

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparative effects of rhythmic Initiation and rhythmic stabilization in patient with bell's palsy

Protocol summary

Study aim

This study will guide the researchers to do more work on rhythmic initiation and rhythmic stabilization. It will guide the researchers to explore the effects of rhythmic initiation and rhythmic stabilization and decreases the facial weakness and increases the muscular movement. It will help them to identify the treatment techniques to improve the facial muscles, symmetry and its movement.

Design

Randomized clinical trials with 32 participants of bells palsy and included by random allocation. Parallel group with blinded outcome assessment

Settings and conduct

Mujahid hospital, Shahid Ahmed heera's health clinic, Allied hospital, Rubina Memorial, Faisal Hospital.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Both gender, Age of 20-40 years, Acute onset 1-3 weeks, Bell's palsy diagnosed with House Brackmann grading index Grade3,4, Steroids intake, Facial asymmetry with facial disability index. Exclusion Criteria: Patient having psychological problems, Patient having Neurological deficits, Patient having Stroke, Patient having Multiple Sclerosis, Facial palsy , Patient having Bilateral facial paralysis.

Intervention groups

Patient was divided into two groups, group A and group B. In group A, Rhythmic initiation along with kabat patterns was applied on patient 12 sessions over 4 weeks, 3 times/weeks, 10-15 min and other group is group B, Rhythmic stabilization along with kabat patterns was applied on patient 12 sessions over 4 weeks, 3 times /weeks, 10-15min. Pre and post assessment were taken before and after intervention, then compare the readings to check the effect of both techniques and its effects of neuroplasticity on bell's palsy. After 1 month follow up was taken.

Main outcome variables

Facial asymmetry and muscular weakness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230708058712N1**

Registration date: **2023-09-18, 1402/06/27**

Registration timing: **registered_while_recruiting**

Last update: **2023-09-18, 1402/06/27**

Update count: **0**

Registration date

2023-09-18, 1402/06/27

Registrant information

Name

Maheen Fatima

Name of organization / entity

The University of Faisalabad

Country

Pakistan

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+92 41 8712728

Email address

maheenfatima208@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-15, 1402/06/24

Expected recruitment end date

2023-10-15, 1402/07/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative effects of rhythmic Initiation and rhythmic stabilization in patient with bell's palsy

Public title

Comparative effects of rhythmic Initiation and rhythmic stabilization in patient with bell's palsy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Acute onset 1-3 weeks Steroids intake Both gender 20-40 years included Bells palsy diagnosed with house brackman grading index Facial asymmetry diagnosed with facial disability index

Exclusion criteria:

Patient having psychological problems Patient having neurological deficits Stroke patient Multiple sclerosis Facial palsy Patient having Bilateral bells palsy

Age

From **20 years** old to **40 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

According to inclusion and exclusion criteria, all enrolled participants would be allocated into two groups randomly by lottery method. The randomization process in this study will follow a simple randomization method at the individual level. Unit of randomization would be individual participants, that means each individual participants would be assigned into two groups that are rhythmic Initiation and rhythmic stabilization groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

The current study will be single blinded, as the outcome assessor should be kept blinded which reduces the risk of biasness. Outcome assessor should have no information about the recruitment of participants. As they would not know which participants belongs to group A and group B, which reduces the risk of biasness.

Placebo

Not used

Assignment

Parallel

Other design features

Randomized clinical trials and purposive sampling

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics review committee

Street address

University Avenue, Faisal town Canal road, Faisalabad.

City

Faisalabad

Postal code

38000

Approval date

2023-08-09, 1402/05/18

Ethics committee reference number

TUF/Addl Reg/SB/388

Health conditions studied

1

Description of health condition studied

Bells palsy is the lower motor neuron lesion which is the injury of CN 7 that is facial nerve. It is caused by viral infection and symptoms like drooping of eyelid, paralysis of one side of face, excessive tearing, difficulty in eating and slurred speech.

ICD-10 code

G51. 0

ICD-10 code description

Bells palsy

Primary outcomes

1

Description

Muscular weakness and facial asymmetry

Timepoint

Before the intervention, 4th week post treatment and 1 month follow up

Method of measurement

House brackmann grading index measure the muscular weakness and facial disability index measure the facial asymmetry

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: group A receive rhythmic initiation with kabat patterns and other intervention group: group B receive rhythmic stabilization with kabat patterns

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Madina teaching hospital, Allied hospital, Mujahid hospital, Faisal hospital, Rubina Memorial, Shahi

Full name of responsible person

Maheen Fatima

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Jarhanwala Road, Faisalabad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Faisalabad

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Grant name

No

Grant code / Reference number

No

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

No

Title of funding source

Self funding

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

The University of Faisalabad

Full name of responsible person

Dr Nisar Fatima

Position

Associate professor

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

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Position

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Other areas of specialty/work

Physiotherapy

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Fax**Email**

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Comparative effects of rhythmic initiation and rhythmic stabilization in patient with Bell's palsy

When the data will become available and for how long

January 2023 to April 2023

To whom data/document is available

People who suffered the bells palsy received the treatment

Under which criteria data/document could be used

Aged 20-40 years of both gender

From where data/document is obtainable

Clinic and hospital

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

Through questionnaire which was done during intervention

Comments