Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 is106, 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, stimulants, 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 participantswill 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

Street address

Ghafari

City

Birjand

Province

South Khorasan

Postal code

9717852577

Phone

+98 56 3238 1427

Fax

Email

Hosseinrahimi92@yahoo.com

Person responsible for scientific 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

Street address

Ghafari

City

Birjand

Province

South Khorasan

Postal code

9717853577

Phone

+98 56 3238 1427

Fax

Email

Hosseinrahimi92@yahoo.com

Person responsible for updating data

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

Street address

Ghafari

City

Birjand

Province

South Khorasan

Postal code

9717853577

Phone

+98 56 3238 1427

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