

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### Evaluate the effects of Sleep hygiene education and music therapy on sleep quality in clients with multiple sclerosis (MS)

#### Protocol summary

improve the quality of sleep

#### Study aim

Evaluating the effect of sleep health education and music therapy on sleep quality in patients with multiple sclerosis

#### Design

Clinical trial without control group, without blinding, sample size of 50 people continuously

#### Settings and conduct

In the MS Association, people with inclusion criteria are selected in a continuous manner. After reaching the sample size, they are divided into four groups and the training of these four groups is done in one day but at different hours. After completing the pre-test questionnaire, the necessary training on how to use music for listening for two weeks is given every night for 30-45 minutes before going to bed without headphones. Also, explanations about sleep hygiene are provided in person. And the music will be provided to the samples and will be filled after the end of the post-test intervention.

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: Having a smart phone! Literate! No hearing impairment !PSQI score greater than five! Ages between 20 to 40 years! Absence of relapse and exacerbation of symptoms! No communication and cognitive problems !Absence of patients other than multiple sclerosis Exclusion criteria: Do not listen to music for 3 consecutive or intermittent nights! Reluctance to continue participation! Patients who have known serious physical and mental disorders and illnesses during the intervention! Changes in treatment and medications! Recurrence of the disease! Participate in programs or treatments that affect sleep simultaneously! Death

#### Intervention groups

The intervention includes music therapy in the form of listening to music for 30-45 minutes two weeks each night before bed and sleep hygiene training.

#### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211023052853N1**

Registration date: **2021-11-16, 1400/08/25**

Registration timing: **prospective**

Last update: **2021-11-16, 1400/08/25**

Update count: **0**

##### Registration date

2021-11-16, 1400/08/25

##### Registrant information

##### Name

Fatemeh Sadeghi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4613 8509

##### Email address

fatemeh.sadeghi.1393@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-12-22, 1400/10/01

##### Expected recruitment end date

2022-04-19, 1401/01/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Evaluate the effects of Sleep hygiene education and music therapy on sleep quality in clients with multiple sclerosis (MS)

### Public title

the effects of Sleep hygiene education and music on sleep quality in clients with MS

### Purpose

Supportive

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Having a smart phone with the ability to play music and have a social network and the ability to use it Literate No hearing impairment PSQI score greater than five Ages between 20 to 40 years Absence of relapse and exacerbation of symptoms No communication and cognitive problems (with patient comments and records) Absence of patients other than multiple sclerosis

#### Exclusion criteria:

Known serious physical-mental illness Participate in programs or treatments that affect sleep

### Age

From **20 years** old to **40 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **50**

### Randomization (investigator's opinion)

N/A

### Randomization description

### Blinding (investigator's opinion)

Not blinded

### Blinding description

### Placebo

Not used

### Assignment

Single

### 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

Unit 7, No. 2, Dariush Dead End, Shabboo Alley, Besarati St, Shahin Shomali Ave, Janatabad

##### City

Tehran

#### Province

Tehran

#### Postal code

1475775931

#### Approval date

2021-10-26, 1400/08/04

#### Ethics committee reference number

IR.IUMS.REC.1400.665

## Health conditions studied

### 1

#### Description of health condition studied

Multiple Sclerosis (MS)

#### ICD-10 code

G35

#### ICD-10 code description

Multiple sclerosis

## Primary outcomes

### 1

#### Description

Sleep quality score on the Pittsburgh questionnaire

#### Timepoint

Before the intervention and 14 days after the intervention

#### Method of measurement

Pittsburgh Sleep Quality Index (PSQI)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: To conduct this research, which is a one-group quasi-experimental study with pre-test-post-test, the researcher after obtaining permission from the ethics committee and obtaining permission to conduct research from Iran University of Medical Sciences due to corona pandemic in full compliance with protocols Behdashti refers to the research environment, which is the Iranian Inflammatory Association, and after coordinating with the relevant officials in the Inflammatory Association and obtaining permission from them in that center, the research objectives will be fully explained to them, and If they wish to participate in the research, the informed consent form will be completed by them. Selects those who have the criteria to enter the research in a continuous manner, which is based on the statistical formula of 50 people. After reaching the sample size due to the corona pandemic, training of the samples is done in a suitable space by observing the distance and health protocols in person. Due to the large number of samples for better teaching and learning and

observing the social distance, the samples are divided into four groups and training of these four groups is done in one day but at different hours. Coordination with the samples is done for the date and time of the training session. After the pre-test session, which includes two questionnaires: 1- Demographic information and 2- Pittsburgh questionnaire, it is completed in person at the Emas Association. The time allotted for filling out this questionnaire is 5-10 minutes. Then, after collecting questionnaires about sleep hygiene and how to use music, the necessary training in person, which includes lying down in a comfortable position and closing your eyes before listening to non-verbal and soothing music and focusing on it. The mental opinion that is accompanied by the sound of nature should be mentioned. It should be mentioned that music is without words and only the sound of nature and has a license from the Ministry of Guidance. 30 minutes before bedtime is given without headphones. Also, explanations about sleep hygiene are provided in person. Before going to bed, use the bed only for sleep and sex, do not take a nap during the day, take a shower, do not watch the clock, exercise, eat a healthy and balanced diet, a good atmosphere, maintain a daily schedule. The instructional booklet and music without words will be provided to the samples. In addition, the researcher's contact phone will be provided to the samples to remove any ambiguity and questions, so that the researcher can follow up by phone to control the condition of the samples. Post-test intervention will be filled electronically by the sample due to the prevalence of coronary pandemic. After collecting the questionnaires, data and scores related to each section of the questionnaire are calculated.

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Iran MS society

##### Full name of responsible person

Fatemeh Sadeghi

##### Street address

No. 35, Shahid Mohammad Shams Alley, Vesal Shirazi St., Enghelab Ave

##### City

Tehran

##### Province

Tehran

##### Postal code

1416864731

##### Phone

+98 21 6695 1187

##### Email

fatemeh.sadeghi.1393@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Hosein Keyvani

##### Street address

Rashid Yasemi St. Vali Asr Ave

##### City

Tehran

##### Province

Tehran

##### Postal code

۱۹۹۶۷۱۳۸۸۳

##### Phone

+98 21 4365 1000

##### Email

fnm@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

Fatemeh Sadeghi

##### Position

MSc in Rehabilitation Nursing student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Nursery

##### Street address

Unit 7, No. 2, Dariush Dead End, Shabboo Alley, Besarati St, Shahin shomali Ave, Janatabad

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Fatemeh Sadeghi

**Position**

MSc in Rehabilitation Nursing Student

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Bachelor

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## Person responsible for updating data

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Iran University of Medical Sciences

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All potential data can be shared after unidentified individuals

**When the data will become available and for how long**

The data can be published after the publication of the article

**To whom data/document is available**

There are no restrictions on access

**Under which criteria data/document could be used**

It can be used in secondary studies and for researchers

**From where data/document is obtainable**

The information will be available as a file attached to the article

**What processes are involved for a request to access data/document**

By search

**Comments**