabriz university of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1479 6770

###### Email address

sehhatief@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tabriz University of Medical Sciences

##### Expected recruitment start date

2010-01-21, 1388/11/01

##### Expected recruitment end date

2011-06-21, 1390/03/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Foot reflexology effect on the severity of premenstrual symptoms (Reflex zone therapy) among female university students living in dormitories of Tehran university of medical sciences

##### Public title

Foot reflexology effect on the severity of Premenstrual symptom (Reflex zone therapy)

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: Girls living in student residences, no major underlying diseases, not taking any medication to relieve premenstrual symptom, not to use painkiller during the study, having regular menstrual cycles, not having genital diseases Exclusion criteria: using hormone drugs, taking antidepressants, having premenstrual symptoms more than 7 day in each cycle, developing tensions and severe psychological crisis within the past

few months

### Age

No age limit

### Gender

Female

### Phase

N/A

### Groups that have been masked

No information

### Sample size

Target sample size: **120**

### 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

Tabriz University of Medical Sciences

##### Street address

University St., Tabriz

##### City

Tabriz

##### Postal code

#### Approval date

2010-11-15, 1389/08/24

#### Ethics committee reference number

8947

## Health conditions studied

### 1

#### Description of health condition studied

Premenstrual symptom

#### ICD-10 code

F50, F59

#### ICD-10 code description

Behavioural syndromes associated with physiological disturbances and physical factors

## Primary outcomes

### 1

#### Description

physical symptoms of Pms.

### Timepoint

2 months before intervention - 2 months after intervention

### Method of measurement

Dickerson Standard questionnaire

## Secondary outcomes

### 1

#### Description

mood symptoms of Pms

#### Timepoint

2 months before Intervention - 2 months after Intervention

#### Method of measurement

Dickerson Standard questionnaire

## Intervention groups

### 1

#### Description

real reflex zone therapy for a treatment period of 8 weeks (once a week for half an hour)

#### Category

Prevention

### 2

#### Description

placebo reflex zone therapy for a treatment period of 8 weeks (once a week for half an hour)

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Tehran University of Medical Sciences

##### Full name of responsible person

##### Street address

##### City

Tehran

### 2

#### Recruitment center

##### Name of recruitment center

Shahid Beheshti Unievrsty of Medical Sciences

##### Full name of responsible person

##### Street address

##### City

Tehran

## Sponsors / Funding sources

1

**Sponsor**

**Name of organization / entity**

Research Deputy of Tabriz university of Medical Sciences

**Full name of responsible person**

Dr.Rashidi

**Street address**

University St., Tabriz

**City**

Tabriz

**Grant name**

**Grant code / Reference number**

<http://www.tbzmed.ac.ir>

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Research Deputy of Tabriz 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**

**Contact**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Nursing and Midwifery faculty, Tabriz university of Medical Sciences

**Full name of responsible person**

Fahimeh Sehhatie Shafaie

**Position**

MS on Midwifery

**Other areas of specialty/work**

**Street address**

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Medical Sciences, Tabriz

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Research Deputy, Tabriz university of Medical Sciences

**Full name of responsible person**

Fahimeh Sehhatie Shafaie

**Position**

MS on Midwifery, Academic member

**Other areas of specialty/work**

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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*