Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the effect of guided mental imagery on motor dysfunction and balance of patients with multiple sclerosis (MS)

Protocol summary

Study aim
Determining the effect of guided mental imagery on motor dysfunction and balance in patients with multiple sclerosis

Design
A clinical trial study of two groups (intervention and control), double-blind, available sampling among the patients referred to the desired treatment centers and simple random assignment of samples in two groups using a computer random number table, one phase on 60 Patient

Settings and conduct
The intervention in this study is in the form of nature-based guided mental imagery audio file.Patients will be divided into intervention and control groups. Double-blind study will be conducted without informing the participants and the statistician.People in two groups will perform a 6-minute-walk, 25-foot-walk and Berg balance test. The intervention group will listen to the audio file and perform the tests again, while the control group will perform the three tests again without receiving any intervention

Participants/Inclusion and exclusion criteria
Patients with multiple sclerosis such as RRMS, PPMS and SPMS, who have been diagnosed for at least one year, are between the ages of 18 and 60, are not under new treatment or high doses of steroids, have good hearing ability, and have a history of do not have any underlying disease that can affect their usual movement ability and can walk at least 50 meters in a six-minute walking test before the intervention, they have the conditions to enter the study, and they will be excluded from the study if they are pregnant

Intervention groups
The intervention group includes 30 patients with MS, eligible to enter the study, who will perform three study tests after listening to the guided mental imagery audio file for 15 minutes. The control group includes 30 eligible patients who will perform three research tests without receiving any intervention

Main outcome variables
Improving walking ability and balance of patients after intervention

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220614055170N1**
Registration date: **2023-11-11, 1402/08/20**
Registration timing: **prospective**

Last update: **2023-11-11, 1402/08/20**
Update count: **0**

Registration date
2023-11-11, 1402/08/20

Registrant information

Name
Atena Shojaie

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-21, 1402/09/30

Expected recruitment end date
2024-02-19, 1402/11/30

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of guided mental imagery on motor dysfunction and balance of patients with multiple sclerosis (MS)

Public title
Effect of guided mental imagery on motor dysfunction and balance of patients with MS
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Suffering from Multiple Sclerosis such as Relapsing-Remitting MS (RRMS), Primary progressive MS and Secondary progressive MS with the confirmation and diagnosis of the relevant doctor Ability to communicate in Persian Acceptable speaking ability Acceptable listening ability to clearly hear the researcher's voice and the audio file Age range between 18 and 60 years The ability to walk at least 50 meters using the patient's usual mobility aids such as canes, walkers, etc. in a six-minute walking test before the intervention Not suffering from any primary neurological, psychological, cardiac, respiratory and other diseases such as osteoarthritis or rheumatoid arthritis, etc., which affect the patient's usual movement ability. Failure to participate in a rehabilitation program or physical activity that improves and helps the disease for at least the last two months, or changing treatment in a way that affects the patient's mobility (physiotherapy or drug therapy) No use of high doses of steroids in the past month, which is defined as high-dose steroid therapy according to the following protocol: steroid use of 50 mg/day intravenously (IV) for six days, 40 mg intramuscularly (IM) for For more than 15 days, 20 mg intramuscularly for more than 30 days Not experiencing any severe clinical relapse in the disease in the past month Getting a score between 1 and 6.5 on the Extended Disability Status Scale (EDSS) means mild to moderate disability. At least one year has passed since the diagnosis of MS
Exclusion criteria:
pregnancy
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
After preparing the list of patients with multiple sclerosis in the desired centers, who meet the inclusion criteria, each patient will be given a number and then the people will be divided into two intervention and control groups according to the table of random numbers by computer.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the participants, after declaring their desire to participate in the research and obtaining informed consent, were blinded to their allocation in the intervention and control groups. Also, the statistician who will finally analyze the results would kept blind from the allocation of people in two groups
Placebo
Not used
Assignment
Factorial
Other design features
The intervention in this study is in the form of nature-based guided mental imagery through the playback of an audio recording by the researcher and its confirmation by the experts in this field, through the Anker Soundcore Life 2 Neo headset with the ability to produce powerful and high-quality sound for the patient. The maximum content playback time is 15 minutes. The theme of the broadcasted file is focused on depicting a view of nature in the form of natural landscapes with accompanying sounds, while the content of that landscape, smells, sounds, sensations, etc. is reported in it. The people present in both groups will perform the 6-minute walk test and the 25-foot walk test once, and their balance will be evaluated by the Berg balance scale by the researcher and under the supervision of the relevant doctor of the project. Then, the people in the intervention group will listen to the guided mental imagery audio file for 15 minutes, and then they will perform both tests again and their balance will be evaluated by the Berg scale. Patients are given a 15-minute rest between each test. People in the control group will do all three tests again after 15 minutes of rest without listening to any audio files. In order to avoid the collision of samples in the two control and intervention groups and the possibility of exchanging information, the two groups will be examined separately on different days but under the same conditions and at the same hours of the day. It should be noted that due to the possible influence of factors such as the duration of MS, the two intervention and control groups will be matched before the intervention.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kerman University of Medical

Sciences

Street address
Kerman University of Medical Sciences, The beginning of HaftBaghAlavi Highway, ImamKhomeini Highway

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Kerman

Province
Kerman

Postal code
7616913555

Approval date
2023-10-29, 1402/08/07

Ethics committee reference number
IR.KMU.REC.1402.289

Health conditions studied

1

Description of health condition studied
Motor and balance dysfunction

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The degree of motor dysfunction of the patient

Timepoint
Measuring the severity of motor dysfunction before and after the intervention

Method of measurement
6-minute walk test and 25-foot walk test

2

Description
The degree of the patient's balance disorder

Timepoint
Measuring the severity of balance disorders before and after the intervention

Method of measurement
Berg Balance scale

Secondary outcomes

1

Description
The degree of motor dysfunction and balance of the patient

Timepoint
Measuring the severity of motor and balance dysfunction before and after the intervention

Method of measurement
Six-minute walk test, 25-foot walk test, Berg balance scale

Intervention groups

1

Description
Intervention group: Includes 30 eligible patients, who will perform six-minute walk, 25-foot walk, and balance tests after listening to a guided mental imagery audio file

Category
Treatment - Other

2

Description
Control group: Including 30 eligible patients, who will perform the six-minute walk, 25-foot walk and balance test without receiving any intervention.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shafa Medical Education Center

Full name of responsible person
Atena Shojaie

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Assistance for Research and Technology of Kerman University of Medical Sciences

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Web page address

https://kmu.ac.ir

Grant name

Research has no financial cost

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Atena Shojaie

Position

Master of medical surgical nursing

Latest degree

Master

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

Master of Medical Surgical nursing

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Person responsible for updating data

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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

The data results from the intervention performed in both the intervention and control groups, including the comparison of the amount of motor disorder and balance before and after, the possible impact of information and individual characteristics of people on data changes, as well as strategies for better implementation of such intervention and limiting factors during the research, has the possibility to share

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

University faculty members, educational, therapeutic, research centers, general public

Under which criteria data/document could be used

It is allowed to use the results of this research to educate nursing students, apply them in the clinical field, continuous training of nursing staff, and for managers of clinical departments and rehabilitation centers to make appropriate decisions.

From where data/document is obtainable

Access through the site of TarjomanDanesh, assistence for Research and Technology of Kerman University of Medical Sciences: https://vresearch.kmu.ac.ir Or via the following email address: shojaie.atena79@gmail.com

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

The research documents will be available six months after the publication of the results on the site of TarjomanDanesh or via the mentioned email

Comments