Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of performing therapeutic selected exercises using virtual reality and routine method on pain, function and quality of life in patients with non-specific chronic low back pain.

Protocol summary

Study aim

Comparison of the effect of selective therapeutic exercise using virtual and normal reality methods on pain, performance and quality of life in patients with non-specific chronic low back pain.

Design

a randomized, single blinded, clinical trial with a parallel group design of 44 patients , enrolled between July 2023 and November 2023.

Settings and conduct

People with non-specific chronic back pain referred to the physiotherapy department of Rofidah Rehabilitation Hospital in 1402 At first, the goals, method of conducting the study and other required information are provided to the participant. Then the patients will be randomly divided into two control and intervention groups. After the completion of the treatment sessions, the evaluation of the end of the treatment period is done, and two weeks after the end of the treatment period, the evaluation will be repeated .Participants will be treated every other day for 10 sessions.

Participants/Inclusion and exclusion criteria

People with non-specific chronic mechanical back pain with the diagnosis of the attending physician and file. People who are between 20-50 years old. Having a history of back pain for at least 12 weeks. Have an average pain of 4-7 on the visual analog scale of pain in the previous seven days ؛ Patients with congenital abnormalities. Fracture of the spine or lower and upper limbs. Any systemic disease or neurological disease Previous back surgery pregnant women

Intervention groups

In the intervention group, physical therapy is performed routinely for the participants. In the next step, the participants take part in virtual reality therapeutic exercise training.

Main outcome variables

kinesiophobia, muscle strength, range of motion, quality of life, disability ,pain ,balance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230411057885N1**
Registration date: **2023-05-15, 1402/02/25**
Registration timing: **prospective**

Last update: **2023-05-15, 1402/02/25**
Update count: **0**

Registration date

2023-05-15, 1402/02/25

Registrant information

Name

fatimah khalifeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 933 454 5341

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-02, 1402/04/11

Expected recruitment end date

2023-12-23, 1402/10/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of performing therapeutic selected exercises using virtual reality and routine method on pain, function and quality of life in patients with non-specific chronic low back pain.

Public title

The effect of virtual reality therapeutic exercise in the treatment of chronic low back pain.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People with non-specific chronic mechanical back pain with the diagnosis of the attending physician and file. People who are between 20-50 years old. They are not involved in any other treatment program during the study. Have stopped taking painkillers 24 hours before the evaluation. Having a history of back pain for at least 12 weeks. Have an average pain of 4-7 on the visual analog scale of pain in the previous seven days.

Exclusion criteria:

Patients with congenital abnormalities. History of trauma Fracture of the spine or lower and upper limbs Any systemic disease or neurological disease Individuals who have taken corticosteroids, benzodiazepines, antidepressants, or anticonvulsants three weeks prior to the evaluation. pregnant women previous back surgeries Vestibular and vision disorders Obese people according to body mass index Aggravation of symptoms so that it is not possible to perform.

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Placement of samples in intervention and control groups is done in a simple random stratified manner. Considering that it is necessary for the groups to be homogeneous in terms of sex, the classes include 2 classes resulting from the sex (two groups). A person is placed in one of the classes based on gender. The desired sample is then randomly placed in one of the two groups, and the next sample placed in the same class is placed in the opposite group.

Blinding (investigator's opinion)

Single blinded

Blinding description

The evaluator of patients participating in the first session and the final 10th session is blinded to the information, purpose and results of the thesis.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical committee of rehabilitation and social welfare sciences university

Street address

velenjak , daneshju boulevard, kodakyar ave

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Postal code

1985713871

Approval date

2023-03-19, 1401/12/28

Ethics committee reference number

IR.USWR.REC.1401.256

Health conditions studied

1

Description of health condition studied

patients suffering chronic non specific low back pain

ICD-10 code

M54.9

ICD-10 code description

Dorsalgia, unspecified

Primary outcomes

1

Description

pain score that is calculated between 0 and 10.

Timepoint

Measuring the pain score before the intervention and at the end of the treatment sessions and two weeks later.

Method of measurement

using the virtual analogue scale

Secondary outcomes

1

Description

kinesiophobia

Timepoint

before the intervention and at the end of the treatment sessions and two weeks later.

Method of measurement

tampa scale of kinesiophobia

Intervention groups

1

Description

Intervention group: It should be noted that all patients are placed in the lying position on the stomach during all stages of using the modalities and a pillow is placed under the abdomen and leg. The spine should be in a neutral position. Using a small towel under the patient's forehead will be used to prevent neck rotation. Applying ten sessions of physiotherapy using modalities that include three modalities. which includes three modalities: 1) Continuous ultrasound with a frequency of 3 MHz for 8 minutes. The application of pulsed ultrasound was standardized in the lower back area between the first and fifth lumbar vertebra and in the area of interest, the distance between the spinous and transverse appendages on the right and left sides, the target muscles including the spinalis, the erector spinae muscles and in the multifidus area, which is below the two The mentioned muscle is located. One minute was considered for each point, after the electric current of TENS continuously in the lower back area in the pain area for 15 minutes using two channels and four electrodes (10 x 10 cm) placed around the pain area with Frequency setting of 20 Hz and pulse width of 10 pulses per second (pps) along with 15 minutes of our infrared heat is used at a distance of 30 cm on the lower back area. The next step, which is the exercise step, first teaches the patient how to perform each exercise. Each exercise mentioned is repeated ten times. The red reference is placed in the middle of the patient's foot, and the ball is displayed at a certain distance from the red marker when it is shown on either side of the patient. The patient is placed individually (alone) with the therapist in a room dedicated to virtual reality and face to face with a distance of 200-250 cm from the device. The progress of the exercises will be done depending on the patient's ability during the sessions.

Category

Rehabilitation

2

Description

Control group: It should be noted that all patients are placed in the lying position on the stomach during all stages of using the modalities and a pillow is placed under the abdomen and leg. The spine should be in a neutral position. Using a small towel under the patient's forehead will be used to prevent neck rotation. Applying ten sessions of physiotherapy using modalities that include three modalities. which includes three modalities: 1) Continuous ultrasound with a frequency of 3 MHz for 8 minutes. The application of pulsed ultrasound was standardized in the lower back area between the first and fifth lumbar vertebra and in the area of interest, the distance between the spinous and transverse appendages on the right and left sides, the target muscles including the spinalis, the erector spinae muscles and in the multifidus area, which is below the two The mentioned muscle is located. One minute was considered for each point, after the electric current of TENS continuously in the lower back area in the pain area for 15 minutes using two channels and four electrodes (10 x 10 cm) placed around the pain area with Frequency setting of 20 Hz and pulse width of 10 pulses per second (pps) along with 15 minutes of our infrared heat is used at a distance of 30 cm on the lower back area.The next step, which is the exercise step, first teaches the patient how to perform each exercise. Each exercise mentioned is repeated five times in the first session, and increased to 10 repetitions in the second session, 15 repetitions in the third session, and 20 repetitions in the fourth session. The remaining sessions are continued with 20 repetitions. The exercises of the control and intervention groups have been selected in such a way that they can be implemented in a similar and corresponding way in each group, with the difference that in the intervention group, the exercises are performed using a virtual reality system.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Rofeideh Rehabilitation Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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
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
Fatimah Khalifeh

Position
PhD student

Latest degree
Master

Other areas of specialty/work
Physiotherapy

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Person responsible for updating data

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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

demographic information and outcomes

When the data will become available and for how long

6 months after article acceptance

To whom data/document is available

other researchers

Under which criteria data/document could be used

more advanced researches like meta analysis

From where data/document is obtainable

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

university of rehabilitation and social welfare sciences

Comments