Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Nov 2026

Effectiveness Evaluation of Lumbar Stabilization Exercise Based on Telerehabilitation in Nonspecific Chronic Low Back Pain

Protocol summary

Study aim

Effectiveness Evaluation of Lumbar Stabilization Exercise Based on Telerehabilitation in Nonspecific Chronic Low Back Pain

Design

A clinical trial with a control group, without blinding, will be randomized on 30 patients. Randomization will be by picking between two choices, "Intervention" or "Control".

Settings and conduct

The intervention in this research is to perform spine stability exercises in three positions: arched, sitting and standing, using a pressure biofeedback device. The intervention group performs exercises at home under remote supervision. The control group performs the same exercises in the clinic under the direct supervision of the therapist.

Participants/Inclusion and exclusion criteria

People with non-specific chronic back pain are in the age range of 20 to 60 years old, who either had back pain for at least 12 weeks before conducting the research, or had back pain at least 3 times during the year before conducting the research, and each time their back pain lasted for more than a week. be These patients must be able to use a laptop or computer.

Intervention groups

The intervention in this research is to perform spine stability exercises in three positions: arched, sitting and standing, using a pressure biofeedback device. The intervention group performs exercises at home under remote supervision. The control group performs the same exercises in the clinic under the direct supervision of the therapist.

Main outcome variables

The main variables in this study are: pain; functional disability; Neuromuscular coordination and muscular endurance. The expected outcomes of this research are: Improving remote service delivery to patients, Reducing treatment costs for patients, Saving the time needed to receive medical services.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221129056656N1**
Registration date: **2022-12-28, 1401/10/07**
Registration timing: **prospective**

Last update: **2022-12-28, 1401/10/07**
Update count: **0**

Registration date

2022-12-28, 1401/10/07

Registrant information

Name

SHIMA KARIMI

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 4462 3852

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-05, 1401/10/15

Expected recruitment end date

2023-02-19, 1401/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness Evaluation of Lumbar Stabilization Exercise Based on Telerehabilitation in Nonspecific Chronic Low Back Pain

Public title

Effectiveness Evaluation of Lumbar Stabilization Exercise Based on Telerehabilitation in Nonspecific Chronic Low Back Pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

People between 20-60 years old, suffer Nonspecific Chronic Low Back Pain Had back pain at least 12 week before research, or suffered back pain at least 3 times, each one more than one week, in one year before research, Know how to use PC or Laptop

Exclusion criteria:

History of spinal, pelvic, lower limb fracture in last year History of any surgery in the spine area History of neuromuscular diseases History of systemic diseases such as rheumatism, joint tuberculosis, diabetes along with neuropathy Acute intervertebral disc herniation in the lumbar region The presence of diffuse and radicular pains in the lower limbs as well as nerve and sensory disorders such as tingling, murmur, etc. in the lower limbs and especially in dermatomes related to the nerve roots Existence of anatomical problems in back and hip radiographs of patients The presence of spondylolisthesis and spondylolysis The presence of acute back pain caused by trauma during the research period (According to the patient's self-report) Patients addicted to alcohol and drugs (Based on the patient's self-report in the questionnaire) Existence of severe pain during the tests so that the pain becomes the cause of movement limitation in performing the measurements and disrupts their correct evaluation. For this purpose, the pain intensity during the tests should be below 7 VAS scale Patients who have done physiotherapy treatment for their back pain in the last 6 months Pregnant women at any stage of pregnancy Obesity (body mass index above 30) History of any shortness of breath based on the public health questionnaire History of any pain, dislocation or fracture in the hip joint area based on the general health questionnaire (regardless of time) History of any injury to the back and lower limbs in the last 3 months based on the general health questionnaire People who participate in preparation programs for competitive sports (training more than 3 days per week)

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible volunteers will randomly assigned to either "intervention" or "control" Simple Random Sampling will be done by picking between two choice "Intervention" and "Control".

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

Ethics Committee of University of Social Welfare and Rehabilitation Sciences

Street address

kodakyar Ave., daneshjo Blvd.,Evin

City

Tehran

Province

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Postal code

1985713871

Approval date

2022-11-23, 1401/09/02

Ethics committee reference number

IR.USWR.REC.1401.167

Health conditions studied

1

Description of health condition studied

Nonspecific Chronic Low Back Pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes

1

Description

Pain Intensity: It is an unpleasant sensory and emotional experience that occurs with real or potential tissue damage or is expressed as such damage. Therefore, pain is more than a signal for tissue damage.

Timepoint

At the beginning of the study, before the exercises and at the end of the exercise period.

Method of measurement

In this research, an analog visual scale is used to determine pain intensity.

2

Description

Functional Disability: The effects and consequences of chronic or acute conditions are said to affect various body systems and cause limitation or lack of people's ability to perform basic and functional activities, such as standing, sitting, dressing and walking in a natural range.

Timepoint

At the beginning of the study, before the exercises and at the end of the exercise period.

Method of measurement

In this research the Oswestry Questionnaire is used to evaluate the level of functional disability of the patients. The total score of the items of this scale is considered as the functional disability level of the people, which is zero without disability and 100 as maximum disability. This questionnaire has ten parts, each part has six sub-parts, which are graded from 0 to 5. The individual's disability score is calculated by multiplying the total points obtained by 2 and then dividing by 100 and is displayed as a percentage.

3

Description

Endurance: Muscle contraction and maintaining it for a predetermined period of time.

Timepoint

At the beginning of the study, before the exercises and at the end of the exercise period.

Method of measurement

Biofeedback will be used to measure the endurance of lumbar muscles. The duration of time when people maintain contraction with an intensity of more than sixty percent of the maximum power will be measured in seconds.

4

Description

Neuromuscular Coordination: It is an essential tool for the successful completion of a movement task, which is described in terms of accuracy and optimality.

Timepoint

At the beginning of the study, before the exercises and at the end of the exercise period.

Method of measurement

Biofeedback will be used to measure the Neuromuscular Coordination of muscles. Each person simulates the ramp pattern of Mehrsam Company's Motor Learning Biofeedback System 5 times. patient will rest 10 seconds between each attempt. In the end, the maximum muscle strength, the error criterion from the model, the similarity coefficient with the model, the error of the maximum increase and the error of the maximum decrease are measured by the software of this system.

5

Description

Patient Satisfaction with Physiotherapy Treatment: Patient Satisfaction is a complex and multidimensional concept. Patient satisfaction with physiotherapy has various aspects, which include the skill of the physiotherapist, the relationship between the physiotherapist and the patient, and the efficiency of the treatment. Measuring patients' satisfaction provides valuable information for physiotherapists to improve physiotherapy services to meet patients' needs.

Timepoint

At the end of Treatment

Method of measurement

Patient Satisfaction with Physiotherapy Treatment will be measured by using MRPS Questionnaire (Persian Version).

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Patients are asked to maintain the contraction of the stabilizing muscles of the lumbar region for 5 to 10 seconds and do 10 times with a 10-second rest between each repetition. This exercise is performed using a pressure biofeedback device at home and controlled remotely by the researcher with the help of AnyDesk software.

Category

Rehabilitation

2

Description

Intervention group 2: In the supine, the patient contracts the stabilizing muscles of the lower back and while maintaining this contraction, slides the heel of one leg on the bed until the knee is completely straightened. Then he returns the leg to the first position and performs the movement with the opposite leg, after 10 seconds of rest, he follows this movement up to 10 repetitions. This exercise is performed using a pressure biofeedback device at home and controlled remotely by the researcher with the help of AnyDesk software.

Category

Rehabilitation

3

Description

Intervention group 3: In supine, the patient has contracted the stabilizing muscles of the lumbar region and very slowly straightened one leg, and after obtaining the full range of knee extension and placing the anterior superior Iliac spine with the patella in line with the ground (between 7 and 10 cm above the surface of the

bed) the extension of the hip joint is stopped and maintained for 5 seconds. Then it returns to the initial position and the movement is performed with the lower limb of the opposite side, after 10 seconds of rest, it performs this movement up to 10 repetitions. This exercise is performed using a pressure biofeedback device at home and controlled remotely by the researcher with the help of AnyDesk software.

Category

Rehabilitation

4

Description

Intervention group 4: The patient sits on a stool with his back to the wall so that the soles of his feet are on the floor, the cushion of the biofeedback device is placed between the lumbar arch of the patient and the wall, the patient performs the contraction of the stabilizing muscles of the lumbar region and maintains this movement for 5 to 10 seconds, 10 times. Repeats with a 10-second rest. Then while the knee is relaxed and bent he raise the thigh up to 45-degree angle of hip joint. Then repeat with other leg for 10 times with a 10-second rest. This exercise is performed using a pressure biofeedback device at home and controlled remotely by the researcher with the help of AnyDesk software.

Category

Rehabilitation

5

Description

Intervention group 5: The patient stands straight with his back against the wall while the biofeedback pillow is placed between the lumbar arch and the wall, first he contracts the stabilizing muscles of the lumbar region and maintains it for 5 to 10 seconds. Perform this movement 10 times with 10 seconds rest between repetitions. Then, keeping the contraction, he raises the lower limb to a 90-degree knee and hip joint. Then repeat with other leg for 10 times with a 10-second rest. This exercise is performed using a pressure biofeedback device at home and controlled remotely by the researcher with the help of AnyDesk software.

Category

Rehabilitation

6

Description

Control group 1: Patients are asked to maintain the contraction of the stabilizing muscles of the lumbar region for 5 to 10 seconds and do 10 times with a 10-second rest between each repetition. This exercise is performed using a pressure biofeedback device in the clinic under the direct supervision of the researcher.

Category

Rehabilitation

7

Description

Control group 2: In the supine, the patient contracts the stabilizing muscles of the lower back and while maintaining this contraction, slides the heel of one leg on the bed until the knee is completely straightened. Then he returns the leg to the first position and performs the movement with the opposite leg, after 10 seconds of rest, he follows this movement up to 10 repetitions. This exercise is performed using a pressure biofeedback device in the clinic under the direct supervision of the researcher.

Category

Rehabilitation

8

Description

Control group 3: In supine, the patient has contracted the stabilizing muscles of the lumbar region and very slowly straightened one leg, and after obtaining the full range of knee extension and placing the anterior superior Iliac spine with the patella in line with the ground (between 7 and 10 cm above the surface of the bed) the extension of the hip joint is stopped and maintained for 5 seconds. Then it returns to the initial position and the movement is performed with the lower limb of the opposite side, after 10 seconds of rest, it performs this movement up to 10 repetitions. This exercise is performed using a pressure biofeedback device in the clinic under the direct supervision of the researcher.

Category

Rehabilitation

9

Description

Control group 4: The patient sits on a stool with his back to the wall so that the soles of his feet are on the floor, the cushion of the biofeedback device is placed between the lumbar arch of the patient and the wall, the patient performs the contraction of the stabilizing muscles of the lumbar region and maintains this movement for 5 to 10 seconds, 10 times. Repeats with a 10-second rest. Then while the knee is relaxed and bent he raise the thigh up to 45-degree angle of hip joint. Then repeat with other leg for 10 times with a 10-second rest. This exercise is performed using a pressure biofeedback device in the clinic under the direct supervision of the researcher.

Category

Rehabilitation

10

Description

Control group 5: The patient stands straight with his back against the wall while the biofeedback pillow is placed between the lumbar arch and the wall, first he contracts the stabilizing muscles of the lumbar region and maintains it for 5 to 10 seconds. Perform this movement 10 times with 10 seconds rest between repetitions. Then, keeping the contraction, he raises the lower limb to a 90-degree knee and hip joint. Then repeat with other leg for 10 times with a 10-second rest. This exercise is

performed using a pressure biofeedback device in the clinic under the direct supervision of the researcher.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
BehBakhsh Physiotherapy Clinick

Full name of responsible person
Shima Karimi

Street address
Unit 7, No. 32, Golestan St., Cent. JanatAbad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
University of social welfare and rehabilitation sciences

Full name of responsible person
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Web page address
https://www.uswr.ac.ir/

Grant name

Grant code / Reference number

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

Title of funding source
University of social welfare and rehabilitation 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
University of social welfare and rehabilitation sciences

Full name of responsible person
Shima Karimi

Position
MS Student

Latest degree
Bachelor

Other areas of specialty/work
Physiotherapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

To protect the privacy of the patients participating in the research.

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available