

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparing the effects of tapping and brushing therapy on ankle dorsiflexion range of motion in hemiparetic spastic cerebral palsy

Protocol summary

Study aim

To compare the effects of tapping and brushing therapy on ankle dorsiflexion range of motion, reduction of calf muscles spasticity and improvement of walking pattern in hemiparetic spastic cerebral palsy.

Design

Randomized Clinical Trial, Single Blind

Settings and conduct

The current study will be including centers of Faisalabad, Punjab, Pakistan. Allied Hospital, Nusrat Abdul Rauf Center for Enablement and Syeda Khatoon-e-Jannat Special Education Centre.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Both genders within ranges of 4-12 years, able to walk with or without assistance, sensations were preserved, diagnosed patients, MAS grading ≤ 3 , able to follow instructions completely. Exclusion criteria: Uncontrollable attacks epilepsy, take botulinum toxin from the previous 3 months, any other neurological conditions, any orthopedic surgery during last 12 months, on affected side.

Intervention groups

Group A will receive baseline intervention (NMES for 20 minutes with frequency of 50 Hz, width about 250 microseconds, ramp on 5 seconds for stimulation and ramp off 10 seconds for rest with intensity 04 to 20 mA varying from patient to patient and routine physical therapy including passive ROM, stretching exercises, strengthening exercises etc) in combination with 10 minutes tapping therapy: Quick tapping will be applied by distal phalanges of hand region, on the fibrous part of the affected muscle. 3-5 times and take a break in each set of tapping. Group B will also receive baseline intervention (NMES and routine physical therapy same as Group A) in combination with 10 minutes brushing therapy: A gentle toothbrush will be used, moved from distal to proximal on the tibial surface of leg, with a break of 10 seconds on a continuous repeated stroke of brush.

Main outcome variables

Ankle dorsiflexion range of motion, Calf muscle spasticity, Walking pattern.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230801059004N1**

Registration date: **2023-09-14, 1402/06/23**

Registration timing: **prospective**

Last update: **2023-09-14, 1402/06/23**

Update count: **0**

Registration date

2023-09-14, 1402/06/23

Registrant information

Name

Jyeshtha Mustafa

Name of organization / entity

The University of Faisalabad

Country

Pakistan

Phone

+92 41 8530071

Email address

jyeshamustafa555@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-18, 1402/06/27

Expected recruitment end date

2023-11-13, 1402/08/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effects of tapping and brushing therapy on ankle dorsiflexion range of motion in hemiparetic spastic cerebral palsy

Public title

Comparing the effects of tapping and brushing therapy on ankle dorsiflexion range of motion in hemiparetic spastic cerebral palsy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age ranges from 4-12 years Study included both male and female genders. The one who was able to walk, either with assistance or without assistance Sensations were preserved in affected lower limb. Participants should be diagnosed with hemiparetic spastic cerebral palsy. According to Modified Ashworth Scale, the grade of their spasticity should be ≤ 3 . Participants should be able to follow instructions completely.

Exclusion criteria:

Uncontrollable attacks of epilepsy Take botulinum toxin from the previous 3 months as enroll in trial. Any other neurological conditions that affect walking pattern other than cerebral palsy Patients undergone any orthopedic surgery during last 12 months, on affected side

Age

From **4 years** old to **12 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

According to inclusion exclusion criteria, all the enrolled participants would be allocated into two groups randomly by chit and draw method. The randomization process in this study will follow a simple randomization method at the individual level. Unit of randomization would be individual participant, that means each individual participant would be randomly assigned to two groups that are tapping therapy group and brushing therapy group.

Blinding (investigator's opinion)

Single blinded

Blinding description

The current study will be single blinded, as the outcome assessor should be kept blinded to reduce risk of biasness. Outcome assessors should have no information about the recruitment of participants. As they would not

know which participant belongs to Group A and B, the risk of biasness will be reduced.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

The University of Faisalabad

Street address

West Canal Road, Faisalabad

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Faisalabad

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38000

Approval date

2023-03-24, 1402/01/04

Ethics committee reference number

TUF/DR/SA/MSPP/2023/240

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

Hemiparetic Spastic Cerebral Palsy

ICD-10 code

G80.2

ICD-10 code description

Spastic hemiplegic cerebral palsy

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

Ankle Dorsiflexion Range of Motion

Timepoint

At baseline then at 3rd week and at 6th week of intervention.

Method of measurement

The Universal Goniometer is a gold standard tool that is reliable for measurement of range of motion among cerebral palsy children.

Secondary outcomes**1****Description**

Calf Muscle Spasticity

Timepoint

At baseline then at 3rd week and at 6th week of intervention.

Method of measurement

Modified ashworth scale has grade of 6 points such as 0, 1, 1+, 2, 3, and 4. It has been scored from 0-4, where 0 means there is no increase in tone while 4 means affected part fixed in flexion or extension. The Modified Ashworth Scale is a gold standard outcome for the measurement of spasticity.

2

Description

Walking Pattern

Timepoint

At baseline then at 3rd week and at 6th week of intervention.

Method of measurement

Observational gait scale is used to evaluate any changes in walking pattern in hemiparetic spastic cerebral palsy children. It has 8 sections and a total greatest score of twenty-two that show a normal walking pattern. Changes are evaluated in frontal and lateral view, 7 out of 8 sections are evaluated in lateral view. The OGS has a good reliability and validity for ankle as well as knee observation in spastic cerebral palsy children.

Intervention groups

1

Description

Intervention group:

Category

Rehabilitation

2

Description

Intervention group:

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Allied Hospital

Full name of responsible person

Jyeshtha Mustafa

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Jail Road adjacent to Faisalabad Medical University,
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<https://pmc.edu.pk/S-Result.aspx>

2

Recruitment center

Name of recruitment center

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Full name of responsible person

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3

Recruitment center

Name of recruitment center

Syeda Khatoon-e-Jannat Special Education Centre

Full name of responsible person

Jyeshtha Mustafa

Street address

Near Fish Farm Younas Town, Satiana Road
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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person

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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
Jyesha Mustafa
Position
Student
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No further information

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

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

Title and more details about the data/document

Comparing the effects of tapping and brushing therapy on ankle dorsiflexion range of motion in hemiparetic

spastic cerebral palsy

When the data will become available and for how long

Data will be available for other people almost 6 months after the completion of study.

To whom data/document is available

Data will be available for other people almost 6 months after the completion of study.

Under which criteria data/document could be used

Data will be shared for further clinical research. The data/document could be used by communicating with

the principle investigator Jyeshtha Mustafa gmail :
jyeshamustafa555@gmail.com

From where data/document is obtainable

Data will be shared through email address. Jyeshtha Mustafa Gmail: jyeshamustafa555@gmail.com

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

The data/document could be used by communicating with the principle investigator Jyeshtha Mustafa gmail :
jyeshamustafa555@gmail.com

Comments