Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effects of virtual reality and routine physical therapy on balance and postural control in adulthood population with risk of fall

Protocol summary

Study aim
To compare effects of virtual reality and routine physical therapy on balance and postural control in adulthood population having risk of fall

Design
Randomized clinical Trial. single-blinded, 64 samples, parallel groups, randomized by computer-generated method and further concealed envelop method used for allocation in the group. In the envelope, 1 will be code for the control group and 2 will be code for the experimental group.

Settings and conduct
The study will be conducted at the Department of Physiotherapy Al-Noor Hospital Pasrur, Sialkot with the approval of UIPT UOL. The study will be single-blinded.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: • Age 40-65 years. • Both gender • Capable of walking with and without any assistance • Having normal and corrected visual and auditory acuity • Having Berg Balance Scale Score from 21-40. • Can understand instructions. • Individuals with disease, diabetes mellitus, knee osteoarthritis grade 1 on Kellgren and Lawrence scale will also be included. Exclusion Criteria: • Any comorbidity. • A history of other neurological, cardiovascular, or orthopedic diseases affecting postural stability • All patients having a pacemaker or a history of serious cardiac event or of cardiorespiratory dysfunction • Severe cognitive impairment or aphasia leading to difficulty in communication

Intervention groups
INTERVENTION GROUP (Virtual Reality Exercise) The intervention group will be receiving simulated balance exercises in the form of 30–60-min sessions on a weekly basis (5 days) for 6 weeks. For simulated balance exercises, Xbox Kinect will be applied, which is a game console simulating balance exercise in the game environment and allows a person to move freely and have diverse positions.

Main outcome variables
Balance and Postural control.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210321050752N4**
Registration date: **2023-09-09, 1402/06/18**
Registration timing: **registered_while_recruiting**

Last update: **2023-09-09, 1402/06/18**
Update count: **0**

Registration date
2023-09-09, 1402/06/18

Registrant information

Name
Muhammad Waqas

Name of organization / entity
The University of Lahore

Country
Pakistan

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-19, 1402/03/29

Expected recruitment end date
2023-12-19, 1402/09/28

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of virtual reality and routine physical therapy on balance and postural control in adulthood population with risk of fall

Public title

Effects of virtual reality and routine physical therapy on balance and postural control

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 40-65 years Both gender Capable of walking with and without any assistance Having normal and corrected visual and auditory acuity Having Berg Balance Scale Score from 21-40 Can understand instructions Individuals with disease, diabetes mellitus, knee osteoarthritis grade 1 on Kellgrenand Lawrence scale will also be included. Patients with no cognitive impairments will be considered (assessed on MDS cognitive performance scale)

Exclusion criteria:

Any comorbidity such as malignancy, inflammatory rheumatologic disease, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, lupus erythematosus etc. A history of other neurological, cardiovascular, or orthopedic diseases affecting postural stability All patients having a pacemaker or a history of serious cardiac event or of cardiorespiratory dysfunction Severe cognitive impairment or aphasia leading to difficulty in communication Participants are unwilling to comply with the protocol.

Age

From **40 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

The lottery method will be used for randomization by using random number-generating software and further concealed envelop method is used for allocation in the group. In the envelop, 1 will be code for the control group and 2 will be code for the experimental group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Assessor will only assess the patient at baseline and after follow-up for treatment outcomes. Assessor safe the data for follow-up and will not share it with any therapist or patient. At any stage, the assessor is unaware of the treatment and control group. The study was single-blinded. The assessor was unaware of the treatment given to either groups 1 or 2.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The University of Lahore

Street address

RAIWIND ROAD CAMPUS: 1-Km, Raiwind Road, Near Thokar Niaz Big, Lahore

City

Lahore

Postal code

5400

Approval date

2023-06-19, 1402/03/29

Ethics committee reference number

REC-UOL-426-06-2023

Health conditions studied

1

Description of health condition studied

Balance

ICD-10 code

R26.8

ICD-10 code description

Other and unspecified abnormalities of gait and mobility

2

Description of health condition studied

Postural control

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Balance

Timepoint

Data will be collected at baseline, at the end of 6th week and after 8th week.

Method of measurement

Berg balance scale will be used to assess balance.

2

Description
Postural control
Timepoint
Data will be collected at baseline, at the end of 6th week and after 8th week.
Method of measurement
Mini-Balance Evaluation Systems Test (Mini-BESTest) will be used to assess the postural control.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention group will be receiving simulated balance exercises in the form of 30–60-min sessions on a weekly basis (5 days) for 6 weeks. For simulated balance exercises, Xbox Kinect will be applied.
Category
Rehabilitation

2

Description
Control group: The control group will receive routine physical therapy five days week for a 6-weeks. The routine physical therapy will include range of motion (upper and lower limbs- 5 reps of each movement), stretching (for trunk and lower extremity muscles with 3 repetitions of 40 seconds sustained stretch) and strengthening exercises
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of Physiotherapy, Al-Noor Hospital Pasrur, Sialkot
Full name of responsible person
Dr. Ejaz Aslam
Street address
Kalaswala Rd Near Lrbt Hospital, Sialkot Road
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Postal code
51480
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+92 345 2133130
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alnoorhospitalpsr@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Self Supported
Full name of responsible person
Samreen Fatima
Street address
St# 76, H#09 Muhala Sirajpura Darogawala Shalamar Town Lahore
City
Lahore
Postal code
1234
Phone
+92 332 0933109
Email
samreen.rehman975@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Self Supported
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
Other

Person responsible for general inquiries

Contact
Name of organization / entity
The University of Lahore
Full name of responsible person
Muhammad Waqas
Position
Lecturer
Latest degree
Master
Other areas of specialty/work
Physiotherapy
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Position

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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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Mini-Balance Evaluation Systems Test (Mini-BESTest) will be used to assess the postural control.

When the data will become available and for how long

6 months after publication.

To whom data/document is available

academic and clinical research writers.

Under which criteria data/document could be used

Never without permission.

From where data/document is obtainable

From Muhammad Waqas through mail id. drwaqasfayyaz@gmail.com or through a Researchgate account. https://www.researchgate.net/profile/Muhammad-Waqas-26?ev=hdr_xprf

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

From Muhammad Waqas through mail id. drwaqasfayyaz@gmail.com or through a Researchgate account. https://www.researchgate.net/profile/Muhammad-Waqas-26?ev=hdr_xprf

Comments