Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

Country
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/AddlReg/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
Street address
GC university. Jhang road, New Campus DR, Faisalabad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Dr. Gulraiz Ayub;PT
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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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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
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 obtainable
En 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