Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 2026

The effect of sleep based occupational therapy intervention on quality of sleep, life and fatigue in patients with multiple sclerosis:

Protocol summary

Study aim
Evaluation of quality of sleep, quality of life and fatigue of multiple sclerosis patients

Design
Clinical trial with community-based and pragmatic control group, with parallel, one-blinded, randomized, clinical trials, with a sample size of approximately 25

Settings and conduct
The interview , training session and intervention willbe conducted at rehabilitation faculty of Iran university of Medical Sciences.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patient with multiple sclerosis; Age between 18-50; EDSS score between 0-6; Not having associated illness like depression; Not having sleep medication; exclusion criteria: Failure to participate in the final evaluation; Relapse the sign and symptom;

Intervention groups
intervention: a group of patient who receive special intervention for sleep and routine occupation therapy intervention control group: Routine occupation therapy intervention

Main outcome variables
sleep quality; fatigue; quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120910010806N6**
Registration date: **2018-03-10, 1396/12/19**
Registration timing: **prospective**

Last update: **2018-03-10, 1396/12/19**
Update count: **0**

Registration date
2018-03-10, 1396/12/19

Registrant information

Name
Malahat Akbarfahimi

Name of organization / entity
Iran University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 21 2222 7124

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-02-20, 1396/12/01

Expected recruitment end date
2018-06-22, 1397/04/01

Actual recruitment start date
2018-04-07, 1397/01/18

Actual recruitment end date
2018-07-23, 1397/05/01

Trial completion date
empty

Scientific title
The effect of sleep based occupational therapy intervention on quality of sleep, life and fatigue in patients with multiple sclerosis:

Public title
quality of sleep, life and fatigue in patient with multiple sclerosis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
patient with MS/ age age between 18-50 EDSS between 0-6 no associated illness like depression no taking sleep medication

Exclusion criteria:
Not attending the final evaluation session Relapsing sign and /or symptoms

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
2

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **25**
Actual sample size reached: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
After review the medical records of patients with multiple sclerosis who refereed to the neurologist clinic in the past six months, patients who meet the inclusion criteria are selected. After obtaining the research criteria, participants are divided into two groups; intervention and control using lottery method of simple random sampling.

Blinding (investigator's opinion)
Single blinded

Blinding description
The evaluation is done by another person

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran University of Medical Sciences

Street address
Mirdamad-Mother Square-Shahid Shah Nazari Avenue-Madadkaran Alley

City
Tehran

Province
Tehran

Postal code
15875-4391

Approval date
2017-01-02, 1395/10/13

Ethics committee reference number
IR.IUMS.REC 1395.9413355002

Health conditions studied

1

Description of health condition studied
Quality of sleep, quality of life and fatigue in multiple sclerosis patients

ICD-10 code
G35

ICD-10 code description
Multiple sclerosis

Primary outcomes

1

Description
sleep Quality

Timepoint
Before intervention, after intervention

Method of measurement
Sleep quality questionnaire

2

Description
fatigue impact

Timepoint
Before intervention, after intervention

Method of measurement
Fatigue Impact Scale

3

Description
quality of life

Timepoint
Before intervention, after intervention

Method of measurement
Quality of Life Questionnaire SF-36

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: a group of patient who receive special intervention for sleep and routine occupation therapy intervention

Category
Treatment - Other

2

Description
Control group: Routine occupation therapy intervention

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
School of Rehabilitation Sciences and Specialist Clinic

Full name of responsible person
Malahat Akbarfahimi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Seid Kazem Malakoti

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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
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Malahat Akbarfahimi

Position
assisstant professor

Latest degree
Ph.D.

Other areas of specialty/work
Occupational Therapy

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Person responsible for scientific inquiries

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Latest degree
Ph.D.

Other areas of specialty/work
Occupational Therapy

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Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person
Benyamin Kor

Position
MsC student

Latest degree
Bachelor

Other areas of specialty/work
Occupational Therapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Because of unwillingness of patients

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is 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
Data is MS patients whose information is not allowed to share

When the data will become available and for how long
Start the access period 6 months after printing the results

To whom data/document is available
Researchers working in academia and academia

Under which criteria data/document could be used
There is no permission to use the data for analysis

From where data/document is obtainable
akbarfahimi.m@iums.ac.ir

What processes are involved for a request to access data/document
Will be responded by sending a request by email in the shortest time

Comments