Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

Country

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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

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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