

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The effect of motor control approach with and without whole body vibration on pain, postural stability, electrical activity and trunk muscle endurance of nurses with chronic non-specific low back pain

Protocol summary

Study aim

The main aim of the study is to compare the effect of motion control approach with and without whole body vibration on pain intensity, body posture stability, electrical activity and endurance of trunk muscles of nurses with non-specific chronic back pain.

Design

A clinical trial with a control groups and two other intervention groups, randomized, on 75 patients, the lottery method is used for randomization.

Settings and conduct

75 nurses suffering from non-specific chronic back pain in Tehran hospitals are randomly selected by lottery method after meeting the entry and exit conditions of the project. All participants are randomly divided into three groups.

Participants/Inclusion and exclusion criteria

inclusion criteria Female nurses aged from 30 to 40 years with more than three years of work experience with non-specific chronic low back pain based on the Start Back Tool questionnaire and pain in low back for more than three months (12 weeks) an intensity of pain between 3 and 7 scores based on visual analog scale questionnaire signed a written informed consent
exclusion criteria patient with nerve root disorders of the lumbar spine, a history of lumbar spine surgery, cognitive disorders, severe neuromuscular abnormalities
Absence of confirmation from the clinical examining doctor in terms of the heart and lungs and the condition of the motor organs

Intervention groups

control group: Carrying out daily nursing activities and also not participating in sports activities such as going to the gym
Movement control group: Performing motor control exercises based on the protocol of Hodges et al. (2009)
Combined group of motor control and vibration of the whole body: First, perform general movements with

the whole body vibration device according to the protocol of Mike et al

Main outcome variables

pain, postural stability, electrical activity and trunk muscle endurance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230227057551N1**

Registration date: **2023-06-12, 1402/03/22**

Registration timing: **prospective**

Last update: **2023-06-12, 1402/03/22**

Update count: **0**

Registration date

2023-06-12, 1402/03/22

Registrant information

Name

Raziyeh Karimi

Name of organization / entity

Kharazmi University

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2023-07-06, 1402/04/15 Actual recruitment start date empty Actual recruitment end date empty Trial completion date empty	
Scientific title The effect of motor control approach with and without whole body vibration on pain, postural stability, electrical activity and trunk muscle endurance of nurses with chronic non-specific low back pain	
Public title The effect of motor control approach with and without whole body vibration on chronic non-specific low back pain	
Purpose Treatment	
Inclusion/Exclusion criteria Inclusion criteria: Female nurses in the age range of 30-40 years Female nurses with more than three years of work experience having lower back pain for more than three months (12 weeks) Getting a score between 3 and 7 from the Visual Analogue Scale questionnaire Not having any specific and regular sports activities Filling the informed consent form to participate in the study Exclusion criteria: Having disorders of the nerve roots of the lumbar spine that have led to a decrease in the strength and reflexes of the lower limbs Having lesions such as fractures, cancer, inflammatory arthritis of the lumbar vertebrae and cauda equina and etc. Having a history of lumbar spine surgery Having cognitive disorders such as Alzheimer's, Parkinson's and dementia Having severe neuromuscular abnormalities Absence of confirmation from the clinical examining doctor in terms of the heart and lungs and the condition of the motor organs	site on the size of the blocks. According to the sample size of this study (75 people), it is considered as blocks of 3, then the number of sets of random numbers that is needed is determined (three sets of 25 numbers are needed for each group), which these three sets include : 1. Experimental group A, 2. Experimental group B and C, control group). After clicking on the confirmation option in the opposite column, the randomization method will be determined based on the individual number, block size and group name from 1 to 25 for each group. For example, the first three players for three groups based on the block of three are as follows. • 1, 3, 1, Group A • 1, 3, 2, Group C • 1, 3, 3, Group B Concealment: Concealment of random allocation will be done using a random block table (25 blocks of 3) generated by the computer before the start of data collection by a researcher who will not be involved in calling or treating patients. Randomization tool: Random numerical sequence is placed in non-transparent and sealed envelopes. Another researcher, a researcher unaware of the initial steps, will open an envelope and proceed with the treatment as assigned by the group.
Age From 30 years old to 40 years old Gender Female	Blinding (investigator's opinion) Not blinded
Phase N/A Groups that have been masked No information	Blinding description Placebo Not used
Sample size Target sample size: 75 Randomization (investigator's opinion) Randomized	Assignment Parallel Other design features
Randomization description Randomization method: block randomization Randomization unit: it is individual. Randomization type: Block randomization will be done using the website https://www.sealedenvelope.com/simple-randomiser/v1/lis. Patients who meet the inclusion criteria will be randomly assigned to two experimental groups (motor control exercises and combined motor control exercises with whole body vibration) and a control group, which will be determined at the beginning of the mentioned	Secondary Ids empty Ethics committees 1 Ethics committee Name of ethics committee Research Ethics Committees of Sports Sciences Research Institute Street address Jannat Abad Central Blvd., North 16 Meter St., Khordad Alley, No. 8, Unit 2 City Tehran Province Tehran Postal code 1474877687 Approval date 2023-01-18, 1401/10/28 Ethics committee reference number IR.SSRC.REC.1401.092 Health conditions studied 1 Description of health condition studied

Chronic non-specific low back pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes

1

Description

intensity of pain

Timepoint

The measurement of pain intensity is done at the beginning of the study (before the start of the intervention) and 8 weeks later (after the end of the intervention period).

Method of measurement

Visual analog scale questionnaire is used to measure pain intensity in eligible patients.

2

Description

The endurance (stability) of trunk muscles

Timepoint

The endurance of the trunk muscles is measured at the beginning of the study (before the start of the intervention) and 8 weeks later (after the end of the intervention period).

Method of measurement

McGill functional tests are used to measure the stability of the extensor, flexor and lateral muscles of the trunk.

3

Description

static and dynamic balance.

Timepoint

The measurement of static and dynamic balance is done at the beginning of the study (before the start of the intervention) and 8 weeks later (after the end of the intervention period).

Method of measurement

In order to evaluate static and dynamic balance, the Shirley, NY Biodex device, made in the USA, is used. This device has various tests to evaluate static and dynamic balance.

4

Description

Electrical activity of trunk muscles

Timepoint

The electrical activity of the trunk muscles is measured at the beginning of the study (before the start of the intervention) and 8 weeks later (after the end of the intervention period).

Method of measurement

In this research, a surface electromyography device (Actos wireless model, made in Switzerland) with a frequency range of 1000 Hz is used.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention first group: they will participate individually and under full supervision for 12 sessions and each session lasts 30 minutes (including movement control exercises with a specific protocol that is adjusted based on the ability of the people). This protocol will be used under the supervision of a specialist doctor. The exercises will be done for 8 weeks (in the first 4 weeks as two sessions per week and in the second 4 weeks as one session per week).

Category

Treatment - Other

2

Description

The second intervention group: Individually and fully supervised for 12 sessions and each session for 45 minutes, first for 30 minutes movement control exercises and then for 15 minutes they will perform the whole body vibration movement protocol. The whole body vibration protocol includes 5 movements (dynamic squat with a cable: with a frequency of 5-6 Hz, squat with extension arms: with a frequency of 6-7 Hz, rising on the toes: with a frequency of 10 Hz, static squat: with a frequency of 8 up to 10 Hz and static squat by standing on the toe: with a frequency of 8 Hz) in two sets with 5 to 8 repetitions on the Wellengang oscillating plate, Mühlacker model, made in Germany with the specified frequency (5 to 8 10 Hz) is done. It should be noted that 30 seconds of active rest is included between each set (including three exercises of quiet standing, hip rotation and hanging with a cable). All exercises will be followed for 8 weeks (in the first 4 weeks as two sessions per week and in the second 4 weeks as one session per week).

Category

Treatment - Other

3

Description

Control group: Carrying out daily nursing activities and also not participating in sports activities such as going to the gym

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

West Nikan hospital

Full name of responsible person

Dr hamidreza habibollahi

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2**Recruitment center****Name of recruitment center**

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Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kharazmi university

Full name of responsible person

Faculty of Physical Education and Sports Sciences

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Shahid Keshvari Complex, end of Shahid Hesari St, end of Mirdamad

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Web page address**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kharazmi university

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**

Kharazmi university

Full name of responsible person

Raziyeh Karimi

Position

Ph.D student

Latest degree

Master

Other areas of specialty/work

Corrective exercises and sports pathology

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Some data, such as information on the main outcome, is shared after de-identifying individuals.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

It will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

Scientific and cultural use for academics is allowed after the publication of the study

From where data/document is obtainable

Applicants should know to send a message to the email listed in the study to receive the desired documents or data Karimiraziye39@gmail.com

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

Finally, one week after sending the request to the e-mail karimiraziye39@gmail.com, I will respond to the requester to receive data/documents.

Comments