Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 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
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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

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/lists. 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
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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
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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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Fax
+98 21 2226 9547
Email
info@khu.ac.ir
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
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Other areas of specialty/work
Corrective exercises and sports pathology
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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