Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of Emotional Freedom Technique (EFT) on fatigue and pain in women with multiple sclerosis

Protocol summary

Study aim

Determining the effect of emotional freedom technique on the severity of fatigue and pain in women with multiple sclerosis

Design

This study is clinical trial ,a single-blind,two parallel groups, and three-stage, pre-test, Immediately and 4-week after the interventional . In this study, considering the probability of a 10% drop ,60 women with multiple sclerosis with the inclusion criteria for referral to MS clinic of Ayatollah Kashani Hospital in Isfahan is selected by simple method and is divided equally into two groups of test and sham by minimiaztion method.

Settings and conduct

In this study, 60 women with MS who referred to the MS Clinic of Ayatollah Kashani Hospital in Isfahan are randomly divided into two groups of 30 subjects in test and placebo (sham). The research subjects are completely unaware of their group and the study is a single-blind.For the test group, the emotional freedom technique (EFT) based on the method provided by Gary Craig, discoverer of this technique, for 4 weeks, and 2 times per week a total of 8 sessions), and each session is performed for half an hour. In the sham group, the EFT psychological part was shared and on false points with a milder tapping at the same time will be done.

Participants/Inclusion and exclusion criteria

Inclusion Criteria.1)Women with MS, 18 to 50 years old.2) Having a fatigue index equal to or greater than 4 based on the scale. Fatigue severity scale. 3)having a pain score at least 4 for at least 6 months.4) A score EDSS equal to or less than 4.5 .5) No other illness other than MS .6)Absence in the menstrual period. 7) Not Pregnancy.8) Non-use of other alternative and complementary methods in the last 6 months.9) Non-drug addiction and psychosis. 10)No harm and wound in the desired acupuncture points. Exclusion Criteria :1)Unwillingness to continue to collaborate in research. 2)Use of other complementary therapies such as acupuncture, yoga, meditation during intervention, 3)absences for more than two consecutive sessions during the study.4) In case of pregnancy, recurrence of illness or hospitalization in hospital during intervention.5)Added new analgesic drug to previous medications

Intervention groups

The intervention groups consisted of two experimental and control groups (sham). In the experimental group, the emotional freedom technique(EFT) will be performed for a period of 4 weeks, two 30-minute session in per week, and in the sham group, with repetition of set up and exposure sentences, such as the experimental group, instead of tapping on the main points EFT, the lighter taps on false points will be performed and all other conditions and duration of intervention in both groups are the same.

Main outcome variables

Severity of fatigue, Severity of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140422017387N6**
Registration date: **2018-01-24, 1396/11/04**
Registration timing: **retrospective**

Last update: **2018-01-24, 1396/11/04**
Update count: **0**

Registration date

2018-01-24, 1396/11/04

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2017-08-21, 1396/05/30

Actual recruitment start date

2017-05-22, 1396/03/01

Actual recruitment end date

2017-09-21, 1396/06/30

Trial completion date

empty

Scientific title

The effect of Emotional Freedom Technique (EFT) on fatigue and pain in women with multiple sclerosis

Public title

The effect of Emotional Freedom Technique on fatigue and pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion Criteria:Women with multiple sclerosis 18 to 50 years old at least 6 months of definite diagnosis of MS Having fatigue severity score equal to or greater than 4 based on Fatigue severity scale(FSS) Having a pain score at least 4 for at least 6 months based on the numerical rating scale of pain(NRS) A score equal to or less than 4.5 on the Expanded Disability Status Scale (EDSS) No other illness other than MS is approved by the physician and medical records of the subject Absence in the menstrual period. Not Pregnancy Non-use of other alternative and complementary methods in the last 6 months Non-drug addiction and psychosis. No harm and wound in the desired acupuncture points

Exclusion criteria:

Exclusion Criteria:unwillingness to continue to collaborate in research Use of other complementary therapies such as acupuncture, yoga, meditation during intervention Absences for more than two consecutive sessions during the study In case of pregnancy, recurrence of illness or hospitalization in hospital during intervention. Added new analgesic drug to previous medications

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

In this research, the samples were selected by simple method among patients with MS who had the criteria for entering the study with informed written consent and then by Minimization method using Mini-py software, they were randomly divided into two groups of test and sham with 1: 1 ratio

Blinding (investigator's opinion)

Single blinded

Blinding description

In this research, the participants will not aware of their intervention

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee Isfahan University of Medical Sciences

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Approval date

2017-05-30, 1396/03/09

Ethics committee reference number

IR.MUI.REC.1396.3.017

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

Primary outcomes

1

Description
The fatigue severity score based on Fatigue severity Scale (FSS)
Timepoint
Before, immediately and four week after interventions
Method of measurement
Questionnaire of the fatigue severity score for MS Patients(FSS)

Secondary outcomes

1

Description
Pain severity based on numerical ratting scale (NRS)
Timepoint
Before, immediately and four week after interventions
Method of measurement
based on 10 numerical ratting scale (NRS)

Intervention groups

1

Description
Intervention group: In the experimental group, the intervention of emotional freedom technique (EFT),for each patient individually is performed for 4 weeks at twice a week for 30 minutes.This technique has four steps, the first step is called "The setup phrase",that patient repeats 3 times "Even though I have pain (the name of the problem), I deeply and completely accept myself",and Concurrent researcher massages the sore spot point (point ST14 acupuncture). In the second step, the patient focusing on the problem, researcher taps 10 times on 13 acupuncture points including points (DU20, BL2, GB1, ST1, GV26, CV24, KD27, SP21, LU11, LI1, HT9, SI3 PC9) with pointed and middle fingertips. In the third step, the researcher taps on gamut point at the back of the hand (TH3 acupuncture point) and at the same time 9 brain stimulator actions involving(closing, opening the eyes, looking Go down and right, looking down and left, turning the eyes clockwise, and then opposing it, whispering a favorite song for 2 seconds, fast counting numbers from 1 to 5, muttering the desired song to For 2 seconds) by the patient is performed and the fourth step is the second step repetition, Performing these 4 steps is called an eft round and these cycles were repeated for 30 minutes.
Category
Treatment - Other

2

Description
In this study, the sham group (placebo) will be the control group.The researcher, while tapping with the point and middle fingers on the false points including biparital, the outer margin of the chin, the sides, the vertex of the nails, the forearm, wants the patient who repeat set up phrase and focussin the problem (like the test group), this procedure will also be performed for 30 minutes , 2 times in weeks within 4 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
MS clinic of Ayatollah Kashani Hospital Isfahan.
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Sponsors / Funding sources

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

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Position

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Latest degree

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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