

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of acupressure on depression, stress, anxiety and fatigue in patients with multiple sclerosis

#### Protocol summary

##### Study aim

Determine the effect of acupressure on stress, anxiety, depression, and fatigue in patients with MS

##### Design

This study is a clinical trial with a control group, with parallel groups, single-blind, Randomized by a coin toss, the sample size is 106, 2-3 phase.

##### Settings and conduct

Depression, anxiety, stress and fatigue are common problems in people with MS. Interventions are needed to improve these complications. 106 participants from MS Association of Mashhad will be randomly assigned to two groups according to inclusion criteria. In the intervention group, the acupressure will be applied at Yintang and Shenmen points for one month. The control group will press 2.5 cm above shenmen and 3 cm above Yin Tang acupoints. DASS42 and FSS questionnaires will be completed before and one day after the intervention. The data analyzer will not be aware of the groups and the type of intervention in each group. Blinding will be done by coding the questionnaires.

##### Participants/Inclusion and exclusion criteria

Relapsing Remitting MS, At least 6 months have passed since the diagnosis of MS, Maximum age 45 years, EDSS scores 1 to 4.5. Exclusion criteria: history of psychosis, addiction to narcotics, stimulant drugs and sedative drugs and tobacco, acne, ulcer or skin lesions in acupressure points.

##### Intervention groups

Intervention group: 53 patients will be included in the intervention group. Participants will press the HT7 and GV29 acupressure points for 15 minutes. The intervention will be for 15 minutes each morning (5 minutes for each hand and 5 minutes for the third eye) for one month. One day after the intervention, patients will complete the DASS42 and FSS questionnaires. Control group: 2.5 cm above shenmen and 3 cm above Yin Tang acupoints will press.

##### Main outcome variables

Stress, anxiety, depression, fatigue

#### General information

##### Reason for update

Sample size correction and convert control group to sham group

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190515043601N5**

Registration date: **2020-04-04, 1399/01/16**

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

Last update: **2020-11-21, 1399/09/01**

Update count: **1**

##### Registration date

2020-04-04, 1399/01/16

##### Registrant information

##### Name

Hossein Rahimi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 56 3238 1427

##### Email address

hosseinrahimi92@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-11-01, 1398/08/10

##### Expected recruitment end date

2020-04-29, 1399/02/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty  
**Trial completion date**

empty

**Scientific title**

The effect of acupressure on depression, stress, anxiety and fatigue in patients with multiple sclerosis

**Public title**

The effect of acupressure on depression, stress, anxiety and fatigue in patients with multiple sclerosis

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Relapsing Remitting MS At least 6 months have passed since the diagnosis of MS Maximum age 45 years EDSS scores 1 to 4.5

**Exclusion criteria:**

History of psychosis Addiction to narcotics, stimulants ,sedatives drugs and tobacco Acne, ulcer or skin lesions in acupressure points

**Age**

To **45 years** old

**Gender**

Both

**Phase**

1-2

**Groups that have been masked**

- Data analyser

**Sample size**

Target sample size: **106**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

106 patients who met inclusion criteria will be randomly assigned to intervention and control groups using the coin toss. All the eligible patients will be included in the study from November 2019 to April 2020 (The Poisson simple random sampling). The first five patients will be allocated to the intervention (head) or control (tail) group, and the second five patients will be allocated to the other group (tails) using tossing a coin. c).

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The data analyst will be unaware of the type of intervention for each group. Pre-intervention questionnaires will be coded in the intervention group with the letter M and the control group with N. Questionnaires will be coded after intervention in intervention group with letter G and control group with H. The coding will be done by the researcher. No one other than the researcher will know about coding.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Birjand University of Medical Sciences

**Street address**

Central Building of Birjand University of Medical Sciences, Ghorfari Street, Birjand, South Khorasan

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9717853577

**Approval date**

2019-10-14, 1398/07/22

**Ethics committee reference number**

IR.BUMS.REC.1398.218

**Health conditions studied**

**1**

**Description of health condition studied**

Stress

**ICD-10 code**

F43.9

**ICD-10 code description**

Reaction to severe stress, unspecified

**2**

**Description of health condition studied**

anxiety

**ICD-10 code**

F06.4

**ICD-10 code description**

Anxiety disorder due to known physiological condition

**3**

**Description of health condition studied**

depression

**ICD-10 code**

F06.31

**ICD-10 code description**

Mood disorder due to known physiological condition with depressive features

**4**

**Description of health condition studied**

fatigue

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

#### Description

The level of stress in MS patients.

#### Timepoint

Before and one day after the end of intervention

#### Method of measurement

Stress score from the depression, anxiety and stress scale-42

### 2

#### Description

The level of anxiety in MS patients.

#### Timepoint

Before and one day after the end of intervention

#### Method of measurement

Anxiety score from the depression, anxiety, stress scale-42

### 3

#### Description

The level of depression in MS patients

#### Timepoint

Before and one day after the end of intervention

#### Method of measurement

Depression score from the depression, anxiety, stress scale-42

### 4

#### Description

The level of fatigue in MS patients.

#### Timepoint

Before and one day after the end of intervention

#### Method of measurement

Fatigue score from the Fatigue severity scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: The participants in this study will be MS patients in Mashhad. Intervention group:53 patients will be included in the intervention group. Participants will press the HT7 and GV29 acupressure points.The intervention will be for 15 minutes each morning (5 minutes for each hand and 5 minutes for the third eye) for one month. One day after the intervention, patients will complete the DASS42 and FSS questionnaires.

#### Category

Treatment - Other

### 2

#### Description

Control group: i participants will press 2.5 cm above shenmen and 3 cm above Yin Tang acupoints .

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ghaem hospital

##### Full name of responsible person

Fatemeh Tara

##### Street address

The beginning of parastar street, Ahmadabad street

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

99199-91766

##### Phone

+98 51 3840 0001

##### Email

Taraf@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Birjand University of Medical Sciences

##### Full name of responsible person

Toba kazemi

##### Street address

Central Building of Birjand University of Medical Sciences,Ghafari Street

##### City

Birjand

##### Province

South Khorasan

##### Postal code

9717853577

##### Phone

+98 56 3239 5000

##### Email

drtooba.kazemi@ gmail.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Birjand 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**

Birjand University of Medical Sciences

**Full name of responsible person**

Hossein Rahimi

**Position**

Instructor

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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**Person responsible for scientific inquiries**

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**Position**

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**Latest degree**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Hossein Rahimi

**Position**

Instructor

**Latest degree**

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**Other areas of specialty/work**

Nursery

**Street address**

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**Fax**

**Email**

Hosseinrahimi92@yahoo.com

**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**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

All potential data can be shared after unidentifiable participants

**When the data will become available and for how long**

Start of access period 12 months after printing results

**To whom data/document is available**

It will only be available to researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

In order to access the data, researchers can request access to the information 12 months after the results are published. Within two weeks, the information will be sent to them. It should be noted that applicants must be faculty members of the Ministry of Health.

**From where data/document is obtainable**

Applicants can apply to the Birjand University of Medical

Sciences School of Nursing and Midwifery for information.

**What processes are involved for a request to access data/document**

After verifying the identity of the applicant, the data will be submitted to the researcher within 2 weeks.

**Comments**