

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Effect of Effleurage Massage on Sleep Quality and Self-efficacy of Multiple Sclerosis Patients in Shiraz Multiple Sclerosis Community 1391-92

#### Protocol summary

2015-05-10, 1394/02/20

#### Summary

This study was performed to investigate the effect of Massage effleurage on Sleep Quality and efficacy in patients with multiple sclerosis a member of MS Shiraz society in 92-1391. The study included 80 patients with MS who were randomly divided into 2 groups Characteristics of patients. Intervention groups participated in 10 sessions, each session lasting 20 minutes and 2 times a weeks. For the control group, no intervention was not performed. Also, in the end of the intervention for patients in the control group was teaching massage. For inclusion of criteria was People (both sexes) aged 20 to 60 years with MS a member of MS Society of Shiraz, Developing MS than 6 months, Lack of stage disease attack, not receiving a massage During the past three months, no other chronic disease, lack of physical damage in the limbs and spine, non-pregnant women. If the patients with increasing severity of the disease that affects sleep quality and self-efficacy and Resulted in the patient being admitted to hospital, No follow-up and massaged by the patient for any reason, acute illness, such as fever, chills, severe pain, are excluded. Before the intervention, 5 and 10 weeks after treatment, sleep quality and self-efficacy in both groups was measured by the Pittsburgh Sleep Quality Questionnaire and general self efficacy.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013121015734N1**

Registration date: **2015-05-10, 1394/02/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

#### Registrant information

##### Name

Mehdi Zarei

##### Name of organization / entity

Shiraz University of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3647 4252

##### Email address

zarei\_mehdi@sums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice chancellor for research, Shiraz University of Medical Science

#### Expected recruitment start date

2013-09-23, 1392/07/01

#### Expected recruitment end date

2013-12-22, 1392/10/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effect of Effleurage Massage on Sleep Quality and Self-efficacy of Multiple Sclerosis Patients in Shiraz Multiple Sclerosis Community 1391-92

#### Public title

Effect of Effleurage Massage on Sleep Quality and Self-efficacy of Multiple Sclerosis Patients

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

inclusion criteria: People (of both sexes) aged 20 to 60 years with MS in MS Society of Shiraz; Getting MS more than 6 months; Lack of stage of disease attack; Not receiving a massage in the last three months; No other chronic diseases; Lack of physical damage in the limbs and spine; non-pregnant women; No history of allergies; seizures and migraines; Not having any sores or lumps in organs; Not having surgery in the last 6 months.

exclusion criteria: Increasing severity of the disease that affects sleep quality and self-efficacy of the patient and cause the patient's stay in hospital; Failure to follow Massage Program by the patient for any reason; Acute illness such as fever, chills, severe pain.

#### **Age**

From **20 years** old to **60 years** old

#### **Gender**

Both

#### **Phase**

2-3

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **80**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Not blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Ethics Committee of Shiraz University of Medical Science

###### **Street address**

zand street

###### **City**

Shiraz

###### **Postal code**

##### **Approval date**

2013-09-23, 1392/07/01

##### **Ethics committee reference number**

279380

### **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**

Self Efficacy

##### **Timepoint**

Before the intervention, 5 and 10 weeks after intervention

##### **Method of measurement**

Self-Efficacy Questionnaire

#### **2**

##### **Description**

Sleep Quality

##### **Timepoint**

Before the intervention, 5 and 10 weeks after intervention

##### **Method of measurement**

Pittsburgh Sleep Quality Questionnaire

### **Secondary outcomes**

empty

### **Intervention groups**

#### **1**

##### **Description**

Control group: No intervention is not performed.

##### **Category**

N/A

#### **2**

##### **Description**

Experimental group: Effleurage massage 2 days in week for 10 weeks

##### **Category**

Rehabilitation

### **Recruitment centers**

#### **1**

##### **Recruitment center**

###### **Name of recruitment center**

MS Society of Fars

###### **Full name of responsible person**

Zeinab Mohebi

###### **Street address**

NO 216, Ghasredasht Street  
**City**  
Shiraz

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Vice chancellor for research, Shiraz University of  
Medical Science

**Full name of responsible person**  
Seyed Basir Hashemi

**Street address**  
Zand Street, Beside Red Cross, University Central  
Building, Shiraz University of Medical Sciences

**City**  
Shiraz

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Vice chancellor for research, Shiraz University of Medical  
Science

**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**  
Shiraz University of Medical Science

**Full name of responsible person**  
Zeinab Mohebi

**Position**  
Master of Science

### Other areas of specialty/work

**Street address**  
Namazi Square, Collage of Nursing and Midwifery

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+98 71 3647 4251

### Fax

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Zmohebi@sums.ac.ir

### Web page address

## Person responsible for scientific inquiries

### Contact

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Zmohebi@sums.ac.ir

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## Person responsible for updating data

### Contact

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Shiraz University of Medical Science

**Full name of responsible person**  
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**Position**  
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### Web page address

## 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*