

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Effect of Music Therapy on Pain Intensity and Sleep Quality of Patients with Multiple Sclerosis

Protocol summary

Study aim

Effect of Music Therapy on Pain Intensity and Sleep Quality of Patients with Multiple Sclerosis.

Design

This study is a clinical trial type between two control and intervention groups in parallel and without blinding, randomized, on 60 patients. STATA software is used for randomization.

Settings and conduct

The Place of Implementation of the study is the Comprehensive Center for MS Patients in Ghaem Hospital in Mashhad. The research population includes Multiple Sclerosis patients. Blinding was not done in this study.

Participants/Inclusion and exclusion criteria

Inclusion Criteria include Patients with MS who have been Diagnosed with Relapsing-Remitting type of the Disease for a Year. Exclusion Criteria include Not Wanting to Participate in the Study and Changing the Course of Disease Recurrence.

Intervention groups

In the intervention group, people listened to the selected wordless music for 14 days, three times a day (morning between 7 and 9, evening between 4 and 6, night between 9 and 11) and each time for 15- They will listen for 10 minutes while waking up or resting. The control group will receive only their routine treatments prescribed by their doctor. Questionnaires will be completed by people before the intervention and 14 days after the intervention.

Main outcome variables

Pain Intensity; Sleep Quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231001059576N1**

Registration date: **2023-11-04, 1402/08/13**

Registration timing: **prospective**

Last update: **2023-11-04, 1402/08/13**

Update count: **0**

Registration date

2023-11-04, 1402/08/13

Registrant information

Name

Milad Rezaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-01, 1402/09/10

Expected recruitment end date

2024-02-29, 1402/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Music Therapy on Pain Intensity and Sleep Quality of Patients with Multiple Sclerosis

Public title

The Effect of Music on Pain Intensity and Sleep Quality

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Refer to the Comprehensive Center for MS patients located in Qaem Hospital Diagnosis of Multiple Sclerosis by a Specialist Doctor in the last year Age between 20 and 50 Years Patients with Relapsing-Remitting MS who are in the Recovery Phase of the Disease Extended Disability Status Scale or EDSS between 0 and 5.5 Undesirable of Sleep Quality based on the Pittsburgh Sleep Quality (score above 5) No addiction Not Regularly Listening to a Particular Style of Music

Exclusion criteria:

Unwillingness to Continue Participating in Research Not listening to Music for 3 Nights in a Row or Alternately Changing the Process of Disease Recurrence Suffering from other Acute or Chronic Debilitating Diseases or Mental Disorders Taking Sleeping Pills The Presence of a Musician among those who live with the Patient under the Same Roof Employment in the music profession

Age

From **20 years** old to **50 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

The random sequence is generated by STATA software. Then this sequence is written on small cards and placed in the closed envelope. Every qualified person who entered the study, the door of the envelope is opened and based on the code on the card, he is placed in one of two groups. This method continues until all people are assigned to two groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The method of choosing the desired theme will be based on Schubert's articles regarding the feeling of musical steps. In this way, after selecting the desired Music determined by the researcher and a music expert, they will be placed in their desired theme group. The reason for choosing three types of happy, sad and invigorating themes is the effect of these themes on people's mood, which according to past research studies, happy themes are rhythmic pieces with a relatively sharp melody that bring vitality and vitality. It inspires excitement and impatience and is associated with stability and calm; Sad themes are sad and glorious and evoke sadness, failure, sorrow and regret in the listener. Sad themes by stimulating and associating memories and releasing sad feelings cause sympathy and relief. Invigorating themes,

powerful rhythm and stimulating melodies with a positive and pleasant feeling give more energy and strength than what excites the spirit. These pieces, like a pleasant and pleasant shock, turn depression, laziness and lethargy into mobility and create a feeling of ability, mastery and determination. In general, the purpose of choosing the music was to start softly and end with hope and excitement after creating a sense of unity.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Faculty of Nursing and Midwifery - Mashhad University of Medical Sciences

Street address

Educational Complex of Shahid Dr. Kharazmi, University Campus, east gate of Ferdowsi University of Mashhad, Azadi Square, Mashhad, Khorasan Razavi

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Approval date

2023-10-17, 1402/07/25

Ethics committee reference number

IR.MUMS.NURSE.REC.1402.089

Health conditions studied

1

Description of health condition studied

Patients with Relapsing-Remitting Multiple Sclerosis who are in the Recovery Phase.

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes

1

Description

Pain Intensity

Timepoint

Pain Intensity will be Measured in the Research Units Participating in the study at the Beginning of the Study (Before the Start of the Intervention) and 14 Days After the Start of the Intervention.

Method of measurement

In this study, Pain Intensity will be Measured Using the McGill Pain Questionnaire

2

Description

Sleep Quality

Timepoint

Pain Intensity will be Measured in the Research Units Participating in the study at the Beginning of the Study (Before the Start of the Intervention) and 14 Days After the Start of the Intervention.

Method of measurement

In this study, Sleep Quality will be Measured Using the Pittsburgh Sleep Quality Index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with Multiple Sclerosis who will Receive Music Therapy in Addition to their Medications Prescribed by their Doctor. Music Therapy is Performed Three Times a Day for Two Weeks (Morning between 7 and 9, Evening between 4 and 6 and Night between 9 and 11) and each time for 10 to 15 Minutes During Waking hours. Or they will Rest and Listen to the Silent Music in Three Themes, Joyful, Sad and Invigorating, Composed by Iranian and Foreign Composers and Approved by Experts and Experts.

Category

Treatment - Other

2

Description

Control group: In this Group, They Will Take the Usual Treatment Interventions Prescribed by Their Doctor, And Music Therapy will not be Done for this group.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive Center for MS Patients

Full name of responsible person

Hamid Reza Zendehtalab

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Hamid Reza Zendehtalab

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

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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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All the data obtained from this research will be shared after completion.

When the data will become available and for how long

Access to the data will be possible 3 months after the results are published.

To whom data/document is available

These data will be used for researchers working in academic and scientific institutions, as well as for people with multiple sclerosis.

Under which criteria data/document could be used

The data obtained from this research can be used in other scientific studies.

From where data/document is obtainable

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

The applicant should send an email to the responsible author and register his request. After verifying the correctness of the information of the mentioned person, the required content will be provided to him by mentioning the source.

Comments