Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 micro-seconds, 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
Jyesha Mustafa

Name of organization / entity
The University of Faisalabad

Country
Pakistan

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+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
City
Faisalabad
Postal code
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
Jyesha Mustafa
Street address
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2

Recruitment center
Name of recruitment center
Nusrat Abdul Rauf Center for Enablement
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
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Near Fish Farm Younas Town, Satiana Road Faisalabad.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Street address
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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
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)
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 Jyesha Mustafa gmail : jyeshamustafa555@gmail.com

From where data/document is obtainable

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

Comments