Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effectiveness of mirror visual feedback therapy combined with home dexterity program as compared to home dexterity program in improving hand function of patients with Parkinson's disease

Protocol summary

Study aim

To compare the effect of Mirror Visual feedback therapy combined with a home dexterity program and home dexterity program in improving hand function of patients with Parkinson's Disease

Design

Two arms Parallel group, single-blind, randomized controlled trial

Settings and conduct

• The study will be conducted in Neurology department Fauji Foundation Hospital. • Patient will be included in study after taking full informed consent. • Participants will be screened thoroughly for any exclusion, before getting enrolled. • Severity of disease will be determined by means of the MDS Unified Parkinson Disease Rating Scale, Part III: Motor (MDS-UPDRS III).

Participants/Inclusion and exclusion criteria

Inclusion Criteria: All patients with stages 1to 3 in Hoehn and Yahr and who would be on a stable medication regimen. Patients with impaired hand dexterity Exclusion Criteria: 1. Patients with history of other neurological conditions, 2. deep brain stimulation, 3. Patients cognitive status < 24, 4. Patients with visual field defects, which will prevent the patient to see their reflection of hand 5. Patients with severe orthopedic conditions of upper limb

Intervention groups

The intervention group (Mirror visual feedback therapy combined with home dexterity program group) will receive Mirror visual feedback therapy combined with home based dexterity Program for 1 hour 3 times a week for 6 weeks. A patient will have to perform six various types of exercises, either bi-manually or unimanually, Both hands will have to be trained equally. The control group (Home dexterity program group) will receive only home dexterity program for 1 hour 3 times a week for 6 weeks

Main outcome variables

Independent Variable: • Mirror Therapy combined with Home based dexterity program • Home dexterity program Dependent Variables: • Hand function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210615051585N5**
Registration date: **2022-05-07, 1401/02/17**
Registration timing: **registered_while_recruiting**

Last update: **2022-05-07, 1401/02/17**
Update count: **0**

Registration date

2022-05-07, 1401/02/17

Registrant information

Name

Saima Gul

Name of organization / entity

Shifa Tameer - e - Millat University

Country

Pakistan

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-21, 1401/01/01

Expected recruitment end date

2022-06-05, 1401/03/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effectiveness of mirror visual feedback therapy combined with home dexterity program as compared to home dexterity program in improving hand function of patients with Parkinson's disease

Public title
Effect of Mirror therapy and home dexterity program in improving hand function of Parkinson's patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients with stages 1to 3 on Hoehn and Yahr scale and who would be on a stable medication regimen Patients with impaired hand dexterity
Exclusion criteria:
Patients with history of other neurological conditions, Deep brain stimulation, Patients cognitive status < 24 Patients with visual field defects, which will prevent the patient to see their reflection of hand Patients with severe orthopedic conditions of upper limb.
Age
From **50 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Random assignment was used for treatment using a sealed envelope. For that, 30 sheets of aluminum paper are properly cut. This paper should be double the size of the paper. 15 Sheets of Carbon paper cut into appropriate size according to the paper used. A standard-sized square paper was taken in which group "(Mirror visual feedback therapy combined with home dexterity program)" was marked. In this way, 15 papers were prepared marked with "(Mirror visual feedback therapy combined with home dexterity program)" and 15 square-shaped papers marked with "(Home dexterity program)". The sheet of paper on which either (Mirror visual feedback therapy combined with home dexterity program) or (Home dexterity program) was marked was folded to fit the envelope. A sheet of Carbon paper was placed on the top of the folded paper (marked either (Mirror visual feedback therapy combined with home dexterity program) or (Home Dexterity Program) facing the envelope. Then the sheet of Aluminum foil was wrapped on the carbon paper (with folded paper inside). All the above prepared were placed in the envelope (which was completely opaque), the envelope was then sealed. In this way 15 envelops of "(Mirror visual feedback therapy combined with home dexterity program)" and 15 envelops of "(Home Dexterity Program)" were prepared with a total number of 30 envelopes. These 30 envelopes were then thoroughly shuffled like a deck of cards. The envelopes were then marked with numbers 1-30. Each participant picked the envelope in order from 1-30 and was given an intervention (Mirror visual feedback therapy combined with home dexterity program or Home Dexterity program) accordingly.
Blinding (investigator's opinion)
Single blinded
Blinding description
Only the researcher doing the study knows which treatment or intervention the participant is receiving. It makes results less likely to be biased. For that, they received an additional device that is not connected and they feel they are receiving treatment apart from their actual treatment.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Institutional Review Board and Ethics Committee (IRB and EC) Shifa International Hospital.
Street address
Department of Rehabilitation Sciences, Dar ul Shifa Campus, Shifa Tameer e Millat University
City
Islamabad
Postal code
25000
Approval date
2021-06-28, 1400/04/07
Ethics committee reference number
IRB#488-21

Health conditions studied

1

Description of health condition studied
Parkinson's patients with impaired hand dexterity
ICD-10 code
G-20
ICD-10 code description

Idiopathic Parkinsonism or Parkinson's disease

Primary outcomes

1

Description
Hand dexterity
Timepoint
Baseline measurement and end of treatment
Method of measurement
Chedoke Arm and Hand Inventory

Secondary outcomes

1

Description
Hand strength
Timepoint
Baseline after intervention
Method of measurement
Hand held dynamometer

2

Description
Reduced rate of tremors
Timepoint
Baseline after intervention
Method of measurement
Clinical rating scale for tremor

3

Description
Hand dominance
Timepoint
Baseline after intervention
Method of measurement
Edinburgh handedness inventory

Intervention groups

1

Description
Mirror visual feedback therapy combined with home dexterity program group: This group will receive Mirror visual feedback therapy combined with a home-based dexterity Program for 1 hour 3 times a week for 6 weeks. A patient will have to perform six various types of exercises, either bi-manually or unimanual. Both hands will have to be trained equally. A mirror box will be used for the performance of Manual dexterity. A plastic foldable triangular box with an attached mirror on a side will be kept on a table so one of the hands of the subject will be reflected by the mirror and another hand will be hidden by the box from the view of the subject. The box will be open from the ends so that the subject can insert their hands into it. The hand which is more affected will be asked to hide behind the mirror.
Category
Rehabilitation

2

Description
Home dexterity program group: This group will perform the same exercises in the home dexterity program but without a mirror box. This protocol will be for 1 hour 3 times a week for 6 weeks. In this group, patients will perform these exercises either bi-manually or unimanual. Both hands have to be trained equally.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Neurology department Fauji Foundation hospital Rawalpindi
Full name of responsible person
Fakhra Khadim
Street address
Fauji Foundaion Hospital Rawalpindi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shifa Tameer e Millat University
Full name of responsible person
Dr Saima Gul
Street address
Department of Rehabilitation Sciences, Dar ul Shifa Campus, Shifa Tameer e Millat University
City
Islamabad
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44000
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saimagul.ahs@stmu.edu.pk
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shifa Tameer e Millat University

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

Shifa Tameer e Millat University

Full name of responsible person

Dr Saima Gul

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Neuroscience

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Full name of responsible person

Dr Saima Gul

Position

Associate Professor

Latest degree

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Person responsible for updating data

Contact

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Shifa Tameer e Millat University

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Due to ethical Considerations

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available