Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

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

Protocol summary

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
improve the quality of sleep

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)

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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

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

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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

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Phone
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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
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Person responsible for updating data

Contact

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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