Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of Acupressure on Physical and Psychological Problems in Multiple Sclerosis Patients

Protocol summary

Study aim

To determine the effect of acupressure on physical and psychological outcomes in patients with multiple sclerosis.

Design

A single-blind, parallel-group, randomized controlled trial with a block randomization design (block size of 4). The target sample size is 70 participants (35 per group). Randomization will be stratified by age at diagnosis and gender. Allocation concealment will be performed using sequentially numbered, sealed opaque envelopes.

Settings and conduct

Eligible patients will be recruited and randomly allocated to either the intervention or control group. The intervention group will receive acupressure training in a face-to-face session and perform the technique at home for 4 weeks, with follow-up via social network (Soroush app) or telephone calls. Outcomes (depression, anxiety, fatigue, sleep quality, and quality of life) will be assessed using validated questionnaires (Beck Depression Inventory, Spielberger State-Trait Anxiety Inventory, Fatigue Severity Scale, Pittsburgh Sleep Quality Index, and SF-36) at baseline and immediately after the 4-week intervention period.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18-50 years; confirmed diagnosis of MS for at least one year;... Exclusion criteria: Inconsistent completion of acupressure sessions;...

Intervention groups

Intervention group: Patients perform acupressure on three acupoints (HT-7/Shenmen, Ki-3, and Yintang/Third Eye) for 4 weeks, three times per week Control group: Patients receive no acupressure intervention and continue their routine care.

Main outcome variables

Mean change in depression score (Beck Depression Inventory) Mean change in anxiety score (Spielberger State-Trait Anxiety Inventory) Mean change in fatigue score (Fatigue Severity Scale) Mean change in sleep quality score (Pittsburgh Sleep Quality Index) Mean change in quality of life score (SF-36 Questionnaire)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260630070019N2**
Registration date: **2026-08-10, 1405/05/19**
Registration timing: **retrospective**

Last update: **2026-08-10, 1405/05/19**
Update count: **0**

Registration date

2026-08-10, 1405/05/19

Registrant information

Name

Faezeh Abadi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2020-03-01, 1398/12/11

Actual recruitment start date

2018-12-22, 1397/10/01

Actual recruitment end date

2020-03-01, 1398/12/11

Trial completion date
2020-03-01, 1398/12/11

Scientific title
The Effect of Acupressure on Physical and Psychological Problems in Multiple Sclerosis Patients

Public title
Effect of Acupressure in Multiple Sclerosis Patients

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 18 and 50 years. Definite diagnosis of Multiple Sclerosis (MS) for at least one year. Not being in the acute relapse or progressive phase of the disease. No other acute or chronic physical, mental, or psychological disorders. No history of acupressure therapy. Not taking sedatives, antidepressants, hypnotics, or anxiolytic medications. Being conscious and alert. Stable hemodynamic status. No local skin problems at acupoints (e.g., wound, burn, abscess, cyst). No history of substance abuse. Providing written informed consent. Pittsburgh Sleep Quality Index score greater than 5. Literacy (at least 6 years of education) to complete the Beck questionnaire. No visual or auditory impairments.

Exclusion criteria:
Inconsistent or non-completion of acupressure sessions. Withdrawal of consent to continue participation in the study. Development of a serious physical or psychological disorder during the study.

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **70**
More than 1 sample in each individual
Number of samples in each individual: **2**
In two stages 1.before and 2. after the intervention
Actual sample size reached: **70**
More than 1 sample in each individual
Actual sample size in each individual: **2**
In two stages 1.before and 2. after the intervention

Randomization (investigator's opinion)
Randomized

Randomization description
Method of randomization: Block randomization with a block size of 4. In this method, each block contains an equal number of allocations to the intervention and control groups (two participants per group per block). This ensures that the sample sizes in both groups remain balanced throughout the recruitment process. Unit of randomization: The unit of randomization is the individual patient. Randomization strata: This study uses stratification to ensure comparability between groups at baseline. The participants will be stratified (matched) based on the following variables: Age at diagnosis Gender This means that within each stratum (e.g., "males aged 30-40"), separate block randomization sequences will be generated to ensure that these key confounding variables are equally distributed between the intervention and control groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this trial, the blinding is designed as a single-blind study. Specifically, the data analyst will be blinded to the group allocation (intervention or control) of the participants. This blinding will be maintained throughout the entire data analysis phase until the final statistical interpretations are completed. Due to the nature of the intervention (acupressure performed by patients themselves at home), it is not feasible to blind the participants or the trainer who teaches the technique. However, to minimize the risk of bias in the analytical phase—one of the most critical stages of the research—the data analyst will remain unaware of the group identities. The data will be provided to the analyst using numerical codes, and the allocation key will not be disclosed to them until all statistical analyses are finalized. This approach ensures objective and unbiased data interpretation.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Fasa university of medical science

Street address
Ebn sina square

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Postal code
۷۴۶۱۶-۸۶۶۸۸

Approval date
2019-11-29, 1398/09/08

Ethics committee reference number
IR.FUMS.REC.1398.042

Health conditions studied

1

Description of health condition studied

Multiple Sclerosis (MS) is a chronic autoimmune disorder of the central nervous system. In this condition, the immune system attacks the protective myelin sheath surrounding nerve fibers in the brain, optic nerves, and spinal cord .

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes

1

Description

Mean score of depression as measured by the Beck Depression Inventory (BDI). This 21-item self-report instrument measures the severity of depressive symptoms over the past two weeks. Each item is scored from 0 to 3, with total scores ranging from 0 to 63. Higher scores indicate greater severity of depression. The primary outcome is the mean change in BDI score from baseline to post-intervention.

Timepoint

Baseline (before the start of the intervention) and immediately after the 4-week intervention period (Week 4).

Method of measurement

Beck Depression Inventory (BDI) - a 21-item self-report questionnaire.

2

Description

Mean score of anxiety as measured by the Spielberger State-Trait Anxiety Inventory (STAI) - Trait scale. This 20-item self-report instrument measures the general tendency to experience anxiety across different situations. Each item is scored from 1 to 4, with total scores ranging from 20 to 80. Higher scores indicate higher levels of anxiety. The primary outcome is the mean change in STAI score from baseline to post-intervention.

Timepoint

Baseline (before the start of the intervention) and immediately after the 4-week intervention period (Week 4).

Method of measurement

Spielberger State-Trait Anxiety Inventory (STAI) - Trait scale, a 20-item self-report questionnaire.

3

Description

Mean score of fatigue as measured by the Fatigue Severity Scale (FSS). This 9-item self-report instrument assesses the severity of fatigue and its impact on daily functioning. Each item is scored from 1 to 7, with the total score calculated as the mean of all items. Total scores range from 1 to 7, with higher scores indicating greater fatigue severity. The primary outcome is the mean change in FSS score from baseline to post-intervention.

Timepoint

Baseline (before the start of the intervention) and immediately after the 4-week intervention period (Week 4).

Method of measurement

Fatigue Severity Scale (FSS) - a 9-item self-report questionnaire.

4

Description

Mean score of sleep quality as measured by the Pittsburgh Sleep Quality Index (PSQI). This 19-item self-report instrument assesses sleep quality and disturbances over a one-month period across seven domains: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction. Each domain is scored from 0 to 3, with a global PSQI score ranging from 0 to 21. A global score of 5 or higher indicates poor sleep quality. The primary outcome is the mean change in PSQI global score from baseline to post-intervention.

Timepoint

Baseline (before the start of the intervention) and immediately after the 4-week intervention period (Week 4).

Method of measurement

Pittsburgh Sleep Quality Index (PSQI) - a 19-item self-report questionnaire.

5

Description

Mean score of quality of life as measured by the SF-36 Health Survey Questionnaire. This 36-item self-report instrument assesses health-related quality of life across eight domains: physical functioning, role limitations due to physical health, bodily pain, general health perceptions, vitality, social functioning, role limitations due to emotional problems, and mental health. Each domain is scored from 0 to 100, with higher scores indicating better quality of life. Domain scores are aggregated into two summary component scores: Physical Component Summary (PCS) and Mental Component Summary (MCS). The primary outcome is the mean change in SF-36 domain scores from baseline to post-intervention.

Timepoint

Baseline (before the start of the intervention) and immediately after the 4-week intervention period (Week 4).

Method of measurement

SF-36 Health Survey Questionnaire - a 36-item self-report questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in this group receive acupressure training and perform the technique at home for 4 weeks. The acupressure is applied on three acupoints: HT-7 (Shenmen point), Ki-3 (Taixi point), and Yintang (Third Eye point). The intervention is performed three times per week (Saturdays, Mondays, and Wednesdays) for 4 consecutive weeks. For HT-7 and Ki-3 points, patients use specialized acupressure bracelets and ankle bands that apply continuous pressure for 30 minutes at each point. For the Yintang point, patients use their thumb or index finger to apply pressure for 10 minutes. The technique is taught in a single face-to-face session by an expert in acupressure therapy, and educational pamphlets are provided for home use. Patients receive daily reminders through a social network application (Soroush) or telephone calls to ensure adherence. The intervention aims to reduce depression, anxiety, fatigue, and improve sleep quality and quality of life in patients with multiple sclerosis.

Category

Other

2

Description

Control group: Patients in this group do not receive any acupressure intervention. They continue to receive their routine standard care and medical treatments as prescribed by their physicians. No specific behavioral intervention is provided during the 4-week study period. However, at the end of the study, if the acupressure technique proves to be effective, the control group participants will be offered the opportunity to receive the acupressure training as an ethical consideration.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Multiple Sclerosis Association of Fasa City

Full name of responsible person

Faezeh Abadi

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Fasa University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Fasa University of Medical Sciences

Full name of responsible person

Faezeh Abadi

Position

assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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zhila fereydoni

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Professor

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
De-identified individual participant data (all collected outcome measures).

When the data will become available and for how long
6 months after publication, available for 5 years.

To whom data/document is available
Researchers from academic institutions.

Under which criteria data/document could be used
Approved research proposal and signed data sharing agreement.

From where data/document is obtainable
Principal Investigator via email.

What processes are involved for a request to access data/document
Submit request → Review by PI and ethics committee (4-6 weeks) → Sign agreement → Data transfer. Total: 3-4 months.

Comments
Requests reviewed case by case.