

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### the effect of self-care training with telenursing method on fatigue and stress of multiple sclerosis patients

#### Protocol summary

##### Study aim

general purpose: Determining the effect of self-care training with telenursing method on fatigue and stress of multiple sclerosis patients in Zahedan City in 2023  
Specific goals: 1- Determining and comparing the average fatigue score of multiple sclerosis patients in two control and intervention groups before and after the intervention 2- Determining and comparing the average stress score of multiple sclerosis patients in two control and intervention groups before and after the intervention

##### Design

Clinical trial with control group, with parallel groups, randomized, on 80 patients.

##### Settings and conduct

The researcher will collect data by referring to the Zahedan MS Association. information about individual characteristics, severity of fatigue; And stress will be completed by the researcher through the interview method. Became. After 8 weeks (the end of the intervention), the questionnaires are completed again.

##### Participants/Inclusion and exclusion criteria

Entry requirements: - Being literate in reading and writing - File in MS forum -Access to mobile phone and internet - At least 1year history of the disease - Obtaining a score of 4 or less than 4 on the EDSS scale of extensive disability status - Do not be part of the treatment team  
Non-entry conditions: - The person's lack of consent to continue the research

##### Intervention groups

In the intervention group, the fatigue and stress self-care training program will be communicated to patients in the form of podcasts and videos through the site. Every week for 6 weeks, training will be uploaded on the site on Saturdays. In the control group, the patients receive routine training provided by the MS Association.

##### Main outcome variables

In this study, the results of fatigue and stress in two intervention and control groups were evaluated before

and after the intervention.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20231230060571N1**

Registration date: **2024-03-04, 1402/12/14**

Registration timing: **retrospective**

Last update: **2024-03-04, 1402/12/14**

Update count: **0**

##### Registration date

2024-03-04, 1402/12/14

##### Registrant information

##### Name

shaghayegh Roshanghiyas

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 54 3328 9595

##### Email address

roshanshaghayegh78@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-06-22, 1402/04/01

##### Expected recruitment end date

2024-01-21, 1402/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

the effect of self-care training with telenursing method on fatigue and stress of multiple sclerosis patients

### Public title

the effect of self-care training with telenursing method on fatigue and stress of multiple sclerosis patients

### Purpose

Education/Guidance

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Being literate in reading and writing Having a file in the MS forum Mobile phone and internet access At least 1 year history of the disease Obtaining an EDSS score of 4 or less than 4 on the extensive disability status scale (adequate ability for self-care) Do not be part of the treatment team

#### Exclusion criteria:

The person's lack of consent to continue the research The occurrence of a severe stressful event during the research

### Age

No age limit

### Gender

Both

### Phase

N/A

### Groups that have been masked

No information

### Sample size

Target sample size: 80

### Randomization (investigator's opinion)

Randomized

### Randomization description

The research units will be selected in an accessible way and will be assigned to two control and intervention groups using a simple random allocation method. In this way, the first sample will be placed in the intervention or control group by lottery, and after that, the research units will be placed in groups in the middle.

### Blinding (investigator's opinion)

Not blinded

### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Zahedan university of Medical

Sciences

### Street address

Zibashahr neighborhood, Alborz St., Kosar East St., P.878

### City

Zahedan

### Province

Sistan-va-Balouchestan

### Postal code

9817945669

### Approval date

2023-06-10, 1402/03/20

### Ethics committee reference number

IR.ZAUMS.REC.1402.069

## Health conditions studied

### 1

#### Description of health condition studied

Multiple Sclerosis

#### ICD-10 code

G35-G37

#### ICD-10 code description

Diseases of the nervous system

## Primary outcomes

### 1

#### Description

Fatigue score in the Fatigue Severity Questionnaire (FSS)

#### Timepoint

At the beginning of the study and 56 days after the beginning of the study

#### Method of measurement

Fatigue Severity Questionnaire (FSS)

### 2

#### Description

Stress score in the perceived stress questionnaire of Cohen et al

#### Timepoint

At the beginning of the study and 56 days after the beginning of the study

#### Method of measurement

perceived stress questionnaire of Cohen et al

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: The fatigue and stress self-care training program will be informed to the patients in the form of podcasts and videos through the site, and the patients will be taught about the website address and

how to use it. Every week for 6 weeks, one training will be given on the site on Saturdays. It will be loaded. patients will be able to ask the researcher their questions by leaving a text or voice message at any time, and the researcher will answer them in the form of a podcast or text message.

**Category**

Other

**2****Description**

Control group: Patients receive routine education provided by the MS Society.

**Category**

Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Zahedan MS Association

**Full name of responsible person**

Ghulam Abdi

**Street address**

Azadegan Blvd., after Shahid Mazari intersection, next to Sadaf Real Estate Company

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

ندارد

**Phone**

+98 54 3343 8108

**Fax****Email**

a3920365@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Abraham Kord

**Street address**

Zahedan - Doctor Hasabi Square - Medical Sciences Campus

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

-

**Phone**

+98 54 3337 2151

**Email**

info@zaums.ac.ir

**Web page address**

https://zaums.ac.ir/

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Zahedan University of Medical Sciences

**Proportion provided by this source**

60

**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**

Zahedan University of Medical Sciences

**Full name of responsible person**

Shaghayegh Roshanghiyas

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

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**Province**

Sistan-va-Balouchestan

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333289595

**Email**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

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roshanshaghayegh78@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Zahedan University of Medical Sciences  
**Full name of responsible person**  
Shaghayegh Roshanghiyas  
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Student  
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**Email**  
roshanshaghayeg76@gmail.com

## 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

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