

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

The study of effectiveness of dry Cupping Therapy on fatigue and quality of life in patients with Multiple Sclerosis

Protocol summary

Study aim

Determine of the effect of dry Cupping Therapy on fatigue and quality of life in patients with Multiple Sclerosis

Design

This study is a clinical trial with two groups (intervention and control), single blinded (the data analyst) and randomized, with 30 patients in each group.

Settings and conduct

This single blinded study (the data analyst), will be done in the Kerman Medical Center of the Special Diseases. In the intervention group, 8 sessions of dry Cupping Therapy will be performed. The variables will be measured before and after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Ability to communicate in Persian language, diagnosis of Multiple Sclerosis according to neurologist confirmation, the severity of mental fatigue at the beginning of the research on the Fatigue Severity Scale (FSS) is equal to or greater than thirty six, the absence of chronic diseases and other conditions that affect the fatigue and quality of life of people, such as diabetes, cancer, etc, Not having surgery for the last six months, abnormal wound and redness from the scapula to the waist. Exclusion criteria: Use of anticoagulants, coagulopathy, getting severe psychological disorders that are inappropriate for participation in this study, a change in the course of the disease that causes the patient to be hospitalized, failure to follow the Dry Cupping Therapy program by the patient for any reason and some cases of recurrence of symptoms during the intervention so that it can affect our intervention.

Intervention groups

In the intervention group, 8 sessions of Dry Cupping Therapy will be performed in 4 weeks and two sessions per week, While patients in the control group will receive routine fatigue reduction methods. The severity of fatigue and the quality of life score will be measured before and after the intervention.

Main outcome variables

fatigue and quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151107024919N8**

Registration date: **2019-07-06, 1398/04/15**

Registration timing: **prospective**

Last update: **2019-07-06, 1398/04/15**

Update count: **0**

Registration date

2019-07-06, 1398/04/15

Registrant information

Name

Batoul Tirgari

Name of organization / entity

Kerman Medical University of Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date

2019-09-06, 1398/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The study of effectiveness of dry Cupping Therapy on fatigue and quality of life in patients with Multiple Sclerosis

Public title
Effect of dry Cupping on fatigue and quality of life in patients with Multiple Sclerosis

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Ability to communicate in Persian language. Diagnosis of Multiple Sclerosis according to neurologist confirmation. The severity of mental fatigue at the beginning of the research on the Fatigue Severity Scale (FSS) is equal to or greater than thirty six. The absence of chronic diseases and other conditions that affect the fatigue and quality of life of people, such as diabetes, cancer, etc. Not having surgery for the last six months, abnormal wound and redness from the scapula to the waist.
Exclusion criteria:
Use of anticoagulants coagulopathy Getting severe psychological disorders that are inappropriate for participation in this study A change in the course of the disease that causes the patient to be hospitalized Failure to follow the Dry Cupping Therapy program by the patient for any reason Some cases of recurrence of symptoms during the intervention so that it can affect our intervention

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In order to allocate the subjects to the intervention and control groups, a randomized classification method is used, so that people in terms of severity of fatigue, quality of life score, drug use by patients, type of disease, duration of illness, etc. are divided into groups. Subsequently, through the use of a simple method and using Excel software from each group, half of the subjects are placed in the intervention group and the other half are in the control group.

Blinding (investigator's opinion)
Single blinded

Blinding description
The data analyst does not know which data is related to the intervention group and which data is related to the

control group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Kerman University of Medical Sciences
Street address
Medical Center of the Special Diseases, No. 78 Alley, Shahid Rajaei Street,
City
kerman
Province
Kerman
Postal code
7619875994

Approval date
2019-06-24, 1398/04/03

Ethics committee reference number
IR.KMU.REC.1398.168

Health conditions studied

1

Description of health condition studied
Multiple sclerosis

ICD-10 code
G35

ICD-10 code description
Multiple sclerosis

Primary outcomes

1

Description
Fatigue severity

Timepoint
The severity of fatigue will be measured before and after the intervention at the end of the fourth week.

Method of measurement
Fatigue Severity Scale

2

Description
Quality of Life

Timepoint
The quality of life score will be measured before and

after the intervention at the end of the fourth week.

Method of measurement

Multiple Sclerosis Quality of Life- 54 Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, 8 sessions of dry Cupping therapy will be performed in 4 weeks and two sessions per week, on Saturday and Tuesday. The intervention will be carried out by the researcher and for this purpose. First, from the scapular to the waist, with 4 to 5 drops of Noshad branded chamomile oil, massage will be carried out for 3 to 4 minutes. Then the Cold dry Cupping, using silicone cups, which can be 6 to 10 numbers depending on the person's body, on the site (on the sides of the spine, around the inter-vertebral line, from the scapula to the waist) will be done.

Category

Other

2

Description

Control group: Patients in the control group receive received routine fatigue reduction methods such as exercise, relaxation techniques, etc..

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Medical Center of the Special Diseases

Full name of responsible person

Batool Tirgari

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Medical Center of the Special Diseases, No. 78 Alley, Shahid Rajaei Street,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhti

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Web page address

<http://kmu.ac.ir/fa/vcrt>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Batool Tirgari

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Kerman University of Medical Sciences, Medical University Campus, Haft- Bagh- Alavi Highway, Kerman

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Person responsible for scientific inquiries

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Person responsible for updating data

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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

Not applicable