

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 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

+92 51 8441751

Email address

saimagul.ahs@stmu.edu.pk

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 1 to 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 envelopes of "(Mirror visual feedback therapy combined with home dexterity program)" and 15 envelopes 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

City

Rawalpindi

Postal code

45730

Phone

+92 331 5932044

Email

fakhrakhadim_dpt48@yahoo.com

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

Postal code

44000

Phone

+92 51 8441751

Fax

+92 51 8441751

Email

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

Department of Rehabilitation Sciences, Dar ul Shifa
Campus, Shifa Tameer e Millat University

City

Islamabad

Province

Punjab

Postal code

44000

Phone

+92 51 8441751

Email

saimagul.ahs@stmu.edu.pk

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

Street address

Department of Rehabilitation Sciences, Dar ul Shifa
Campus, Shifa Tameer e Millat University

City

Islamabad

Province

Punjab

Postal code

44000

Phone

+92 51 8441751

Email

saimaa.gul@gmail.com

Person responsible for scientific 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

Street address**Person responsible for updating data****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

Street address

Department of Rehabilitation Sciences, Dar ul Shifa
Campus, Shifa Tameer e Millat University

City

Islamabad

Province

Punjab

Postal code

44000

Phone

+92 51 8441751

Email

saimagul.ahs@stmu.edu.pk

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