

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Effect of acupressure on sleep quality in women with multiple sclerosis in Isfahan MS society

Protocol summary

Summary

Multiple sclerosis (MS) is a neurological, chronic and progressive disease that results from collection of environmental, genetic and autoimmune factors. The disease, commonly affects people between the age of 20 and 50 years. Common symptoms of MS, which will greatly reduce the quality of life is sleep disorders and poor quality of sleep. Acupressure as a branch of acupuncture is non-pharmacological approach that use in relieving some symptoms including quality of sleep. Therefore, this randomized controlled trial will determine the effect of acupressure on quality of sleep in women with MS. The subjects of this clinical trial (The women with the age of 20-50 years old, the sleep quality score should be 5 or more, Ability for reading and writing) randomly assign into the acupressure group (n=50), which receive acupressure at the true point (shen-men), or the placebo group (n=50), which receive touching instead of acupressure at placebo point. Quality of sleep is main outcome that measure in both groups before and after intervention with Pittsburgh Scale. The women who do not continue the trial for any reason, or the participants who do not feel the heavy and numbness during the intervention at the shen-men point or women that do not perform intervention for more than three nights will be excluded. In the experimental group, participants will be trained for the intervention (acupressure) which is pressing about five minutes at Shen-men point for each side of the body once at night for four consecutive weeks by themselves. The similar procedure that is touching beside of Shen-men point will be implemented for the placebo group.

General information

Acronym

MS

IRCT registration information

IRCT registration number: **IRCT201204256247N5**

Registration date: **2012-09-15, 1391/06/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-09-15, 1391/06/25

Registrant information

Name

Farideh Bastani

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Tehran University Of Medical Sciences

Expected recruitment start date

2012-05-21, 1391/03/01

Expected recruitment end date

2012-09-22, 1391/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of acupressure on sleep quality in women with multiple sclerosis in Isfahan MS society

Public title

Acupressure and sleep quality in women with multiple sclerosis (MS)

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria consisted of: The age between 20-50 years old, The sleep quality score should be 5 or more (with any medication), six months past from diagnosis of Multiple Sclerosis in women, No presence of scars, scratches and deformity in the area of the point of Shen-men for the experimental or placebo groups, Ability for reading and writing (literate), No previous experiences of acupressure in the participants, No history of mental illnesses, physical diseases such as depression, insulin-dependent diabetes, heart failure or chronic pain in the women, and the EDSS score should be between 1- 4.5. Exclusion criteria: Lack of willingness to continue participation in the trial for any reason, Patients who do acupressure in the Shen-men point do not have warmth, heaviness, swelling, and numbness with any reason, Patients with more than 3 nights, do not perform the intervention, Patients during the intervention process have serious known physical and psychological disorders.

Age

From **20 years** old to **50 years** old

Gender

Female

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

In this study, Patients who do not have a history of using acupressure and do not have information about acupressure. The Patients assign randomly two groups. This study perform single blind.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethic Committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Ghods St., Keshavarz Blvd., Tehran, Iran

City

Tehran

Postal code**Approval date**

2012-03-02, 1390/12/12

Ethics committee reference number

12269

Health conditions studied**1****Description of health condition studied**

multiple sclerosis

ICD-10 code

G35, H48.1

ICD-10 code description

Demyelinating diseases of the central nervous system

Primary outcomes**1****Description**

Quality of sleep

Timepoint

Before the beginning of the intervention and one month after the intervention

Method of measurement

Pittsburgh Sleep Quality Scale

Secondary outcomes

empty

Intervention groups**1****Description**

The women in the experimental group receive the intervention (acupressure) at the point of Shen-men for five minutes on each side of the body, once at night for four consecutive weeks.

Category

Treatment - Other

2**Description**

The women in the control (placebo) group receive the intervention (touching instead of acupressure) at the beside of Shen-men point for five minutes on each side of the body, once at night for four consecutive weeks.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan MS Society

Full name of responsible person

Dr. Etemadi

Street address

The MS Society of Isfahan, No. one, Ground Floor,
Building Behesht, Bozorgmehr St.

City

Isfahan

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 Fotouhi

Street address

Tehran University of Central Organization, Ghods St.,
Keshavarz Blvd., Tehran, Iran

City

Tehran

Grant name**Grant code / Reference number****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

Contact

Name of organization / entity

Faculty of Nursing and Midwifery, Tehran University of
Medical Sciences

Full name of responsible person

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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