Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 gradeⅡ-Ⅲ, SB facial grading score ≥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

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Name of organization / entity
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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 gradeⅡ-Ⅲ (mild to moderate). Sunny Brook facial grading scale score ≥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
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info@afh.com.pk
Web page address
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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
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https://www.marham.pk/hospitals/faisalabad/dr-shahid-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
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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 updating data

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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