

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 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 will be 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)

##### Phone

+98 21 2222 7124

##### Email address

akbarfahimi.m@iums.ac.ir

#### 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 referred 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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**Fax****Email**

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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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admins@iums.ac.ir

**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**

assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Occupational Therapy

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Malahat Akbarfahim

**Position**

Assistant Professor

**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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**Email**

benyamin.kor@gmail.com

## 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**