

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4447 5025

##### Email address

std\_karimiraziye39@khu.ac.ir

##### 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

**Age**

From **30 years** old to **40 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **75**

**Randomization (investigator's opinion)**

Randomized

**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/lits>. 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

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.

**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**

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

**Street address**

in front of Jovanmardan Park, North side of Hemet highway

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Tehran

**Province**

Tehran

**Postal code**

1477877687

**Phone**

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**Email**

info@westnikanhospital.com

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

Khatam-al- Anbya Hospital

**Full name of responsible person**

dr mahmood almasi

**Street address**

Rashid Yasmi St, above Mirdamad Blvd, Valiasr St

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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

**Street address**

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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**Full name of responsible person**

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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**Person responsible for updating data****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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+98 21 4447 5025

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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**