Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The study of effectiveness of Guided Imagery on fatigue, stigma, and mood in patients with Multiple Sclerosis

Protocol summary

Study aim

Determine of the effect of Guided Imagery on fatigue, stigma, and mood in patients with Multiple Sclerosis

Design

This study is a clinical trial with two groups (intervention and control), double blinded (the data analyst and participants) and randomized, with 30 patients in each group.

Settings and conduct

This double blinded study (the data analyst and participants), will be done in the Kerman Medical Center of the Special Diseases. In the intervention group, 48 sessions of Guided Imagery will be performed in 4 weeks and six sessions per week in two turns at the morning (between 08:00 and 09:00) and in the evening (between 20:00 and 21:00). The variables will be measured before and four weeks after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Full consciousness؛ acceptable ability to hear, see and speak؛ have ability to read and write in Persian language؛ diagnosis of Relapsing-Remitting Multiple Sclerosis by neurologist؛ getting a degree of fatigue less than average 6 based on Fatigue Severity Scale (FSS) questionnaire; Use of sedatives, antidepressants and narcotics؛ No existence of a history of mental illness and hospitalization continuously؛ No other neurological disorders؛ No previous experience use of relaxation techniques (including Guided Imagery).

Intervention groups

In the intervention group, 48 sessions of Guided Imagery will be performed in 4 weeks and six sessions per week in two turns at the morning (between 08:00 and 09:00) and in the evening (between 20:00 and 21:00), While patients in the control group will receive routine care. The severity of fatigue, stigma, and mood score will be measured before and four weeks after the intervention.

Main outcome variables

Fatigue, Stigma and Mood

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151107024919N11**
Registration date: **2020-10-22, 1399/08/01**
Registration timing: **retrospective**

Last update: **2020-10-22, 1399/08/01**
Update count: **0**

Registration date

2020-10-22, 1399/08/01

Registrant information

Name

Batoul Tirgari

Name of organization / entity

Kerman Medical University of Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 3132 5207

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The study of effectiveness of Guided Imagery on fatigue, stigma, and mood in patients with Multiple Sclerosis

Public title
Effect of Guided Imagery on fatigue, stigma, and mood in patients with Multiple Sclerosis

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Full consciousness Acceptable ability to hear, see and speak Have ability to read and write in Persian language Diagnosis of Relapsing-Remitting Multiple Sclerosis by neurologist Getting a degree of fatigue less than average 6 based on Fatigue Severity Scale (FSS) questionnaire

Exclusion criteria:
Use of sedatives, antidepressants and narcotics Existence of a history of mental illness and hospitalization continuously Getting other neurological disorders Previous experience use of relaxation techniques (including Guided Imagery)

Age
From **18 years** old to **70 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
In order to allocate the subjects to the intervention and control groups,a randomized block method is used, Block randomization method is a method in which participants are randomly selected in terms of severity of fatigue, type of disease, duration of illness, numbers of recurrences per year, family history of the Multiple sclerosis disease, etc are placed in the blocks. Subsequently, through the use of a simple method and using R Test from each group, half of the subjects are placed in the intervention group and the other half are in the control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
Given that the intervention takes place at home; this study is double-blind. the data analyst do not know which data is related to the intervention group and which data is related to the control group, and participants do not know in which intervention or control group they were placed.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Medical Center of the Special Diseases., No. 78 Alley., Shahid Rajaee Street.,

City
Kerman

Province
Kerman

Postal code
7619875994

Approval date
2020-07-06, 1399/04/16

Ethics committee reference number
IR.KMU.REC.1399.263

Health conditions studied

1

Description of health condition studied
Multiple sclerosis

ICD-10 code
G35

ICD-10 code description
Multiple sclerosis

Primary outcomes

1

Description
Fatigue

Timepoint
The severity of fatigue will be measured before and four weeks after the end of the intervention

Method of measurement
Fatigue severity scale

2

Description
Stigma

Timepoint
The severity of stigma will be measured before and four weeks after the end of the intervention

Method of measurement
Reece Stigma Scale_Multiple Sclerosis

3

Description

Mood

Timepoint

The severity of mood will be measured before and four weeks after the end of the intervention

Method of measurement

Profile Of Mood State

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, 48 sessions of guided imagery will be performed in 4 weeks and six sessions per week in two turns at the morning (between 08:00 and 09:00) and in the evening (between 20:00 and 21:00). Morning and evening sessions will be held at the patient's home. Patients will listen to the Audio- Recorded Guided Imagery Script for 25 minutes via headphone and will follow the instructions. Also, disturbing noises will be controlled through meetings formation in quiet rooms. Also at home, it is attempted to allocate a room for the patient to listen to the Audio-Recorded Guided Imagery Script with the coordination of the patient and the family.

Category

N/A

2

Description

Control group: Patients in the control group received routine cares.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Medical Center of the Special Diseases

Full name of responsible person

Batool Tirgari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhti

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No 2, Research and Technology Dept., Ibn Sina Ave., Kerman

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Web page address

http://kmu.ac.ir/fa/vcrt

Grant name

Grant code / Reference number

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

No

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

Batool Tirgari

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Batool Tirgari

Position
Associate professor

Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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

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

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

Clinical Study Report
Undecided - It is not yet known if there will be 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
Not applicable