Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Oct 2026

Investigating the effect of upper extremity game play in the form of "Tele_Rehabilitation" on upper limb sensory-motor function of people with idiopathic Parkinson.

Protocol summary

Study aim

Investigating the effect of upper extremity game play activities in the form of "Tele_Rehabilitation" on upper limb sensory- motor function of people with idiopathic Parkinson's disease

Design

The type of study will be experimental and clinical trial. Patients will be selected as simple or non-probable cases with inclusion criteria. Participants will then be randomly divided into three groups: One group receives upper extremity game play activities in the form of "Tele-Rehabilitation" in clinic. The other group will do the same upper extremity game play in the form of "Tele-Rehabilitation" at home (These two groups also have traditional exercises). The control group only receives occupational therapy traditional exercises in the clinic. All three groups participant will be assessed before and after doing interventions and also will be followed up after two months.

Settings and conduct

The type of study will be experimental and clinical trial. Patients are referred to clinics and hospitals affiliated to Iran University of Medical Sciences. Patients are selected as simple or non-probable cases with inclusion criteria.

Participants/Inclusion and exclusion criteria

Inclusion criteria of participant: - People with Parkinson's disease on a scale of 1 to 4 on Hoehn&Yahr Scale; - level of cognitive performance above 21; - No orthopedic problem;

Intervention groups

- Intervention group based on upper extremity game play activities with "Tele-Rehabilitation" in the clinic, (with traditional exercise), - Intervention group based on upper extremity game play activities with "Tele-Rehabilitation" at home(with traditional exercise), - Control group by using of occupational therapy traditional exercises in the clinic

Main outcome variables

Wrist Position Sense Test, Shoulder Position Sense Test, Hand Active Sensation Test, Motor function of upper extremity, Power grip

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140416017301N8**
Registration date: **2020-02-20, 1398/12/01**
Registration timing: **registered_while_recruiting**

Last update: **2020-02-20, 1398/12/01**
Update count: **0**

Registration date

2020-02-20, 1398/12/01

Registrant information

Name

Akram Azad

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2226 2450

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-06-19, 1399/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of upper extremity game play in the form of "Tele_Rehabilitation" on upper limb sensory-motor function of people with idiopathic Parkinson.

Public title

Comparison of the effect of using of "Tele_Rehabilitation" and "Traditional methods" on Upper limb Sensory-Motor Function of people with idiopathic Parkinson

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People with idiopathic Parkinson's disease on a scale of 1 to 4 on Hoehn & Yahr Scale Level of cognitive performance equal or above 21

Exclusion criteria:

having orthopedic problem

Age

From **35 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

After finding patients as cases in hand or simple non probable which have inclusion criteria people as absolute random(envelope sealed method) will be divided into three groups. All 3 groups participants will be received traditional treatment. In the other two groups, in addition to traditional treatment of the third group, they receive a treatment (Tele-rehab) in two different ways (with and without the therapist). In absolute random method (envelope and paper method), the name of group s will be written on a piece of paper and put in an envelope and the participants will be asked to choose one of the papers randomly then the patient will be placed in the chosen group.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the participants are blind (in each 3 groups will be done traditional exercises) and the outcome assessor is also blind (Participants at a specific day without knowledge of each other's treatment referred to a center where the outcome assessor would be solely responsible for taking tests from patients without knowledge of the interventions and related participants).

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Etics committee of Iran University of Medical Sciences

Street address

Mirdamad Blvd., Modar Sq., Shah-Nazare St., School of Rehabilitation

City

Tehran

Province

Tehran

Postal code

1545913187

Approval date

2019-10-30, 1398/08/08

Ethics committee reference number

IR.IUMS.REC.1398.790

Health conditions studied

1

Description of health condition studied

Parkinson

ICD-10 code

G20

ICD-10 code description

Parkinson's disease

Primary outcomes

1

Description

Sensory_ Motor Function in Upper Limb

Timepoint

Before intervention, after intervention , follow up after 2 month of intervention

Method of measurement

Wrist Position Sense Test, Shouder Position Sense Test, Hand Active Sensation Test, Box-Block Test, Purde-Peg Board Test, Coin Rotation Test, Nine hole Peg Test, Grip Dynamometer

Secondary outcomes

1

Description
Quality of Life
Timepoint
Before intervention, after intervention, follow up 2 month after intervention
Method of measurement
 Parkinson Disease Questionnaire

Intervention groups

1

Description
Intervention group- based on upper extremity game play activities with "Tele-Rehabilitation" in clinic: In this group, upper extremity exercise will be done with virtual reality technology in motor pattern needed for Parkinson diseases. Interventions will be done three days a week, for 24 sessions and everyone 1:15 minutes with presence of occupational therapist. Also occupational therapy traditional exercises include such as stretching, twisting, postural control and coordination will be done in each session.
Category
Rehabilitation

2

Description
Intervention group- Intervention group based on upper extremity game play activities with "Tele-Rehabilitation" at home: In this group, upper extremity exercise will be done with virtual reality technology in motor pattern needed for Parkinson diseases. Interventions will be done three days a week, for 24 sessions and everyone 1:15 minutes without presence of occupational therapist and also occupational therapy traditional exercises such as stretching, twisting, postural control and coordination will be done. Before starting these sessions patients will come to clinic for training and familiarizing with exercises and doing test before intervention.
Category
Rehabilitation

3

Description
Control group- Occupational therapy traditional exercise: This exercises will be done for one and half hour and include such as stretching, twisting, postural control and coordination.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
School of Rehabilitation clinic, Shafa-Yahyaian Hospital
Full name of responsible person
Akram Azad
Street address
Shahnazari Ave., Moder Square,. Mirdamad Blvd
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Sponsors / Funding sources

1

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Full name of responsible person
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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
Iran University of Medical Sciences
Proportion provided by this source
10
Public or private sector
Public
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
Iran University of Medical Sciences
Full name of responsible person
Akram Azad
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Occupational Therapy
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Mirdamad Blv., Modar Sq., Shahnazari Ave., School of Rehabilitation
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable