

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Proprioceptive neuromuscular facilitation in adjunct to mirror therapy on clinical recovery ,synkinesis and quality of life in patients with Bell's palsy

Protocol summary

Study aim

1) To determine the effects of Proprioceptive Neuromuscular facilitation with and without Mirror Therapy on clinical recovery in Bell's palsy patients 2) To determine the effects of Proprioceptive Neuromuscular facilitation with and without Mirror Therapy on synkinesis in Bell's palsy patients 3) To determine the effects of Proprioceptive Neuromuscular facilitation with and without Mirror Therapy on quality of life in Bell's palsy patients

Design

Two arm parallel group randomized trail with blinded assessor and outcome assessment of 60 participants

Settings and conduct

Data will be conducted from department of Physical Therapy, Sir Ganga Ram Hospital, Lahore. This is a single blinded study in which outcome evaluation assessor will be unaware of treatment which assigned to groups. Data will be assessed by assessor at baseline, at the end of 3rd week, at the end of 6th and at the end of 9th week.

Participants/Inclusion and exclusion criteria

Inclusion criteria: • Aged between 25-50 years • Both Male and females • Patients with unilateral Bells' Palsy diagnosed by neurologist • Patients with moderate to severe Bell's palsy (House-Brackmann Scale facial nerve grading 3 and 4) • Patients with unilateral bell's palsy
Exclusion Criteria: • Patients with Autoimmune/ hematologic disease • Patients with Inflammatory disease(e.g. Rheumatoid arthritis) • Patients with any neurodegenerative disease • Patients with cognitive impairments

Intervention groups

All the screened and willing participants will be randomly allocated to two groups where Group A will receive proprioceptive neuromuscular facilitation with mirror therapy and Group B will receive proprioceptive neuromuscular facilitation without mirror therapy by

lottery method.

Main outcome variables

House Brackman scale(HBS), Synkinesis Assessment Questionnaire, and Facial clinimetric Evaluation Scale(FaCE)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241001063232N1**
Registration date: **2024-10-20, 1403/07/29**
Registration timing: **retrospective**

Last update: **2024-10-20, 1403/07/29**

Update count: **0**

Registration date

2024-10-20, 1403/07/29

Registrant information

Name

Sadia Ghafoor

Name of organization / entity

University of Lahore

Country

Pakistan

Phone

+92 300 9477922

Email address

sgrana14@outlook.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-15, 1402/11/26

Expected recruitment end date

2024-10-01, 1403/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Proprioceptive neuromuscular facilitation in adjunct to mirror therapy on clinical recovery ,synkinesis and quality of life in patients with Bell's palsy

Public title

Proprioceptive neuromuscular facilitation in adjunct to mirror therapy on clinical recovery ,synkinesis and quality of life in patients with Bell's palsy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Aged between 25-50 years Both Male and females
Patients with unilateral Bells' Palsy diagnosed by neurologist
Patients with moderate to severe Bell's palsy (House-Brackmann Scale facial nerve grading 3 and 4)
Patients with unilateral bell's palsy

Exclusion criteria:

Patients with Autoimmune/ hematologic disease
Patients with Inflammatory disease(e.g. Rheumatoid arthritis)
Patients with any neurodegenerative disease
Patients with cognitive impairments

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization will be used by one of the research team members who will be blinded and not involve in patients recruitment or assessment or data analysis. Participants are randomly allocated into two groups through lottery method

Blinding (investigator's opinion)

Single blinded

Blinding description

This is single blinded study in which assessor will be unaware of treatment

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of University of Lahore

Street address

University of Lahore Teaching Hospital Lahore ,
Punjab , Pakistan

City

Lahore

Postal code

55150

Approval date

2024-03-07, 1402/12/17

Ethics committee reference number

REC-UOL-671-03-2024

Health conditions studied

1

Description of health condition studied

Bell palsy is an idiopathic peripheral nerve disorder involving the facial nerve (ie, cranial nerve VII) and manifesting as acute, ipsilateral facial muscle weakness. It affects individuals across multiple ages and both sexes, with an annual incidence ranging from 11.5 to 53.3 per 100,000 persons across multiple populations.

ICD-10 code

G51.0

ICD-10 code description

Bell's palsy

Primary outcomes

1

Description

The House-Brackmann Scale (HBS) is one of several analysis tools that have been developed to quantify facial function and provide reproducible information in measuring the global degree of paresis and paralysis.

Timepoint

9th weeks

Method of measurement

It is a widely accepted system and is simple, sensitive, accurate, and reliable, grading facial function in 6 stages, from normal (HB I) to total paralysis (HB VI).

2

Description

The Synkinesis Assessment Questionnaire comprises nine questions and is a valid and reliable measurement for synkinesis. It correlates well with the synkinesis aspect of FGS.

Timepoint

9th week

Method of measurement

Chuang et al. introduced a four-category classification: I) Good smile with mild synkinesis, II) Acceptable smile with moderate to severe synkinesis, III) Unacceptable smile with severe synkinesis, and IV) Poor smile with mild synkinesis.

3

Description

The Facial Clinimetric Evaluation Scale (FaCE) is a patient-based instrument that measures facial impairment and disability in evaluating quality-of-life issues that are caused by facial disability.

Timepoint

9th weeks

Method of measurement

This questionnaire consists of 15 questions on a 5-point Likert Scale and comprises 6 domains: facial movement, facial comfort, oral function, eye comfort, lacrimal control, and social function. Total and domain scores range from 0 (worst) to 100 (best). This scale has been used in several studies on patient satisfaction following treatment.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The participants randomly allocated in Group A will be received the PNF with mirror therapy (MT). After electrical muscle stimulation proprioceptive neuromuscular facilitation techniques (PNF) will be done. Proprioceptive neuromuscular facilitation techniques (PNF) that will be used are rhythmic initiation and repeated stretch as shown in figure 1 using mirror. Participants will be sit upright, maintaining good posture. Keep mirror at eye level. With both eyes open, look into mirror with only on unaffected side. Patients will be observed the mirror reflection for one to two minutes, then trying to visualize the mirror image as the affected side. Once the subject will be engaged with mirror side then proprioceptive exercises will be performed.

Category

Treatment - Other

2

Description

Intervention group: In group B patients will be received PNF without mirror therapy (MT). After electrical muscle stimulation, proprioceptive neuromuscular facilitation techniques (PNF) will be done. Proprioceptive neuromuscular facilitation techniques (PNF) that will be used are rhythmic initiation and repeated stretch.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Sir Ganga Ram Hospital

Full name of responsible person

Momna Asghar

Street address

University of Lahore Teaching Hospital Lahore ,
Punjab , Pakistan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Lahore

Full name of responsible person

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1 km Defence Road near Bhuptian Chowk Lahore
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Sgrana14@outlook.com

Grant name

No

Grant code / Reference number

none

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

Sadia Ghafoor

Position

Punjab

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Demographic data and data related to final outcome will be shared by maintaining the confidentiality

When the data will become available and for how long

Data will be available after the publication of findings till six months

To whom data/document is available

Sadia Ghafoor

Under which criteria data/document could be used

For research purpose

From where data/document is obtainable

To the corresponding author of the study , Sadia Ghafoor and can contact on +92 304 787995 , sgrana1@outlook.com

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

Open access and there is the traditional public data release where anyone can get access to the data

Comments