

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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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##### Phone

+92 42 111 865 865

##### Email

umair.ahmed@uipt.uol.edu.pk

##### Web page address

https://uol.edu.pk/

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

University of Lahore

##### Full name of responsible person

Umair Ahamd

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

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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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Umair Ahmed  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
University of Lahore  
**Full name of responsible person**  
Muhammad Waqar  
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Research Coordinator  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Physiotherapy  
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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