

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 2026

### The effectiveness of one type of Iranian Traditional massage on lumbar radiculopathy

#### Protocol summary

##### Summary

Patients suffering from chronic lumbar radiculopathy, who meet inclusion criteria and have been referred to the two selected clinics, will be selected for this research but they will be removed from the study when any of the exclusion criteria applies. First clinic is traditional massage clinic and the second one is neurosurgery clinic in "Imam Khomeini's hospital". Patients of Case (treatment) group will undergo Iranian Traditional massage, while patients of Control group will be treated in classic conservative treatments way. We will select about 30 patients from each of the groups. They will fill two Standard questionnaires and will determine their pain severity according to V.A.S in first visit before treating as well as 1 month and 3 months after starting treatment. At the end, participants in each group will be classified in similar blocks of sex, age and socioeconomics specifications and results of corresponding blocks will be compared.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012061810060N1**

Registration date: **2013-10-09, 1392/07/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-10-09, 1392/07/17

##### Registrant information

##### Name

Mamak Hashemi

##### Name of organization / entity

Traditional Medicine Faculty

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8840 8319

##### Email address

m-hashemi@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Traditional Persian and Pharmacy Research Center, Tehran University of Medical Sciences

##### Expected recruitment start date

2012-12-21, 1391/10/01

##### Expected recruitment end date

2013-06-20, 1392/03/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effectiveness of one type of Iranian Traditional massage on lumbar radiculopathy

##### Public title

The effectiveness of of Iraninan traditional massage on low-back-pain

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: lumbar radiculopathy radiating below the knee; pain lasting longer than 8 weeks (continuous or non- continuous); age between 25-55 years old; no indication for surgery or patient's disagreement or medical problem interfering surgery in case of surgery indication. Exclusion criteria: history of low-back surgery; any suspicious sign during the treatment period requiring further evaluating or intervention; red flag signs; sign &

symptoms of "Quadra Equina" syndrome (Numbness or weakness of the muscles of the lower extremities, Anus pain, perineal or saddle anesthesia, bowel and bladder disturbances, absent lower spincture reflexes, sexual dysfunction); accelerating picture of pain in acute phase; sever or exacerbated pain picture; patient's disagreement.

**Age**

From **25 years** old to **55 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**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**

Medical Ethics Committee in research, Tehran  
University of Medical Sciences

**Street address**

Tehran University of Medical Sciences, Keshavarz  
Blvd, Qods St,

**City**

Tehran

**Postal code****Approval date**

2010-09-23, 1389/07/01

**Ethics committee reference number**

90-04-86-13815-79684

**Health conditions studied****1****Description of health condition studied**

Lumbar radiculopathy

**ICD-10 code**

M51.1+

**ICD-10 code description**

Lumbar and other intervertebral disc disorders with radiculopathy

**Primary outcomes****1****Description**

Pain

**Timepoint**

Before intervention, 1 & 3 months after intervention initiation

**Method of measurement**

Visual analog scale

**2****Description**

Low back Pain disability

**Timepoint**

Before intervention, 1 & 3 months after intervention initiation

**Method of measurement**

Standard Rolland-Morris Questionnaire

**3****Description**

Quality of life

**Timepoint**

Before intervention, 1 & 3 months after intervention initiation

**Method of measurement**

W.H.O Quality of life Questionnaire (BREF)

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Traditional massage explanation The Maneuvers done in therapy sessions consist of: • Lower limb massages (Anterior, posterior, internal & external borders); this massage is done 1 time by massager's palm in each therapy session and 5 times every day by someone else (family) at home. - Anterior massage; in supine position massage starts from inguinal region to ankle without significant pressure on the knee -Internal lateral massage; in supine position massage starts on internal lateral of lower limb, starts from inguinal to ankle. - External lateral massage; in supine position massage starts on external lateral of lower limb, starts from hip to ankle. - Posterior; in prone position lower limbs given massage from hip to ankle. • Plantar Massage: Feet palms are massaged by a cylinder shape instrument or wood rolling pin. • Lumbar massage (7 parts) 1- Lumbar region is massaged several minutes using almond oil for relaxing muscles and fascias. 2- Cross massage; patient

lays in supine position crosses one lower limb over the other, fixing his or her body grasping bed sides. The massager massages the above limb which is stretched from proximal to distal regarding same general conditions. 3- knee-chest (prostrate) or fetus position massage; patient is given massage in knee-chest (prostrate) position. If this position is difficult he/she may lie on the side folding lower limbs like fetus position, instead. 4- Stretching upward (in case of severe lumbar stiffness); Patient lies in supine position, someone raises lower limbs one to one to separate lumbar region from bed then the massager massages stretched back. 5- Massage paravertebral muscles; patient's paravertebral muscles are given massage in prone position by massager's thumb (circulating pressure by thumb) from neck to end of spine several times. 6- Skin pinch; different parts of back skin and subcutaneous tissue are pressed between 1th and 2nd fingers of both massager's hand and pulled out in prone position to recover skin and fascia elasticity. Cupping is a replacement for this maneuver. 7- Kneading back muscles & stretch; Patient lies in prone extending his/her upper limbs fixing body by grasping bed top, someone pulls the lower limbs. The massager massages his/her back and lower limbs in stretched position. • Trigger points release; tender points found in massage process are being pressed to release. • Cupping; cupping with several size cups is done to improve blood circulation if signs and symptoms of poor circulation are present. • Dressing; after massage session and rubbing oil, patient's back is dressed and wrapped by cotton cloth (30 cm \* 400 cm). • Abdomen massage; since constipation delays low back pain recovery, abdomen is massaged by massager's palm clockwise to help stool movement. \*All massages done by massager's hand, apply pressure about 1 kg force.

### Category

Rehabilitation

## 2

### Description

Control group: standard medical treatment for lumbar radiculopathy by neurosurgeon.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Heravi Traditional Medicine clinic

##### Full name of responsible person

Kamran Mahlooji Kermanshahi

##### Street address

West jamali, Heravi SQ

##### City

Tehran

## 2

#### Recruitment center

##### Name of recruitment center

Neurosurgery Clinic. Imama khomeini hospital

##### Full name of responsible person

Mamak Hashemi

##### Street address

Imama Khomeini hospital, Keshavarz boulevard

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Research Institute for Islamic and Complementary Medicine (RICM), Iran University of Medical Science

##### Full name of responsible person

Bagher Minaie Ph.D

##### Street address

Behesht ST. Vahdat eslami ST. Hafez Ave.

##### City

Tehran

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Research Institute for Islamic and Complementary Medicine (RICM), Iran University of Medical Science

#### Proportion provided by this source

#### 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

## 2

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Fariba Akbari

##### Street address

4th floor, Central organization of Tehran University of medical sciences, Ghods ST corner, Keshavarz Boulevard

##### City

Tehran

#### Grant name

#### Grant code / Reference number

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

Yes

**Title of funding source**

Tehran University of Medical Sciences

**Proportion provided by this source****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*

Behesht St, Vahdat Islami St, Hafez Ave

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**Web page address****Person responsible for updating data****Person responsible for general inquiries****Contact****Name of organization / entity**

Traditional Medicine Faculty, Tehran University of  
Medical sciences

**Full name of responsible person**

Mamak Hashemi Habibabadi

**Position**

General practitioner, Traditional Medicine Resident

**Other areas of specialty/work****Street address**

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Traditional medicine faculty, Tehran university of  
medical sciences.

**Full name of responsible person**

Mamak Hashemi Habibabadi

**Position**

General practitioner, Traditional Medicine Resident

**Other areas of specialty/work****Street 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*