

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

Zahedan University of Medical Sciences

Full name of responsible person

Shaghayegh Roshanghiyas

Position

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
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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

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