Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effects of vestibular stimulation on motor function and balance in children with hypotonic cerebral palsy : A Randomized Controlled Trial

Protocol summary

Study aim
The aim of our study is to determine the effects of vestibular stimulation on motor function and balance in children with hypotonic cerebral palsy

Design
Two arm parallel group randomized trial

Settings and conduct
Data will be collected from Department of Pediatric Rehabilitation, Shaikh Zayed Hospital Lahore. The study will be double blinded as care giver and assessor will be unaware of the treatment given to patient.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: • Children with age range from 5-10 years will be included in our study • Children who will have good head control • Patients with hypotonic cerebral palsy • Children who will be able to maintain ring sitting position. Exclusion Criteria: • Children will not respond to Visual and auditory stimuli due to blindness or deafness or severe mental retardation. • Children with uncontrolled convulsion or shunt. • Children with severe medical problems. • Children with orthopedic condition

Intervention groups
Participants will be divided into two groups one will be control group which will receive only conventional physical therapy the other group will be experimental group and this group will receive vestibular stimulation along with conventional physical therapy.

Main outcome variables
Gross motor function and balance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211221053479N1**
Registration date: **2022-01-02, 1400/10/12**
Registration timing: **registered_while_recruiting**
Last update: **2022-01-02, 1400/10/12**
Update count: **0**

Registration date
2022-01-02, 1400/10/12

Registrant information

Name
Mahwash Zulfiqar

Name of organization / entity
University of Lahore

Country
Pakistan

Phone
+92 335 5077906

Email address
msptn02193018@student.uol.edu.pk

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-01, 1400/04/10

Expected recruitment end date
2022-01-20, 1400/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effects of vestibular stimulation on motor function and balance in children with hypotonic cerebral palsy : A Randomized Controlled Trial

Public title
Vestibular stimulation's effect on balance and motor function in cerebral palsy patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children of age between 5-10 year will be included in our study Patients who will have good head control will be included Children with Hypotonic cerebral palsy will be included in our study Children who will be able to maintain ring sitting position will be included

Exclusion criteria:

Children who will not respond to Visual and auditory stimuli due to blindness or deafness or severe mental retardation Children with uncontrolled convulsion or any kind of shunt Children with severe medical problems Children with orthopedic condition.

Age

From **5 years** old to **10 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Outcome assessor

Sample size

Target sample size: **68**

More than 1 sample in each individual

Number of samples in each individual: **4**

Data will be collected at baseline, 1st, 3rd and 5th week post intervention.

Randomization (investigator's opinion)

Randomized

Randomization description

Purposive Random Sampling technique will be carried out. For this purpose, Computer generated randomization method will be used to allocate our participants in 2 groups. Total 68 numbers will be added and the software will randomly allocate the numbers into either group A or Group B. These numbers will be given to Athetoid Cerebral palsy patient's care giver who will come to the outpatient department of physical therapy. The numbers will be assigned according to their visit i.e.those who will come first will be given 1 number in such a way as if for example the software has allocated 1 into group B, he will receive the treatment designed for group B and who will come at 10th number Will be given 10th number concealed envelope and so forth. The concealed envelope will be used for this purpose. Allocation concealment will be done by sequential numbering of patients

Blinding (investigator's opinion)

Double blinded

Blinding description

The study will be double blinded and care giver and outcome assessor will be unaware of treatment given to patients. Both the outcome assessor and caregiver will not be explained about treatment given to patient.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of University of Lahore

Street address

1km.off defence road, Lahore

City

Lahore

Postal code

537000

Approval date

2021-07-01, 1400/04/10

Ethics committee reference number

IRB-UOL-FAHS/893/2021

Health conditions studied

1

Description of health condition studied

Hypotonic cerebral palsy

ICD-10 code

G80

ICD-10 code description

Cerebral palsy

Primary outcomes

1

Description

Balance

Timepoint

Balance will be assessed at baseline, 1st, 3rd and 5th week post intervention.

Method of measurement

Balance will be assessed using pediatric balance scale

2

Description

Gross motor function

Timepoint

Gross motor function will be assessed using gross motor function scale at baseline, 1st,3rd and 5th week post intervention.

Method of measurement

Gross motor function will be assessed using gross motor function scale

Secondary outcomes

empty

Intervention groups

1

Description
Control group: will receive conventional physical therapy for hypotonic cerebral palsy. For conventional physiotherapy group, the training duration for each session will be 30 minutes with 5 minutes of rest period. Participants in group A will be given Conventional Physiotherapy. It includes Passive Soft tissue elongation of tight muscles, Lower limb resistance exercises, Movement transitions, balance board and foam board standing, walking and stair climbing
Category
Treatment - Other

2

Description
Intervention group: will receive vestibular stimulation along with the routine physical therapy and for intervention group,the session will last 30 minutes with 10 minutes of rest period in between. Along with conventional physical therapy vestibular stimulation wi be given and will include exercises such as Swinging in standing in all directions, trampoline jumps, rocking movement in rocking chair,gaze stabilization exercises and visual pursuit exercises under supervision
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shaikh Zayed Hospital Lahore
Full name of responsible person
Muhammad Amir Saeed
Street address
University Avenue, Block D, Muslim Town, Lahore
City
Lahore
Postal code
53700
Phone
+92 52 3310611
Email
Muhammadaamirsaeed@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of Lahore
Full name of responsible person
Dr. Ashfaq Ahmad
Street address
1 km. Off defence road, Lahore
City
Lahore
Postal code
537000
Phone
+92 52 3310611
Email
hod@uipt.uol.edu.pk
Grant name
Postgraduation research
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
University of Lahore
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
University of Lahore
Full name of responsible person
Mahwash Zulfiqar
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Physiotherapy
Street address
118 /3A Judicial Colony Phase 2, Lahore
City
Lahore
Province
Punjab
Postal code
537000
Phone
+92 335 5077906
Email
Zulfiqar1991khan@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
University of Lahore
Full name of responsible person

Mahwash Zulfiqar

Position
Student

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Person responsible for updating data

Contact

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University of Lahore

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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
The title of our study is"EFFECTS OF VESTIBULAR STIMULATION ON MOTOR FUNCTION AND BALANCE IN CHILDREN WITH HYPOTONIC CEREBRAL PALSY: A RANDOMIZED CONTROLLED TRIAL". All collected deidentified IPD will be shared

When the data will become available and for how long
Data will become available from 12_06_2022 to 12_07_2023

To whom data/document is available
Those involved in research related to Cerebral Palsy's Interventions

Under which criteria data/document could be used
For citation purposes only.

From where data/document is obtainable
Data will be obtained from Principal investigator via email using the email address zulfiqar1991khan@gmail.com

What processes are involved for a request to access data/document
Data can be accessed Upon request to principal investigator via Email. And the mailing address is zulfiqar1991khan@gmail.com

Comments