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 Physcial 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
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Name of organization / entity
The University of Lahore
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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 neurological diseases such as Parkinson’s disease, stroke and epilepsy 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 patient will be allocated

**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 alternate 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

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

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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

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
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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**