

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effects of ischemic conditioning along with bimanual task training to improve skill learning in children with unilateral cerebral palsy

Protocol summary

Study aim

To investigate the effects of ischemic conditioning along with bimanual task training to improve skill learning in children with unilateral cerebral palsy

Design

consecutive sampling

Settings and conduct

The Children Hospital & institute of child health
Faisalabad

Participants/Inclusion and exclusion criteria

Children diagnosed with Unilateral Cerebral palsy UCP. Children with age: 8-16 years. Children having Manual Ability Classification System (MACS) levels I – III. Children having ability to complete a stack of three cups in 1 min. Mainstream in school. Children with other developmental disabilities such as Autism, attention deficit hyperactivity disorder, developmental coordination disorders. Children with absent active motor threshold. Children with known cardiorespiratory, vascular and metabolic disorders. Children with neoplasm and hydrocephalus. Children who are currently receiving or received other adjunct therapies such as RTMs and TDs in the past 6 months. Children with active seizures or seizures within last two years and currently on anti-seizures medication. Children with metal implants and incompatible medical devices.

Intervention groups

After taking informed consent from participants fulfilling the inclusion criteria, they will be randomized into two groups (Group A and Group B). Group A will receive Ischemic conditioning with 20 mmHg and bimanual task training of 15 repetitions each, for 6 consecutive days. Group B will receive only ischemic conditioning with 25 mmHg for 5 consecutive days.

Main outcome variables

Movement Time Measure of bimanual coordination Goal Synchronization Total Task Duration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240316061313N1**

Registration date: **2024-05-11, 1403/02/22**

Registration timing: **retrospective**

Last update: **2024-05-11, 1403/02/22**

Update count: **0**

Registration date

2024-05-11, 1403/02/22

Registrant information

Name

Ulvina Riaz

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

2024-02-17, 1402/11/28

Expected recruitment end date

2024-03-30, 1403/01/11

Actual recruitment start date

2024-02-17, 1402/11/28

Actual recruitment end date

2024-04-30, 1403/02/11

Trial completion date

2024-05-02, 1403/02/13

Scientific title

Effects of ischemic conditioning along with bimanual task training to improve skill learning in children with unilateral cerebral palsy

Public title

ischemic conditioning along with bimanual task training to improve skill learning in children with unilateral cerebral palsy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

- Children diagnosed with Unilateral Cerebral palsy UCP.
- Children with age: 8-16 years .
- Children having Manual Ability Classification System (MACS) levels I - III
- Children having ability to complete a stack of three cups in 1 min
- Mainstream in school.

Exclusion criteria:

- Children with other developmental disabilities such as Autism, attention deficit hyperactivity disorder, developmental coordination disorders.
- Children with absent active motor threshold
- Children with known cardiorespiratory, vascular and metabolic disorders
- Children with neoplasm and hydrocephalus.
- Children who are currently receiving or received other adjunct therapies such as RTMs and TDs in the past 6 months
- Children with active seizures or seizures within the last two years and currently on anti-seizure medication.
- Children with metal implants and incompatible medical devices.

Age

From **8 years** old to **16 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **22**

Actual sample size reached: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Lottery method

Blinding (investigator's opinion)

Single blinded

Blinding description

In a single-blind study, either the participants or the researchers are unaware of which participants belong to the control group and which belong to the experimental group. This helps to prevent bias in the data collection process.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research and Ethics /Technical Committe for The University of Faisalabad

Street address

Faisal Town,West Canal Road,Faisalabad

City

Faisalabad

Postal code

38000

Approval date

2024-01-05, 1402/10/15

Ethics committee reference number

TUF/AddIReg/SB/760

Health conditions studied

1

Description of health condition studied

hemiplegic cerebral palsy

ICD-10 code

G80

ICD-10 code description

cerebral palsy

Primary outcomes

1

Description

Movement Time

Timepoint

before and after 6 week of intervention

Method of measurement

Sphygmomanometer

Secondary outcomes

1

Description

Measure of bimanual coordination

Timepoint

before and after 6 week of intervention

Method of measurement

Assisted hand assessment scale

2

Description

Goal Synchronization

Timepoint

before and after 6 week of intervention

Method of measurement

stopwatch

3**Description**

Total Task Duration

Timepoint

before and after 6 week of intervention

Method of measurement

stopwatch,

Intervention groups**1****Description**

control group: Group A participants in this study will undergo a comprehensive intervention regimen over a span of six consecutive days. This intervention comprises two main components: Ischemic conditioning . Each day, participants will engage in Ischemic conditioning, a technique involving the induction of brief episodes of ischemia followed by reperfusion to potentially induce protective effects participants will undergo bimanual task training sessions, involving 15 repetitions of specific tasks designed to enhance coordination and functionality of both hands simultaneously.

Category

Rehabilitation

2**Description**

Intervention group: Group B participants in this study will undergo a comprehensive intervention regimen over a span of six consecutive days. This intervention comprises one component ischemic conditioning. Each day, participants will engage in Ischemic conditioning, a technique involving the induction of brief episodes of ischemia followed by reperfusion to potentially induce protective effects participants, involving 15 repetitions of specific tasks designed to enhance coordination and functionality of both hands simultaneously.

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Children Hospital & institute of child Health
Faisalabad

Full name of responsible person

Dr. ulvina; PT

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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

Dr. Syed saqlain;PT

Position

Consultant clinical physiotherapist

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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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

No - There is not 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

effect of ischemic conditioning along with bimanual task training to improve skill learning in children with unilateral cerebral palsy

When the data will become available and for how long

15 days after publication

To whom data/document is available

google scholar

Under which criteria data/document could be used

Access to the data will be facilitated through a specified mechanism, such as a secure online portal or data sharing platform. Requests for access will be reviewed by a designated committee or entity responsible for ensuring that they meet the established criteria and comply with relevant regulations and guidelines. Additional supporting information and documents may be provided to assist requesters

From where data/document is obtainableEn The University of Faisalabad 38000 <https://tuf.edu.pk/> 00924187509715**What processes are involved for a request to access data/document**

What processes are involved for a request to access data/document En To receive the documents or data files, the process typically involves the following steps: 1. Request Initiation: The applicant submits a formal request specifying the documents or data files they need. 2. Verification and Authorization: The organization verifies the request and ensures that the applicant is authorized to access the requested documents or data files. This may involve confirming the identity of the requester and checking their permissions. 3. Processing Time: The processing time varies depending on the complexity of the request, the volume of documents or data files, and any legal or regulatory requirements. It could range from a few hours to several weeks. 4. Document Retrieval or Data Extraction: Once the request is approved, the organization retrieves the documents from their archives or extracts the requested data from their databases. 5. Quality Assurance: Before releasing the documents or data files to the applicant, the organization may conduct quality checks to ensure accuracy and completeness. 6. Delivery: The documents or data files are delivered to the applicant through a secure channel, such as encrypted email, secure file

transfer protocols, or a secure online portal. 7.
Confirmation of Receipt: The applicant acknowledges receipt of the documents or data files, confirming that

they have received the information they requested.
Comments