Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 afterl 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 Unievrsity 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

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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