Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

Impact of telephone counseling and follow-up on fatigue, pain and quality of life of Multiple Sclerosis patients: a randomized clinical trial in two groups (experimental and control)

Protocol summary

Summary

Objectives: effect of telephone counseling and follow-up on fatigue, pain, and quality of life in multiple sclerosis patients. Design: randomized clinical trial. Setting and conduct: Multiple Sclerosis patients who will refer to Multiple Sclerosis Clinic of Sina Farshchian educational hospital in Hamadan Iran. Inclusion criteria: diagnosis of the disease by a neurologist; age over 18 years; history of the disease for at least 6 months; lack of relapse; lack of any other acute or chronic disease; mobile access and lack of any cognitive or psychological disorder. Exclusion criteria: no ability to continue participation to any reason (such as accident, death or moving to another city); hospitalization during the study period; no willingness to continue participation in study; no possibility to cell phone connection. Interventions: At the first, the patients in the intervention and control groups will receive an educational package. Then, telephone counseling and follow-up intervention will be conducted, lasting 5-15 minutes, according to the established agreement, between eight morning and eight evening. The telephone counselling and follow-up plan is as follows: at the first week, researcher will conduct two counselling calls about the treatment plan (providing advice on how properly take drugs according to the physician's orders). At second week, researcher will conduct two phone calls focusing on a diet plan which involves consuming proper foodstuffs, the importance of maintaining a healthy diet, appropriate nutrition for controlling bladder problems and constipation, appropriate nutrition for controlling chewing and swallowing problems and role of vitamins in recovery of multiple sclerosis disease. In third week, researcher will conduct two phone calls addressing the importance of exercise, recommended activities, and advice on how to do them. At forth week, researcher will conduct two phone calls focusing the role of stress in relapsing the symptoms and decreasing stress. During the second 4-week period, all the content of delivered educational package will be reviewed by making one follow-up call every week. Patients could freely call the researcher for counseling if they have any questions. The control group will receive only routine care. Measurement of major consequences: Fatigue, pain, and quality of life will be assessed by Croup Fatigue Questionnaire before and after the intervention; the pain will be assessed using the visual analogue scale before and after the intervention, and MSQol-54 by questionnaire before and after the intervention. Main outcome measures (variables) are fatigue, pain and quality of life.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017052734161N1**
Registration date: **2017-09-01, 1396/06/10**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-09-01, 1396/06/10

Registrant information

Name

Sakineh Abdolmaleki

Name of organization / entity

Hamadan University of Medical Sciences

Country

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Recruitment status
Recruitment complete
Funding source
Vice chancellor for research, Hamadan University of Medical Science

Expected recruitment start date
2017-06-21, 1396/03/31
Expected recruitment end date
2017-09-21, 1396/06/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Impact of telephone counseling and follow-up on fatigue, pain and quality of life of Multiple Sclerosis patients: a randomized clinical trial in two groups (experimental and control)

Public title
Impact of telephone counseling and follow-up on fatigue, pain and quality of life in Multiple Sclerosis patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: diagnosis of the disease by a neurologist; age over 18 years; history of the disease for at least 6 months; lack of relapse; lack of any other acute or chronic disease; mobile access; lack of any cognitive or psychological disorder. Exclusion criteria: no ability to continue participation for any reason (such as accident, death or moving to another city); hospitalization during the study period; lack of willingness to continue participation in study; no possibility of cell phone connection.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
1
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Conventional sampling using block randomization method in groups (balances) and completely random in two intervention groups (patients with telephone counseling and follow-up) and control (routine care) Will be placed.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Hamadan University of Medical Sciences
Street address
Hamadan University of Medical Sciences, Shahid Fahmide boulvard،Hamadan
City
Hamadan
Postal code
6517838698
Approval date
2017-05-27, 1396/03/06
Ethics committee reference number
IR.UMSHA.REC.1396.183

Health conditions studied

1

Description of health condition studied
Multiple sclerosis
ICD-10 code
G35-G37
ICD-10 code description
Demyelinating diseases of the central nervous system

2

Description of health condition studied
Fatigue
ICD-10 code
R53
ICD-10 code description
Malaise and fatigue

3

Description of health condition studied
Pain
ICD-10 code
R25-R29
ICD-10 code description
Symptoms and signs involving the nervous and musculoskeletal system

4

Description of health condition studied
Quality of life
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Fatigue
Timepoint
Before and after intervention
Method of measurement
Fatigue Severity Scale for patient with multiple sclerosis

2

Description
pain
Timepoint
Before and after intervention
Method of measurement
Visual analog scale

Secondary outcomes

1

Description
Quality of life
Timepoint
Before and after intervention
Method of measurement
MSQoL-54 questionnaire

Intervention groups

1

Description
Intervention group: an educational package will be delivered to all patients. Then, two months telephone counseling and follow-up program will be conducted, lasting for 5-15 minutes by phone call agreement between eight morning and eight evening. The telephone follow-up plan is as follows: two phone calls at first week about treatment plan (providing advice on how to properly take drugs according to the physician’s orders) two phone calls at second week focusing on a diet plan which involves consuming appropriate foodstuffs, the importance of maintaining a healthy diet, appropriate nutrition to control bladder and constipation problems,appropriate nutrition to control chewing and swallowing problems, and the role of vitamins in the disease; two phone calls at third week addressing the importance of exercise, recommended activities, and advice on how to do them; two phone calls at forth week focusing on the role of stress in relapsing of symptoms and methods to decreasing stress; and during the second 4-week period, all the contents delivered within the first 4 weeks will be reviewed by making one follow-up call every week. Patients are free to call the researcher to receive counseling if they have any questions.
Category
Treatment - Other

2

Description
Control group: Patient Control group will receive Educational package and routine care will receive.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Farshchian Educational hospital (MS clinic)
Full name of responsible person
Sakineh Abdolmaleki
Street address
Sina Farshchian educational hospital of Hamadan، Mirzadeheshghi street.
City
Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research and Technology of Hamadan University of Medical Sciences
Full name of responsible person
Dr. Saeid Bashirian
Street address
Hamadan University of Medical Sciences, Shahid Fahmide boulevard, Hamadan
City
Hamadan
Grant name
از محل یک درصد بودجه طرح های تحقیقاتی دانشگاه
Grant code / Reference number
IR.UMSHA.REC.1396.183
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research and Technology of Hamadan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Department of health economics and management

Full name of responsible person
Dr. Ali bikmoradi

Position
Doctor of health and treatment management

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)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty