Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of Benson relaxation technique on fatigue and general health in multiple sclerosis patients admitted to kashan shahid beheshti hospital in 2017

Protocol summary

Study aim
Determining the effect of Benson relaxation technique on fatigue and general health in multiple sclerosis patients
Design
In this randomized clinical trial, patients will be randomly assigned to two groups of 30 people.
Settings and conduct
Benson relaxation technique will be performed in a room at Kashan Shahid Beheshti Hospital for 20 minutes for 4 weeks (daily, twice daily).
Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with Multiple Sclerosis Relapsing-Remitting؛ Type Age 20-45 years ؛Not having had any attacks in the past three months؛ Having the consent to participate in the study؛ No known psychiatric disorders, dementia and mental retardation. Exclusion criteria: Use of other Complementary therapies
Intervention groups
In the intervention group, Benson relaxation technique will be performed for 20 minutes during 4weeks (daily, twice daily). The control group will be performed no intervention for 4 weeks.
Main outcome variables
Fatigue and general health

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20111210008348N44**
Registration date: **2020-06-17, 1399/03/28**
Registration timing: **prospective**

Last update: **2020-06-17, 1399/03/28**
Update count: **0**
Registration date
2020-06-17, 1399/03/28

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-06-21, 1399/04/01
Expected recruitment end date
2020-09-20, 1399/06/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Benson relaxation technique on fatigue and general health in multiple sclerosis patients admitted to kashan shahid beheshti hospital in 2017

Public title
The effect of Benson relaxation on fatigue and general health in multiple sclerosis patients
Purpose
Treatment
Inclusion/Exclusion criteria

Inclusion criteria:
Patients with Multiple Sclerosis Relapsing-Remitting Type Age 20-45 years No acute attack of multiple sclerosis in the last three months Having the consent to participate in the study. No known psychiatric disorders, dementia and mental retardation
Exclusion criteria:
Use of other Complementary therapies

Age
From **20 years** old to **45 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation in two groups of intervention and control will be simple randomization. Randomization is carried out by creating a random sequence of numbers using on an line randomizer tool (https://www.randomizer.org).

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 Kashan University of Medical Sciences

Street address
Ravand Street, Kashan University of Medical Sciences.

City
Kashan

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Isfehan

Postal code
8715981151

Approval date
2017-08-16, 1396/05/25

Ethics committee reference number
IR.KAUMS.NUHEPM.REC.1396.31

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 and after intervention

Method of measurement
Brief Fatigue Inventory

Secondary outcomes

1

Description
General health

Timepoint
Before and after the intervention

Method of measurement
Goldberg General Health Questionnaire

Intervention groups

1

Description
Intervention group: In addition to routine care (physiotherapy, light exercise, medication), the Bensone relaxation technique will be performed for 4 weeks (every day, twice a day) for 20 minutes. The Benson's relaxation technique includes the following steps: Being comfortable, closing eyes, relaxing all the muscles of the body, breathing slowly.

Category
Treatment - Other

2

Description
Control group: Routine care including joint physiotherapy, light exercise, medication will be performed for patients by health personnel .

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Clinic of Kashan Shahid Beheshti Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

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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
Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Neda Mirbagher
Position
Associate
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Person responsible for updating data

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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