Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 multidimentional 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
Inclusio 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. Excclusio 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/cm2 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)

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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
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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 psycho-education 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/cm2 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/cm2 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

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

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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