

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Effect of multidimensional physiotherapy treatment based on biopsychosocial approach on clinical findings and electroencephalography spectrum in chronic nonspecific low back pain: A Randomized Controlled Trial

#### Protocol summary

##### Study aim

The effect of multidimensional treatment in the treatment of patients with nonspecific chronic low back pain

##### Design

Two arm parallel group double blind randomized controlled trial.

##### Settings and conduct

Patients with non-specific chronic low back pain will be selected from medical centers of Iran University of Medical Sciences. Participants will randomly divide into two groups of intervention (multidimensional treatment) and active control (usual physiotherapy), each group will receive a twelve-session treatment with equal time. Participants and assessors will blind. Evaluation will be done before treatment and at the end of treatment and after 1 and 4 months.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18-50, non-specific chronic low back pain, Disability based on Oswestry Disability Index (ODI) between 20-60, Fear of movement based on Tampa scale for kinesiophobia > 37. Exclusion criteria: Any evidence of a specific medical diagnosis for low back pain, History of lumbar surgery in the past 3 years, Beck's Anxiety Inventory > 26, Beck's Depression Inventory II > 29, Pregnancy, Having other therapies during the present research

##### Intervention groups

Patients in the intervention group will receive multidimensional treatment include psycho-education based on cognitive behavioral therapy (CBT), education, graded exposure, postural and lifestyle correction. Patients will be received all treatment in one session. In the active control group, treatment will include electrotherapy, education, and trunk general exercises. Electrotherapy in both groups consisted of 20 minutes of

TENS at 100 Hz, superficial heat by Hot Pack and 5 minutes ultrasound with 1 MHz frequency and 1.2 W/cm<sup>2</sup> intensity in the lumbar where the patient reported the most pain. Treatment in both groups is twelve sessions and will be performed twice a week.

##### Main outcome variables

Pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140810018754N11**

Registration date: **2020-01-17, 1398/10/27**

Registration timing: **prospective**

Last update: **2020-01-17, 1398/10/27**

Update count: **0**

##### Registration date

2020-01-17, 1398/10/27

##### Registrant information

##### Name

Javad Sarrafzadeh

##### Name of organization / entity

Iran University of Medical Sciences, School of Rehabilitation Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

00982122228051-00982122227124

##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

**Expected recruitment start date**

2020-04-05, 1399/01/17

**Expected recruitment end date**

2021-03-02, 1399/12/12

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effect of multidimensional physiotherapy treatment based on biopsychosocial approach on clinical findings and electroencephalography spectrum in chronic nonspecific low back pain: A Randomized Controlled Trial

**Public title**

effect of multidimensional treatment based on biopsychosocial approach in chronic non specific low back pain

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age between 18-50 Permanent or intermittent local pain between L1 to gluteal fold without any radicular pain for 3 months or more and between 3-7/10 based on Numeric Rating Scale (NRS) Disability based on Oswestry Disability Index (ODI) between 20-60 Fear of movement based on Tampa scale for kinesiophobia > 37 Minimum level of education Native Persian speaking

**Exclusion criteria:**

Any evidence of e specific medical diagnosis include spondylolisthesis, fracture, tumor or inflammation disease Rheumatoid disease, fibromyalgia, neuropathy, Progressive neurological disease History of headache, dizziness, nausea, epilepsy, migraines and mental disorders History of lumbar surgery in the past 3 years Beck's Anxiety Inventory > 26 Beck's Depression Inventory II > 29 Pregnancy Having other therapies during the present research

**Age**

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

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **70**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Participants will be randomized to either active control or experimental group (1:1 ratio) using a stratified block allocation with stratification factors being gender (male or female). Then Randomization will be done by an

independent investigator and will be concealed from patients and the other investigators.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, participants in each group did not meet each other in the waiting rooms (no contamination). The outcome assessor will not be aware of the grouping of patients.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

**Street address**

5th floor, Iran University of Medical Sciences, Hemmat highway, between Sheikh Fazlollah Nuri and Chamran highways

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۴۳۹۶۱۴۵۳۵

**Approval date**

2020-01-14, 1398/10/24

**Ethics committee reference number**

IR.IUMS.REC.1398.1041

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

non-specific chronic low back pain

**ICD-10 code**

M54.5

**ICD-10 code description**

Low back pain

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

pain

**Timepoint**

Before the study, end of 6 weeks of treatment, 1 and 4 months follow-up

**Method of measurement**

Numeric Rating Scale

**Secondary outcomes****1****Description**

Quality of Life

**Timepoint**

Before study, end of 6 weeks treatment, 1 and 4 months follow-up

**Method of measurement**

Sf36 questionnaire

**2****Description**

Fear Avoidance Believes

**Timepoint**

Before study, end of 6 weeks treatment, 1 and 4 months follow-up

**Method of measurement**

Fear Avoidance Believes questionnaire

**3****Description**

Kinesiophobia

**Timepoint**

Before study, end of 6 weeks treatment, 1 and 4 months follow-up

**Method of measurement**

Tampa scale of kinesiophobia

**4****Description**

Pain Catastrophizing

**Timepoint**

Before study, end of 6 weeks treatment, 1 and 4 months follow-up

**Method of measurement**

Pain Catastrophizing Scale

**5****Description**

Disability

**Timepoint**

Before study, end of 6 weeks treatment, 1 and 4 months follow-up

**Method of measurement**

Oswestry disability scalequestionnaire

**6****Description**

Forward flexion ROM

**Timepoint**

Before study, end of 6 weeks treatment, 1 and 4 months follow-up

**Method of measurement**

Tape

**7****Description**

Absolute power of frequency spectrum

**Timepoint**

Before study, end of 6 weeks treatment, 1 and 4 months follow-up

**Method of measurement**

Electroencephalography

**8****Description**

Relative power of the frequency spectrum

**Timepoint**

Before study, end of 6 weeks treatment, 1 and 4 months follow-up

**Method of measurement**

Electroencephalography

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

Patients in the intervention group will be received multidimensional treatment include psychoeducation based on cognitive behavioral therapy (CBT), education, graded exposure, postural correction exercise, Lifestyle change, and electrotherapy. Twelve 30 minute psychoeducation sessions consist of the following sessions: Psychoeducation on Pain and Targeting (3 sessions), Anxiety Management, Interpersonal Conflict Management, Problem Solving Training, Training Coping strategy, Managing pain recurrent, preventing unnecessary medication use, enhancing one's ability to cope with labeling and stigma, empowering one to create a daily sleep routine, training relaxation techniques. Patients will also receive recommendations for lifestyle modifications, such as encouraging active living and a gradual increase in activity levels, improving the work environment, and training on how to perform daily and work activities correctly. Other treatments include postural correction and training of the necessary exercises, as well as the gradual initiation of movements and activities that the patient is afraid to perform. By asking the patient to perform hierarchical activities that he or she fears. The first step is to identify the movements that the patient is afraid of. The exercise begins with a movement that the patient has the least fear of, and that movement begins with the simplest state and the lowest level with the patient least feared, and gradually becomes more difficult. All of these are taught to the patient in each practice session. The patient is also asked to repeat the practice of each session at home once a day. Electrotherapy, including 20 minutes of skin electrical nerve stimulation (TENS) at 100 Hz in the lumbar region where the patient reports the most pain. The intensity of TENS is regulated by the patient. Surface heat will be placed in the lumbar area by

Hot Pack at the same time as TENS. Ultrasound with a frequency of 1 MHz and intensity of 1.2 W/cm<sup>2</sup> will be performed using a 5 cm square applicator on the paravertebral muscle where the patient reports the most pain, for 5 minutes. The treatment in this group is twelve sessions and will be performed twice a week.

#### Category

Rehabilitation

## 2

#### Description

Patients in the active control group, treatment will include electrotherapy, education, and trunk general exercises. Education in this group includes an explanation of the basic biomechanical anatomy of the spine, common causes of spinal pain, pain processing, ergonomic advice on how to perform daily activities and postures (such as sitting, standing, moving objects, etc.) and training for postural correction exercises. General Trunk Exercise will focus on abdominal and paraspinal muscles to improve blood flow, mobility, strength, and endurance in each session, and the patient will be asked to perform exercises in each session. The intensity and type of exercise will progress toward functional training. The patient is also asked to do exercise at home once a day. Electrotherapy, including 20 minutes of skin electrical nerve stimulation (TENS) at 100 Hz in the lumbar region where the patient reports the most pain. The intensity of TENS is regulated by the patient. Surface heat will be placed in the lumbar area by Hot Pack at the same time as TENS. Ultrasound with a frequency of 1 MHz and intensity of 1.2 W/cm<sup>2</sup> will be performed using a 5 cm square applicator on the paravertebral muscle where the patient reports the most pain, for 5 minutes. The treatment in this group is twelve sessions and will be performed twice a week.

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

physiotherapy clinic of School of Rehabilitation Sciences, Iran University of Medical Sciences

##### Full name of responsible person

Sarrafzadeh Javad

##### Street address

Madadkaran St., Shahnazari St., Madar Squ., Mirdamad St.,

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Tehran

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##### Web page address

<http://rehab.iums.ac.ir>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Dr. Seyed Kazem Malakouti, Vice chancellor for research

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5th Floor, Iran University of Medical Sciences, Hemmat highway

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research@iums.ac.ir

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<http://vcr.iums.ac.ir/>

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Iran 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

Iran University of Medical Sciences

##### Full name of responsible person

Javad Sarrafzadeh

##### Position

Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Physiotherapy

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Physiotherapy department, School of Rehabilitation Sciences, Madadkaran street., Shahnazari street, Madar squ., Mirdamad street

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## Person responsible for scientific inquiries

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

All data or results of the present study will be presented in an article or some articles that will be published after completing the study.

**When the data will become available and for how long**

After completing the present study and publishing the resulting article or articles

**To whom data/document is available**

All researchers in the field of the present study

**Under which criteria data/document could be used**

With the same goal as the present study and with mention of the present study as the reference. All intellectual property rights of the present study belongs to the Iran University of Medical Sciences.

**From where data/document is obtainable**

The corresponding author of the article or articles derived from this study

**What processes are involved for a request to access data/document**

Written request from the author responsible for the present review after the publication of the resulting article or articles

**Comments**