Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigation the effect of reflexology on fatigue, stress, and cortisol level in women with multiplesclerosis

Protocol summary

Study aim
Determine the effect of reflexology, cortisol stress and cortisol levels in women with multiple sclerosis, and this intervention to improve the quality of life

Design
A clinical trial with a single blind, randomized, control group of 60 women with multiple sclerosis

Settings and conduct
This study is done in multiple sclerosis patients in MS clinic in Yazd, using a one-stop technique with two groups of intervention and control

Participants/Inclusion and exclusion criteria
The population of this study is women with multiple sclerosis of 20 to 40 years old. Entry requirements: history of at least one year of MS, type of relapse, recurrence disorder, disability rating of 1-4 / 5, non compliance: mental illness, acute phase of the disease, corticosteroid use, pregnancy, smoking, alcohol and drugs, participation in yoga classes

Intervention groups
Before and after the intervention and one month after the intervention, the Fatigue Questionnaire and the stress test were completed and interviewed by a neurologist and psychologist. Cortisol was taken in the intervention group for four weeks, three times a week for foot reflexology. First, she is trained by the researcher and in the presence of her, and she is trained to do this at home three times a week and is conducted by the researcher for telephone massage. The patient is asked to lie down the bed in bed.The foot reflexology was then resting for 30 minutes (for 15 minutes each) and directing the Solar Plexus at 6 minutes, 3 minutes, and again for 6 minutes, at a pressure of rotational pressure of 4-3 Kg, weekly 3 sessions for 4 weeks. In the control group, creating the same conditions with the intervention group, simple foot massage of the foot without compression of the standard reflexology points of the foot is performed with the same duration of the intervention group

Main outcome variables
Fatigue score, estress score, cortisol level

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180304038936N1**
Registration date: **2018-07-10, 1397/04/19**
Registration timing: **registered_while_recruiting**

Last update: **2018-07-10, 1397/04/19**
Update count: **0**

Registration date
2018-07-10, 1397/04/19

Registrant information
Name
Ahmadreza Sayadi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 34 3425 5900
Email address
a.sayadi@rums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-06-24, 1397/04/03
Expected recruitment end date
2018-09-25, 1397/07/03
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigation the effect of reflexology on fatigue, stress, and cortisol level in women with multiplesclerosis

Public title
Investigation the effect of reflexology on fatigue, stress and cortisol level in women with multiple sclerosis

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
THe absence of the patient in the acute phase of the disease Age 20 to 40 years old Type of relapse-suppression disease Having astrong companion Disability score rating 1-4/5 Iranian nationality

Exclusion criteria:
Simultaneous physical illness Mental ilness Acute stage of the disease corticosteroid use two months befor study Pregnancy Smoking,alchol and narcotics Participating in yoga classes, meditation and relaxation Hearing impairment and tongue Lesion on the foot of the foot

Age
From **20 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In order to randomize this study, the first two groups are selected by lottery method.Selecting the rest of the group is done by minimizing the procedure.The tool is a randomized packet

Blinding (investigator's opinion)
Single blinded

Blinding description
Participants do not know which group is being investigated as intervention group.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Rafsangan University of Medical Sciences

Street address
Central Office of Medical Sciences, imam ali Blvd, Rafsangan

City
Rafsangan

Province
Kerman

Postal code
771793777

Approval date
2018-04-17, 1397/01/28

Ethics committee reference number
IR.RUMS.REC.1397.026

Health conditions studied

1

Description of health condition studied
Fatigue

ICD-10 code

ICD-10 code description

2

Description of health condition studied
Stress

ICD-10 code

ICD-10 code description

3

Description of health condition studied
Cortisol

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Fatigue

Timepoint
Befor the intervention, one month after the intervention, one month after the end of intervention

Method of measurement
Fatigue score is obtained using the fatigue criterion.this tool consists of 9 questions with a grading scale of 1-7.

2

Description
Stress

Timepoint
Befor the intervention, one month after the intervention, one month after the end of intervention

Method of measurement
Stress score is obtained by stress syndrome

questionnaire.The questionnaire consists of 50 items that are based on a 6-point Likert scale, and measures four subscales of physical, emotional, cognitive, and behavioral.

3

Description
cortisol
Timepoint
Befor the intervention, one month after the intervention, one month after the end of intervention
Method of measurement
At 8 o'clock in the morning, take the patient's blood sampl and It will be sent to the laboratory within one to one hour.

Secondary outcomes

1

Description
Fatigue rating based on fatigue severity questionnaire
Timepoint
Before the intervention, one month after the intervention, one month after the end of the intervention
Method of measurement
The questionnaire was used to measure the fatigue intensity of physical, psychological, emotional, behavioral, and social dimensions. This tool consists of nine questions ranging from one to seven. Exhaustion is considered to be a mild fatigue, moderate fatigue, severe fatigue.

2

Description
Stress score based on stress syndrome questionnaire
Timepoint
Before the intervention, one month after the intervention, one month after the end of the intervention
Method of measurement
Stress syndrome questionnaire consists of 4 subscales of physical, emotional, cognitive and therapeutic exercises and 50 items. Scoring this scale is based on a 6-point Likert scale

3

Description
cortisol level
Timepoint
Before the intervention, one month after the intervention, one month after the end of the intervention
Method of measurement
Patients' blood samples are taken from the patient at the time indicated, and then sent to the laboratory at -20 ° C after centrifugation

Intervention groups

1

Description
Intervention group: The patient is asked to lie down the bed in bed.Then, we perform foot reflexology for 15 minutes per leg.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
MS Society located at Shahid Sadoughi Hospital, Yazd
Full name of responsible person
Ahmad reza sayadi
Street address
Shahid Sadoughi Hospital, MS Society
City
yazd
Province
Yazd
Postal code
89161-56546
Phone
+98 35 3820 6733
Email
a.sayadi@rums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Hakimi hamid
Street address
Central Office of Imam Ali Blvd., Rafsanjan University of Medical Sciences
City
Rafsangan
Province
Kerman
Postal code
7717933777
Phone
+98 34 3428 0038
Fax
Email
a.sayadi@rums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rafsanjan 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
Rafsanjan University of Medical Sciences

Full name of responsible person
Ahmad reza sayadi

Position
ph.d

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Central Office of Imam Ali Blvd., Rafsanjan University of Medical Sciences

City
Rafsangan

Province
Kerman

Postal code
7717933777

Phone
+98 35 3820 6733

Email
a.sayadi@rums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Rafsanjan University of Medical Sciences

Full name of responsible person
Ahmadreza Sayadi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Central Office of Imam Ali Blvd., Rafsanjan University of Medical Sciences

City
Rafsangan

Province
Kerman

Postal code
771793777

Phone
+98 34280038

Email
a.sayadi@rums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Rafsanjan University of Medical Sciences

Full name of responsible person
Ahmadreza Sayadi

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Faculty of Nursing, Nursing Street

City
Rafsangan

Province
Kerman

Postal code
7717933777

Phone
+98 34345900

Email
sayadiahmad@yahoo.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