Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of relaxation on pain, fatigue and quality of life in women with multiple sclerosis

Protocol summary

Summary

Objective: Effect of relaxation on pain, fatigue and quality of life in women with multiple sclerosis. Design: Randomized clinical trial at two groups of intervention and control. The studied population: Patients of woman with multiple sclerosis who will refer to MS Association, Sample population: 70 people at two groups of intervention and control. Setting: patients with multiple sclerosis who will refer to MS Association with following criteria to be studied: (a) definite diagnosis of multiple sclerosis by neurologist; (b) age 20-45; (c) do not have acute illness; (d) EDSS (Expanded Disability Status Scale) is equal or less than 4/5; (e) to have pain and fatigue symptoms. The patients will be excluded from the study with the following criteria: (a) being disable to continue for participating in sessions for any reason; (b) being hospitalized. Interventions: relaxation will be done in way of Jacobson on 12 sessions of forty to sixty minutes, during four weeks at intervention group. Patients will be received routine cares at control group. Measurement of main outcome: pain, fatigue and life's quality will be studied in accordance with questionnaires as follows: (a) pain will be evaluated by visual pain scale before and eight weeks after intervention; (b) fatigue will be evaluated in accordance with fatigue severity scale questionnaire before and eight weeks after intervention; (c) life's quality will be evaluated in accordance with 54 items questionnaire of life's quality of multiple sclerosis patients before and eight weeks after intervention.

General information

Acronym

ms

IRCT registration information

IRCT registration number: **IRCT201302109759N3**
Registration date: **2013-04-01, 1392/01/12**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2013-04-01, 1392/01/12

Registrant information

Name

Ali Bikmoradi

Name of organization / entity

Hamadan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice_chancellor of Research and Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2013-03-10, 1391/12/20

Expected recruitment end date

2013-05-10, 1392/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of relaxation on pain, fatigue and quality of life in women with multiple sclerosis

Public title

Effect of relaxation on Patients with multiple sclerosis

Purpose

Supportive

Inclusion/Exclusion criteria
Inclusion criteria: (a) certain diagnosis of multiple sclerosis by neurologist; (b) age between 20-45; (c) not to be in acute phase of disease; (d) EDSS (Expanded Disability Status Scale) which is equal or less than 4/5 according to neurologist's view; (e) to have pain and fatigue symptoms. Exclusion criteria: (a) lack of ability to participate in the relaxation sessions for any reason; (b) to be hospitalized in hospital.

Age
From **20 years** old to **45 years** old

Gender
Female

Phase
2

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
In this study, the balanced block randomization will be used and the patients allocated in two groups of intervention (body relaxation) and control (routine cares).

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethical Human Subject Review Board of Hamadan University of Medical Sciences

Street address
Hamadan University of Medical Sciences, Shaheed Fahmideh Ave.

City
Hamadan

Postal code
6517838698

Approval date
2013-02-14, 1391/11/26

Ethics committee reference number
4025/9/35/16/پ/د

Health conditions studied

1

Description of health condition studied
Multiple sclerosis

ICD-10 code
G35

ICD-10 code description
Demyelinating diseases of the central nervous system

Primary outcomes

1

Description
pain

Timepoint
Before and after intervention

Method of measurement
Visual pain Scale

2

Description
Fatigue

Timepoint
Before and after intervention

Method of measurement
Fatigue Severity Scale for patient with multiple sclerosis

3

Description
Quality of life

Timepoint
Before and after intervention

Method of measurement
MSQoL-54 questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Control group: in the control group the patients will be received only routine cares.

Category
Other

2

Description
Intervention group: relaxation will be done in way of Jacobson under 12 forty to sixty minute sessions during four weeks at intervention group.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Hamadan Association for Support of Patients with Multiple Sclerosis

Full name of responsible person
Azadeh Zafari

Street address
Shahid Fahmideh Ave., School of Nursing and Midwifery, Hamadan University of Medical Sciences

City
Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice-chancellor of Research and Technology, Hamadan University of Medical Sciences

Full name of responsible person
Dr. Ahmad Tavilani

Street address
Shaheed Fahmideh Ave., Hamadan University of Medical Sciences,

City
Hamadan

Grant name
از محل یک درصد بودجه طرح های تحقیقاتی دانشگاه

Grant code / Reference number

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

Title of funding source
Vice-chancellor of Research and Technology, 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
Hamadan University of Medical Sciences, Nursing and Midwifery School

Full name of responsible person
Dr. Ali Bikmoradi

Position
Medical Education Management

Other areas of specialty/work

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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