

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparative effectiveness of Cranial Nerve Seventh (VII) Mobilization versus Manual Manipulation of facial muscles for improving muscular movement and Synkinesis among Bell's palsy patients; Randomized Clinical Trial

#### Protocol summary

##### Study aim

To compare the effectiveness of Cranial Nerve VII mobilization and manual manipulation of facial muscles among patients of acute Bell's palsy and to improve the voluntary movements of facial muscles and to reduce Synkinesis among patients.

##### Design

A randomized, single blinded, clinical trial with a parallel group design of 26 patients, enrolled between July 2024 and October 2024

##### Settings and conduct

The patients were recruited from the Aziz Fatima Hospital Faisalabad, Nusrat Abdul Rauf Center for Enablement Faisalabad and Madinah Teaching Hospital Faisalabad. It was a single blinded trail in which patients were blinded

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 15-45 y/o, acute stage, HBG scale gradell-III, SB facial grading score  $\geq 40$ . Exclusion criteria: Diagnosed Neurodegenerative Disorders, Diagnosed intra-cranial Tumors, Diagnosed Viral infection, Presence of severe comorbidities

##### Intervention groups

Both groups received superficial heat therapy, nerve stimulation and facial muscle exercises with addition of Manual Manipulation of facial muscles (which are supplied by Cranial Nerve VII) in Group A and Cranial Nerve VII Mobilization technique in Group B.

##### Main outcome variables

The primary outcome to be achieved from this study includes voluntary movement, Synkinesis and facial expressions. The secondary outcome includes the facial symmetry.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20240726062547N1**

Registration date: **2024-10-01, 1403/07/10**

Registration timing: **registered\_while\_recruiting**

Last update: **2024-10-01, 1403/07/10**

Update count: **0**

##### Registration date

2024-10-01, 1403/07/10

##### Registrant information

##### Name

Aleena Shabbir

##### Name of organization / entity

The University of Faisalabad

##### Country

Pakistan

##### Phone

+92 41 8750971

##### Email address

dpt-fa19-064@tuf.edu.pk

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-07-29, 1403/05/08

##### Expected recruitment end date

2024-10-29, 1403/08/08

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Comparative effectiveness of Cranial Nerve Seventh (VII) Mobilization versus Manual Manipulation of facial muscles for improving muscular movement and Synkinesis among Bell's palsy patients; Randomized Clinical Trial

**Public title**

Cranial Nerve Seventh (VII) Mobilization versus Manual Manipulation of facial muscles for Bell's palsy patients

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Acute stage (onset within first week). House Brackmann grading scale score gradell-III (mild to moderate). Sunny Brook facial grading scale score  $\geq 40$  (mild to moderate). Diagnosed unilateral Bell's palsy by clinical and neurological assessment. No previous history of Bell's palsy and stroke. Diagnosed Bell's palsy pt receiving standard drug treatment (SDT). No previous History of physiotherapy treatment sessions for Bell's palsy.

**Exclusion criteria:**

Diagnosed Neurodegenerative Disorders (Multiple sclerosis, Myasthenia gravis and Guillain-Barre syndrome). Diagnosed intra cranial Tumors(55), parotid gland tumors(56),facial nerve schwannomas (56)and squamous cell carcinoma. Diagnosed Viral infection (herpes simplex, herpes zoster). Diagnosed for more than 14 days. Multiple episodes (more than 1) of Bell's palsy. Presence of severe comorbidities (diabetes, hypertension) that could impact the implementation of the treatment and performance. Diagnosed Traumatic injury to the 7th cranial nerve. Pacemakers or implanted electrical devices. Unwilling to participate in the study.

**Age**

From **15 years** old to **45 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **28**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

A computer software called Online randomize generator was used. the software generated a random sequence. Allocation concealment was carried out.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Participants were blinded in the study as they did not know which group were they being allocated to. Group allocation sequence was selected by a computer software called online randomize generator.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

A clinical trial to find out better effective treatment protocol for bell's palsy patients

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethical Institutional Review Board

**Street address**

Gulistan colony no.1, W.E block, House no.5, Faisalabad, Pakistan

**City**

Faisalabad

**Postal code**

38610

**Approval date**

2024-08-13, 1403/05/23

**Ethics committee reference number**

TUF/IRB/394/24

**Health conditions studied****1****Description of health condition studied**

Bell's palsy

**ICD-10 code**

G51.0

**ICD-10 code description**

Bell's palsy

**Primary outcomes****1****Description**

Voluntary movement

**Timepoint**

Before intervention and after 15th session

**Method of measurement**

House-Brackmann grading scale

**2****Description**

Synkinesis

**Timepoint**

Before intervention and after 15th session

**Method of measurement**

Sunny Brook Facial Grading Scale

### 3

#### **Description**

Facial expressions

#### **Timepoint**

Before intervention and after 15th session

#### **Method of measurement**

Sunny Brook Facial Grading Scale

## **Secondary outcomes**

### 1

#### **Description**

Symmetry of face

#### **Timepoint**

Before intervention and after 15th session

#### **Method of measurement**

Sunnybrook Facial Grading Scale

## **Intervention groups**

### 1

#### **Description**

Intervention group: Manual Manipulation of facial muscles group

#### **Category**

Treatment - Other

### 2

#### **Description**

Intervention group: Cranial Nerve seventh (VII) Mobilization group

#### **Category**

Treatment - Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Aziz Fatima Hospital

##### **Full name of responsible person**

Dr. Basit Mahmood

##### **Street address**

Raja Road, Gulistan Colony no. 1, Faisalabad, Pakistan

##### **City**

Faisalabad

##### **Postal code**

38000

##### **Phone**

+92 41 8780910

##### **Email**

info@afh.com.pk

##### **Web page address**

<https://afh.com.pk/>

### 2

#### **Recruitment center**

##### **Name of recruitment center**

Nusrat Abdul Rauf Center for Enablement

##### **Full name of responsible person**

Prof. Shahid Ahmed Heera

##### **Street address**

Main Blvd, near Manzar Medical Center & Poly Clinic, D Ground Block D People's Colony No 1, Faisalabad, Pakistan

##### **City**

Faisalabad

##### **Postal code**

03822

##### **Phone**

+92 41 8727918

##### **Email**

Shahidheera@gmail.com

##### **Web page address**

<https://www.marham.pk/hospitals/faisalabad/dr-shahid-d-ahmed-heera-clinic/peoples-colony-1>

### 3

#### **Recruitment center**

##### **Name of recruitment center**

Madina Teaching Hospital

##### **Full name of responsible person**

Birg Dr Habib ur Rehman

##### **Street address**

Sargodha Rd, University Town, Faisalabad, Pakistan

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## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

The University of Faisalabad

##### **Full name of responsible person**

Dr. Maryam Safdar

##### **Street address**

Sargodha Road, University Town, Faisalabad, Pakistan

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studentaffairshsw@tuf.edu.pk

##### **Web page address**

<https://tuf.edu.pk/n/contact>

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

The University of Faisalabad

**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**

The University of Faisalabad

**Full name of responsible person**

Aleena Shabbir

**Position**

House Officer

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Fax**

**Email**

Haramshafique11@gmail.com

## 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**

Undecided - It is not yet known if there will be 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**

Undecided - It is not yet known if there will be 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