

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

EFFECTS OF VIRTUAL REALITY EXERCISES ON CLINICAL OUTCOMES IN PATIENTS WITH CHRONIC LOW BACK PAIN: A RANDOMIZED CONTROLLED TRIAL

Protocol summary

Study aim

To compare the Effects of Virtual Reality Exercises and routine Physical Therapy on pain Intensity, Lumbar range of Motion, Muscle Endurance, Functional disability and Quality of life in patients with chronic low back pain

Design

Randomized controlled trial a single blinded study

Settings and conduct

The study would be single blinded as assessors of the study would be kept blind of the treatment group to which the patient will be allocated and will be done at The Physiotherapy Department of Government Services Hospital Lahore.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 25-50 years, Both males and females, Low back pain that persists for more than 12 weeks, Non radiating low back pain, Localized pain in Lumbar region . Exclusion Criteria: History of any trauma or fracture of the spine or lower limb, cardiac ,metabolic, endocrine, Pott's disease or any other systematic disease, neurological diseases such as Parkinson's disease, stroke and epilepsy. Previous surgery of spine, corticosteroid or anticoagulants, Drug abuse, Congenital deformity, pathology or musculoskeletal disorder in lower limb, exposure to virtual reality games or exercises in past three months and Virtual reality games phobia

Intervention groups

Group A will get Virtual Reality Exercises. The Kinect device will be used for Virtual Reality Exercises in which patient will do exercises through Reflex ridge (trunk slide flexion, jumping, sitting to avoid hitting the obstacles combine movements of arms and legs) and Body Ball VR games (pushing head, moving arm and kicking ball) as displayed on wall mounted LCD. Group B will get only Routine Physical Therapy exercises. Both groups will get Patient education, posture care, back exercises etc (as described in detail in main section of Intervention

groups)

Main outcome variables

Pain intensity, Lumbar range of motion , Functional disability and Muscle endurance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200330046895N1**

Registration date: **2020-04-19, 1399/01/31**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-19, 1399/01/31**

Update count: **0**

Registration date

2020-04-19, 1399/01/31

Registrant information

Name

Muhammad Waqar Afzal

Name of organization / entity

The University of Lahore

Country

Pakistan

Phone

+92 42 37812194

Email address

waqarafzal621@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-15, 1399/01/27

Expected recruitment end date

2020-10-15, 1399/07/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

EFFECTS OF VIRTUAL REALITY EXERCISES ON CLINICAL OUTCOMES IN PATIENTS WITH CHRONIC LOW BACK PAIN: A RANDOMIZED CONTROLLED TRIAL

Public title

EFFECTS OF VIRTUAL REALITY EXERCISES ON CLINICAL OUTCOMES IN PATIENTS WITH CHRONIC LOW BACK PAIN: A RANDOMIZED CONTROLLED TRIAL

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Low back pain that persists for more than 12 weeks Non radiating low back pain Localized pain in lumbar spine Both males and females Age between 25 to 50 years

Exclusion criteria:

History of any trauma or fracture of the spine or lower limb History of any cardiac ,metabolic, endocrine, Pott's disease or any other systematic disease History of any neurological diseases such as Parkinson's disease, stroke and epilepsy History of any Previous surgery of spine Patient on corticosteroid or anticoagulants History of any Drug abuse Any Congenital deformity History of any pain, pathology or musculoskeletal disorder in lower limb History of any neurological conditions History of having exposure to virtual reality games or exercises in past three months Virtual reality games phobia Pregnant female

AgeFrom **25 years** old to **50 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample sizeTarget sample size: **84****Randomization (investigator's opinion)**

Randomized

Randomization description

The subjects fulfilling the inclusion criteria will be enrolled after independent outcome assessor Then coin toss method will be used for randomization .The coin will be thrown in air having two sides with label "A" and "B". The subject's randomization method reduces the chances of bias group allocation.

Blinding (investigator's opinion)

Single blinded

Blinding description

The study would be single blinded as assessor of the study will be kept blind of the treatment group to which the pateint will be alloacted

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

The University of Lahore, 1 - KM Defence Road, Lahore

City

Lahore

Postal code

54000

Approval date

2020-01-22, 1398/11/02

Ethics committee reference number

IRB-UOL-FAHS/696/2020

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 Intensity

Timepoint

before intervention and then on 4th, 8th and 12th week

Method of measurement

Visual analogue scale

2**Description**

Functional disability

Timepoint

before intervention and then on 4th, 8th and 12th week

Method of measurement

Modified Oswestry low back Disability Questionnaire

3

Description

Lumbar Range of motion

Timepoint

before intervention and then on 4th, 8th and 12th week

Method of measurement

Inclinometer

Secondary outcomes

1

Description

Quality of Life

Timepoint

before intervention and then After 12th session

Method of measurement

SF-36

2

Description

Muscle Endurance

Timepoint

before intervention then on 4th, 8th and 12th session

Method of measurement

Biering-Sorensen test

Intervention groups

1

Description

Intervention group: Group A will get Virtual reality exercises. The Kinect device will be used for Virtual Reality (VR) Exercises in which patient will perform exercises through reflex ridge VR game which includes trunk slide flexion, jumping, sitting to avoid hitting the obstacles and combine movement of legs and arms 5 minutes as displayed on wall mounted LCD, then after 30 seconds rest patient will perform exercises through Body Ball VR game which includes moving arm, pushing head and kicking the ball for 5 minutes. Prior to VR exercise thermotherapy through hot pack for 10 minutes will be applied on Lumbar region. In addition to VR exercise patients will get routine physical therapy which includes patient education ,posture care and exercises as three sets of 10 repetition of bridging, prone leg raises, trunk extension in prone with arms behind the back, trunk rotation exercises, knee to chest and prone position with diagonal elevation of the arm and leg exercise. This will be done on alterante days and total twelve sessions will be given.

Category

Rehabilitation

2

Description

Intervention group: Group B Routine physical Therapy exercise, patients will get thermotherapy through hot pack for 10 minutes will be applied on Lumbar region

before exercises then routine physical therapy which includes patient education ,posture care and exercises as three sets of 10 repetition of bridging, prone leg raises, trunk extension in prone with arms behind the back, trunk rotation exercises, knee to chest and prone position with diagonal elevation of the arm and leg exercise. This will be done on alterante days and total twelve sessions will be given.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

The Physiotherapy Department of Government Services Hospital Lahore

Full name of responsible person

Muhammad Sharif Waqas

Street address

Ghaus-ul-Azam, Shadman Jail Road, Punjab, Lahore

City

Lahore

Postal code

54000

Phone

+92 42 35963421

Email

waqasphysio@gmail.com

Web page address

<http://sims.edu.pk/shl.aspx>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University Of Lahore

Full name of responsible person

Muhammad Waqar

Street address

The University Of Lahore 1-Km Defence Road. Near Bhuptian Chowk, Lahore

City

Lahore

Postal code

54000

Phone

+92 42 37812194

Email

waqarafzal621@gmail.com

Grant name

Grant code / Reference number

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

No

Title of funding source

The University of Lahore

Proportion provided by this source

100
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
The University of Lahore
Full name of responsible person
Ashfaq Ahmad
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
The University Of Lahore 1-Km Defence Road, Near
Bhuptian Chowk, Lahore
City
Lahore
Province
Punjab
Postal code
54000
Phone
+92 42 35963421
Email
ashfaaqpt@gmail.com
Web page address
<https://www.uol.edu.pk/>

Person responsible for scientific inquiries

Contact

Name of organization / entity
The University of Lahore
Full name of responsible person
Ashfaq Ahmad
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
The University Of Lahore 1-Km Defence Road, Near
Bhuptian Chowk, Lahore
City
Lahore
Province
Punjab
Postal code

54000
Phone
+92 42 35963421
Email
ashfaaqpt@gmail.com
Web page address
<https://www.uol.edu.pk/>

Person responsible for updating data

Contact

Name of organization / entity
The University of Lahore
Full name of responsible person
Muhammad Waqar Afzal
Position
Assistant Professor
Latest degree
Master
Other areas of specialty/work
Physiotherapy
Street address
61-A Alhamd Park Near neelam block Allama Iqbal
town
City
Lahore
Province
Punjab
Postal code
54000
Phone
+92 42 37812194
Email
waqarafzal621@gmail.com

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

EFFECTS OF VIRTUAL REALITY EXERCISES ON CLINICAL
OUTCOMES IN PATIENTS WITH CHRONIC LOW BACK PAIN:
A RANDOMIZED CONTROLLED TRIAL and all collected
deidentified IPD will be shared.

When the data will become available and for how long

After Publication

To whom data/document is available

people working in academic institutions and researchers

Under which criteria data/document could be used

on permission from investigator

From where data/document is obtainable

Through email to Investigator waqarafzal621@gmail.com

What processes are involved for a request to access

data/document

Through Email and phone waqarafzal621@gmail.com
00923214668377

Comments