

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Aug 2022

EFFECTS OF VIRTUAL REALITY WITH MOTOR IMAGERY TECHNIQUES IN ADDITION TO ROUTINE PHYSICAL THERAPY IN PATIENTS WITH PARKINSON'S DISEASE: A RANDOMIZED CONTROLLED TRIAL

Protocol summary

Study aim

1. To compare the effects of virtual reality with motor imagery techniques in addition to routine physical therapy on balance in patients with Parkinson's disease
2. To compare the effects of virtual reality with motor imagery techniques in addition to routine physical therapy on motor function in patients with Parkinson's disease
3. To compare the effects of virtual reality with motor imagery techniques in addition to routine physical therapy on activities of daily living in patients with Parkinson's disease

Design

parallel group, single blind, randomized controlled trial

Settings and conduct

Department of Physical Therapy, Safi Hospital, Faisalabad, Pakistan.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Idiopathic Parkinson's disease Modified Hoehn and Yahr (H&Y) Stage-1 to Stage-3 Between the ages of 50 and 80 years of both gender Independent in transfers Score equal to or greater than 24 score on the Mini-Mental State Examination (MMSE)(62). Previous lack of participation in balance or motor training
Exclusion Criteria: The following exclusion criteria will be applied: History of any neurological conditions such as stroke, multiple sclerosis, epilepsy other than Parkinson's disease History of orthopedic issues such as pain, fracture or lower limb pathology History of visual abnormalities History of any chronic or cardiovascular pathology that can interfere with the transfer procedure or can affect the training sessions The participants having severe dyskinesia's or "on-off" phases Previous history of surgery for PD. History of Virtual games used in past 3 months Virtual game phobia

Intervention groups

Intervention Group- will get Routine Physical Therapy +

Virtual Reality + Motor Imagery 60 minutes of session, Alternative three days/ week for 12 weeks.

Main outcome variables

Motor Function, Balance and Activities of Daily Living

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200221046567N1**

Registration date: **2020-04-01, 1399/01/13**

Registration timing: **prospective**

Last update: **2020-04-01, 1399/01/13**

Update count: **0**

Registration date

2020-04-01, 1399/01/13

Registrant information

Name

Muhammad Kashif

Name of organization / entity

Riphah International University

Country

Pakistan

Phone

+92 41 8777210

Email address

kashif.shaffi@gmail.com

Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2641-07-06, 2020/04/15

Expected recruitment end date

2642-01-05, 2020/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

EFFECTS OF VIRTUAL REALITY WITH MOTOR IMAGERY TECHNIQUES IN ADDITION TO ROUTINE PHYSICAL THERAPY IN PATIENTS WITH PARKINSON'S DISEASE: A RANDOMIZED CONTROLLED TRIAL

Public title

EFFECTS OF VIRTUAL REALITY WITH MOTOR IMAGERY TECHNIQUES IN ADDITION TO ROUTINE PHYSICAL THERAPY IN PATIENTS WITH PARKINSON'S DISEASE: A RANDOMIZED CONTROLLED TRIAL

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Idiopathic Parkinson's disease Modified Hoehn and Yahr (H&Y) Stage-1 to Stage-3 Between the ages of 50 and 80 years of both gender Independent in transfers Score equal to or greater than 24 score on the Mini-Mental State Examination (MMSE) Previous lack of participation in balance or motor training

Exclusion criteria:

History of any neurological conditions such as stroke, multiple sclerosis, epilepsy other than Parkinson's disease History of orthopedic issues such as pain, fracture or lower limb pathology History of visual abnormalities History of any chronic or cardiovascular pathology that can interfere with the transfer procedure or can affect the training sessions The participants having severe dyskinesia's or "on-off" phases Previous history of surgery for PD. History of Virtual games used in past 3 months Virtual game phobia

Age

From **50 years** old to **80 years** old

Gender

Both

Phase

1

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

Lottery method

Blinding (investigator's opinion)

Single blinded

Blinding description

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.

Placebo

Not used

Assignment

Factorial

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Institutional Review Board of University Institute of Physical Therapy, The University of Lahore

Street address

1 KM Raiwind Road

City

Lahore

Postal code

54792

Approval date

2641-04-11, 2020/01/22

Ethics committee reference number

IRB-UOL-FAHS/694/2020

Health conditions studied**1****Description of health condition studied**

PARKINSON'S DISEASE

ICD-10 code

G20

ICD-10 code description

Parkinson's disease, virtual reality, motor imagery, balance, motor function, activities of daily living

Primary outcomes**1****Description**

Balance

Timepoint

before intervention and 6, 12 week and after one month of intervention

Method of measurement

Berg Balance Scale and Activities specific Balance Confidence Scale

2**Description**

Motor Function

Timepoint

before intervention and 6, 12 week and after one month of intervention

Method of measurement

Unified Parkinson's Disease Rating Scale (UPDRS) (Part-III)

3

Description

Activities of Daily livings

Timepoint

before intervention and 6, 12 week and after one month of intervention

Method of measurement

Unified Parkinson's Disease Rating Scale (Part-II)

Secondary outcomes

empty

Intervention groups

1

Description

Category

empty

2

Description

Intervention group:

Category

Treatment - Other

3

Description

Control group:

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Safi Hospital

Full name of responsible person

Muhammad Kashif

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Satiana Road

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Faisalabad

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3800

Phone

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kashif.shaffi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Lahore

Full name of responsible person

Prof. Dr Ashfaq Ahmad

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Phone

+92 42 35322501

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ashfaq.ahmad@uipt.uol.edu.pk

Grant name

Grant code / Reference number

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

Yes

Title of funding source

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

University of Lahore

Full name of responsible person

Muhammad Kashif

Position

PhD Scholar

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

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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

IPD collected for the primary outcome measure only

When the data will become available and for how long

After the publication of the study.

To whom data/document is available

academic institutions and researchers

Under which criteria data/document could be used

On informed request from the investigators

From where data/document is obtainable

via email or telephonic contact with investigators

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

on email request, data will be provided within week.

Comments