

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Investigation the effect of breathing yoga “Bhramary Pranayama” on fatigue and depression in patients with multiple sclerosis

Protocol summary

Study aim

Determination the effect of breathing yoga “Bhramary Pranayama” on fatigue and depression in patients with multiple sclerosis

Design

A randomized clinical trial with a parallel group design of 80 patients

Settings and conduct

In this randomized clinical trial, the study population are patients with multiple sclerosis who will referred to M.S association of Rafsanjan. Participants will select by convenience sampling method based on inclusion criteria of the study. Random allocation of the participants will carry out using the minimization method. The intervention group performed Bramari Pranayama yoga and the control group received usual care. Demographic questionnaire and the FSS and Beck depression questionnaires are data collection tool which will completed before the intervention and 28 days after the intervention in both groups.

Participants/Inclusion and exclusion criteria

Having relapsing-remitting MS, EDSS score less than 4, age between 18-60 years old, confirmation of M.S by a neurologist, getting score above 36 from the FSS questionnaire, getting score above 14 from Beck questionnaire and ability to do yoga independently are inclusion criteria. Having other neurological diseases except M.S, suffering from other diseases such as cancer, autoimmune diseases, cognitive problems and use of drugs or alcohol are exclusion criteria.

Intervention groups

Intervention group: For 4 weeks, they will do Bramari Pranayama yoga twice a day (morning and evening) for 20 minutes each time. Control group: will receive the usual care of the community.

Main outcome variables

Fatigue Depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150713023190N14**

Registration date: **2023-07-22, 1402/04/31**

Registration timing: **retrospective**

Last update: **2023-07-22, 1402/04/31**

Update count: **0**

Registration date

2023-07-22, 1402/04/31

Registrant information

Name

Tabandeh Sadeghi

Name of organization / entity

Rafsanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 34 3425 5900

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-01, 1402/04/10

Expected recruitment end date

2023-07-03, 1402/04/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the effect of breathing yoga “Bhramary Pranayama” on fatigue and depression in patients with multiple sclerosis

Public title

The effect of breathing yoga “Bhramary Pranayama” on fatigue and depression in patients with multiple sclerosis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Having relapsing-remitting M.S EDSS score less than 4
Age between 18-60 years old
Confirmation of M.S by a neurologist
Getting a score above 36 from the FSS questionnaire
Getting a score above 14 from Beck questionnaire
Ability to do yoga independently

Exclusion criteria:

Having other neurological diseases except M.S
Suffering from other diseases such as cancer, autoimmune diseases and cognitive problems.
Use of drugs or alcohol

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Stratified randomization by minimization method: in this method, initially, the patients will categorize based on key variables, such as scores from fatigue severity scale and depression questionnaires. Afterwards, from the patients who will meet the inclusion criteria, the first participant will place in the intervention or control group by coin flip, and other participants will allocate to the study group with lower total of variables. The variables will stratify according to the following table :
Variables
Category Intervention group Control group
Depression questionnaire score 14-19 20-28 29-63
Fatigue Severity Scale (FSS) questionnaire score 36-49 50-63

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Rafsanjan University of Medical Sciences

Street address

Imam Ali Blvd

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Approval date

2023-06-14, 1402/03/24

Ethics committee reference number

IR.RUMS.REC.1402.036

Health conditions studied

1

Description of health condition studied

Multiple Sclerosis

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes

1

Description

Fatigue

Timepoint

Before the intervention and 28 days after the intervention

Method of measurement

Fatigue Severity Scale

2

Description

Depression

Timepoint

Before the intervention and 28 days after the intervention

Method of measurement

Beck Depression Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For 4 weeks, they will do Bramari

Pranayama yoga twice a day (morning and evening) for 20 minutes each time. In the Bramari Pranayama, the participants will sit in a comfortable position with eyes closed and will be instructed to close both ears using their index fingers. The subjects will be instructed to concentrate on their breathing pattern and maximum inhalation through both the nostrils followed by maximum exhalation. During exhalation, the subject will be asked to chant the word "Mmmm" in such a way that the humming bee sound brought vibration in their laryngeal walls.

Category

Treatment - Other

2**Description**

Control group: Will receive the usual care (Medical, pharmaceutical and financial support, recreational programs) of the M.S association.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Rafsanjan MS association

Full name of responsible person

Fatemeh Ayoubi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Rafsanjan University of Medical Sciences

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

Rafsanjan 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**

Rafsanjan University of Medical Sciences

Full name of responsible person

Tabandeh Sadeghi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable