# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 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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**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**

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**Province**

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**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
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## Sponsors / Funding sources

**1**

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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
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**Position**
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**Latest degree**
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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