Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

Phone
+98 34 3425 5900

Email address
t.sadeghi@rums.ac.ir

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 instructed to close both ears using their index fingers. The subjects will instructed to concentrate on their breathing pattern and maximum inhalation through both the nostrils followed by maximum exhalation. During exhalation, the subject will 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

Street address
Shariati Ave

City
Rafsanjan

Province
Kerman

Postal code
7717933777

Phone
+98 34 3428 0001

Email
ayoobi.fatemeh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rafsanjan University of Medical Sciences

Full name of responsible person
Reza Vazirinejad

Street address
Imam Ali Blvd

City
Rafsanjan

Province
Kerman

Postal code
7717933777

Phone
+98 34 3428 0097

Email
vcrt@rums.ac

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
Nursery

Street address
Parastar Ave

City
Rafsanjan

Province
Kerman

Postal code
7718796755

Phone
+98 34 3425 5900

Email
t.b_sadeghi@yahoo.com

Person responsible for scientific 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

Nursery
Street address
Parastar Ave
City
Rafsanjan
Province
Kerman
Postal code
7718796755
Phone
0098 34 342555900
Email
t.b_sadeghi@yahoo.com

Person responsible for updating data

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
Nursery
Street address
Parastar Ave
City
Rafsanjan
Province
Kerman
Postal code
7718796755
Phone
+98 34 3425 5900
Email
t.b_sadeghi@yahoo.com

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