Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effectiveness of educational intervention through pictograms on fatigue and sleep quality of patients with Multiple Sclerosis

Protocol summary

Study aim

Determining the effectiveness of educational intervention through pictograms on fatigue and sleep quality in patients with multiple sclerosis

Design

This is a quasi-experimental study, with a sample size of 40 people in each group, based on the formula and findings of a similar study, with a 10% dropout rate. Convenience sampling will be used and the subjects will be assigned to two experimental and control groups using the card method.

Settings and conduct

MS Association of Shahrekord, intervention continues for 2 months Blinding of participants and statistical analyst

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-Confirmation of the disease by a neurologist 2-Age range between 20 and 50 years 3-No history of underlying diseases such as orthopedic, cardiovascular diseases, epilepsy, anemia 4- No history of mental disorder such as uncontrolled depression according to the diagnosis and confirmation of the doctor 5-No history of drug addiction and smoking 6-EDSS score between zero and 5 7-Awareness of the type of disease and willingness to participate in the study 8-Ability to read and write in Persian Exclusion criteria: 1-Unwillingness to continue participating in the study 2-The extent of the individual's disability, confirmed by the attending physician and determined by the EDSS score, indicates that the patient is unable to continue participating in the study. 3- Occurrence of an acute attack of the disease during the study

Intervention groups

For the experimental group, educational intervention-educational pictograms will be used, for the control group, only routine care will be provided and the researcher will not have a role in implementing this care.

Main outcome variables

The outcome variables are fatigue severity and sleep quality.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240630062284N1**
Registration date: **2025-06-06, 1404/03/16**
Registration timing: **prospective**

Last update: **2025-06-06, 1404/03/16**
Update count: **0**

Registration date

2025-06-06, 1404/03/16

Registrant information

Name

Komeil Zamani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3776 4013

Email address

komeilzamani20@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-07-23, 1404/05/01

Expected recruitment end date

2025-12-21, 1404/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of educational intervention through pictograms on fatigue and sleep quality of patients with Multiple Sclerosis

Public title

Investigating the effectiveness of educational intervention through pictograms on fatigue and sleep quality of patients with Multiple Sclerosis

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Confirmation of the disease by a neurologist Age range between 20 and 50 years No history of underlying diseases such as orthopedic, cardiovascular diseases, epilepsy, anemia No history of mental disorder such as uncontrolled depression as diagnosed and confirmed by a doctor No history of drug addiction and smoking EDSS score between zero and 5 Awareness of the type of disease and willingness to participate in the study Ability to read and write in Persian

Exclusion criteria:

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients who meet the inclusion criteria will be enrolled into the study using convenience sampling and will be divided into two equal intervention and control groups using block randomization with equal block sizes. Sealed envelopes will be used to ensure allocation concealment.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants are aware of the purpose of the study but not the type of educational intervention. The data analyst will not have a role in data collection and statistical analysis will be performed in a blinded manner.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahrekord University of Medical Sciences

Street address

Shahrekord, Kashani Blvd., University Headquarters

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

۸۸۱۵۷۱۳۴۷۱

Approval date

2023-05-30, 1402/03/09

Ethics committee reference number

IR.SKUMS.REC.1402.036

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

Score obtained from completing the Pittsburgh Sleep Questionnaire

Timepoint

Two months after the start of the intervention

Method of measurement

Pittsburgh Sleep Quality Questionnaire

2

Description

Score obtained from the FSS fatigue scale

Timepoint

Two months after the start of the intervention

Method of measurement

fatigue severity scale questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Two months of use of pictogram content (including key points about the nature of the disease and medications, activity and diet before bedtime, stress management, principles of a balanced rest and activity schedule, and energy conservation)
Category
Treatment - Other

2

Description
Control group: For the control group, only routine care will be provided, and the researcher will have no role in implementing this care.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Chaharmahal and Bakhtiari Province MS Patients Support Association (Shahrekord County)
Full name of responsible person
dr. asghar bayati
Street address
Deputy of Research and Technology, Shahrekord University of Medical Sciences, Kashani Blvd., Shahrekord, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
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Email
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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
Shahre-kord 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
Shahre-kord University of Medical Sciences
Full name of responsible person
Shirmohammad Davoodvand
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for scientific inquiries

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Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Full name of responsible person

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Assistant Professor

Latest degree

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Other areas of specialty/work

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Phone

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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

Not applicable

Title and more details about the data/document

Biographical data such as age and gender are essential for better presentation of research results, and since this data is anonymous, there is no reason not to publish it.

When the data will become available and for how long

Due to the anonymity and coding of the data, they will be available after the study is completed.

To whom data/document is available

This data will be accessible to various health professionals and researchers.

Under which criteria data/document could be used

No analysis of this data is permitted and it will only be used for comparison with and citation of results from other studies.

From where data/document is obtainable

The download of the resulting article will be done according to the policy of the journal that publishes it. Therefore, the use of biographical data tables and other sections of the journal is possible after downloading. The email address of the responsible author included in the article will be available for communication with other authors and for guidance.

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

For this purpose, the applicant can contact the office of the journal that published the article, the corresponding author, and the Vice President for Research of Shahrekord University of Medical Sciences. The duration of access depends on the policy of the journal and the Vice President for Research of the university, but the corresponding author will respond to the request of colleagues within a week.

Comments