

# 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

##### Phone

+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

**Street address**

Jarhanwala Road, Faisalabad

**City**

Faisalabad

**Postal code**

38000

**Phone****Email**

maheenfati208@gmail.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

The University of Faisalabad

**Full name of responsible person**

Dr Nisar Fatima

**Street address**

Faisal town Canal road, Faisalabad

**City**

Faisalabad

**Postal code**

38000

**Phone**

+92 331 8711448

**Email**

nisar.fatima@gmail.com

**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**

Physiotherapy

**Street address**

Sargodha road, Faisalabad

**City**

Faisalabad

**Province**

Punjab

**Postal code**

38000

**Phone**

0098 41 8868326

**Email**

nisar.fatima@tuf.edu.pk

## Person responsible for scientific 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**

Physiotherapy

**Street address**

Sargodha road, Faisalabad

**City**

Faisalabad

**Province**

Punjab

**Postal code**

38000

**Phone**

0098 41 8868326

**Email**

nisar.fatima@tuf.edu.pk

## Person responsible for updating data

### Contact

**Name of organization / entity**

The University of Faisalabad

**Full name of responsible person**

Maheen Fatima

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

**Street address**

P-167 Al Najaf colony Faisalabad

**City**

Faisalabad

**Province**

Punjab

**Postal code**

38000

**Phone**

+92 41 8712728

**Fax****Email**

maheenfatima208@gmail.com

**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**