

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 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)

##### Phone

+98 933 454 5341

##### Email address

fatimah.khalifeh@hotmail.com

##### 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

##### City

Tehran

##### Province

Tehran

##### 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**

Fatimah Nader Khalifeh

##### **Street address**

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##### **City**

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##### **Province**

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##### **Postal code**

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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**

Hamid Reza Khanke

##### **Street address**

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**Phone**

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**Email**

hamid.khanke@ki.se

**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 scientific inquiries

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**Other areas of specialty/work**

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## Person responsible for updating data

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**Position**

PhD student

**Latest degree**

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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**

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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fatimah.khalifeh@hotmail.com

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

university of rehabilitation and social welfare sciences

**Comments**