

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

Phone

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Email address

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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 Kellgren and 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 Lrht Hospital, Sialkot Road

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Sialkot

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Phone

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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
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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

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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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

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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