# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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
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Pakistan
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**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 accessor 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**

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**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**
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Master
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## Person responsible for scientific inquiries

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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 confidentially
**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**