Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Pakistan

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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 acessor should be kept blinded which reduces the risk of biasnes. Outcome acessor 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.

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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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Sponsors / Funding sources

1

Sponsor

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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

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Position
Associate professor

Latest degree
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Person responsible for updating data

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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