Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 sinlge blinded as assessors of the study would be kept blind of the treatment group to which the patient will be allocated and willbe 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 monthsand 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 movemnts 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 Physcial Therapy exercies. 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
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Pakistan
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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
Age
From **25 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target 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 alloacated
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
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Ghaus-ul-Azam, Shadman Jail Road, Punjab، Lahore
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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
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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Ashfaq Ahmad

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

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Person responsible for updating data

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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
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