

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of Different Virtual Reality Based Exercises in addition to Routine Physiotherapy on Chronic Low back Pain

Protocol summary

Study aim

To compare different Virtual reality based exercises with routine physiotherapy in patients with chronic low back pain

Design

A concealed, single blinded randomised controlled trial will be conducted on 100 patients, single centered study

Settings and conduct

University of lahore teaching hospital, Pain Center, single blinded study (patient will be blinded to the recruited group)

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Both male and female patients, age between 25-80 years, Clinically diagnosed with Chronic Low back pain and willing to participate in the study.
Exclusion Criteria: Any fracture or dislocation of lumbar spine, Any history of surgery on lumbar spine, hip or pelvis, Spinal tumors or infections in the intervertebral disc, Inflammatory diseases such as rheumatism, Spinal deformity such as scoliosis, spondylololsthesis. Patients taking medications e.g Non-Steroidal Anti-Inflammatory Drugs (NSAIDS) for pain, Pregnant females, Virtual reality Phobia

Intervention groups

Patients will be randomly divided into control and experimental groups. The control group will receive routine physical therapy while the experimental groups will receive Virtual reality based exercises alongwith the routine physical therapy

Main outcome variables

Pain, Functional Disability , fear avoidance belief and Range of Motion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230426057995N1**

Registration date: **2023-05-01, 1402/02/11**

Registration timing: **prospective**

Last update: **2023-05-01, 1402/02/11**

Update count: **0**

Registration date

2023-05-01, 1402/02/11

Registrant information

Name

Muhammad Waqar

Name of organization / entity

The University of Lahore

Country

Pakistan

Phone

+92 42 111 865 865

Email address

waqarafzalpt@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-13, 1402/02/23

Expected recruitment end date

2023-07-20, 1402/04/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Different Virtual Reality Based Exercises in addition to Routine Physiotherapy on Chronic Low back Pain

Public title

Effects of Virtual Reality Based Exercises on Chronic Low back Pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Both male and female patients, age between 25-80 years. Clinically diagnosed as Chronic Low Back Pain and willing to participate in the study

Exclusion criteria:

Any fracture or dislocation of lumbar vertebra, history of any surgery of lumbar spine, hip or pelvis Spinal tumors or infections, any disc Inflammatory diseases such as rheumatism, Spinal deformity such as scoliosis, spondylolysis Patients taking medications e.g NSAIDS for pain, Pregnant females, Virtual reality phobia

Age

From **25 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

By using computer generated random number table, patients will be randomly assigned into two groups. All those random numbers will be enclosed in sealed envelopes. A third person (who will further not be the part of research) will open envelopes and the patients will be allocated to the mentioned group accordingly.

Blinding (investigator's opinion)

Single blinded

Blinding description

An independent assessor, who will be a senior and experienced physiotherapist and further will not be the part of study will perform the assessment of patients

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Institutional Review Board

Street address

1-Km Defence Road, near Bhuptian Chowk, Lahore,

Punjab

City

Lahore

Postal code

54000

Approval date

2020-01-23, 1398/11/03

Ethics committee reference number

IRB-UOL-FAHS/696-IV/2020

Health conditions studied

1

Description of health condition studied

Chronic low back pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes

1

Description

Pain

Timepoint

Before Intervention then after 3rd and 6th Week after Intervention

Method of measurement

Numeric pain rating scale

2

Description

Functional status

Timepoint

Before Intervention then after 3rd and 6th Week after Intervention

Method of measurement

Back Pain Functional Scale

3

Description

Fear Avoidance

Timepoint

Before Intervention then after 3rd and 6th Week after Intervention

Method of measurement

Fear avoidance belief questionnaire

Secondary outcomes

1

Description

Range of Motion

Timepoint

Before Intervention and 6th week after Intervention

Method of measurement

Inclinometer

Intervention groups

1

Description

Intervention group: Virtual Reality Exercises with Body ball game

Category

Rehabilitation

2

Description

Intervention group: Virtual Reality Exercises with Rally Ball game

Category

Rehabilitation

3

Description

Intervention group: Virtual Reality Exercises with Fruit Ninja game

Category

Rehabilitation

4

Description

Control group: Routine Physiotherapy

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

University of Lahore teaching hospital

Full name of responsible person

Umair Ahmad

Street address

1-Km Defence Road,, near Bhuptian Chowk., Lahore, Punjab

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Lahore

Full name of responsible person

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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 Lahore

Proportion provided by this source

1

Public or private sector

Private

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 Lahore

Full name of responsible person

Umair Ahmad

Position

Head of the department

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

Contact

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University of Lahore
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Other areas of specialty/work
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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Primary outcome measure will be available (Effects of VR on Chronic low back) through email at waqarafzalpt@gmail.com

When the data will become available and for how long

After 4 weeks of publications

To whom data/document is available

people working in academic, clinician dealing with low back pain

Under which criteria data/document could be used

By providing the educational background as academic institutions or registered clinician through registered by the registering body of the Country

From where data/document is obtainable

Through email at waqarafzalpt@gmail.com

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

Requesting through email at waqarafzalpt@gmail.com with all relevant details

Comments