

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

COMPARATIVE EFFECT OF HOLD-RELAX PERIPHERAL NEUROMUSCULAR FACILITATION TECHNIQUE WITH AND WITHOUT CONVENTIONAL PHYSICAL THERAPY ON KNEE TORQUE AND MOTOR FUNCTION IN CHILDREN WITH SPASTIC CEREBRAL PALSY

Protocol summary

Study aim

To compare the effect of conventional physiotherapy with and without hold- relax PNF Exercises on knee torque and motor function in children with spastic cerebral palsy.

Design

single-blind randomized controlled trial

Settings and conduct

Ambulatory patients of cerebral palsy having GMFC of 1 and 2 in the rehabilitation department of Rehab Care School for Special Children Lahore fulfill the inclusion criteria of the study. The assessor was not aware of the treatment given to either group.

Participants/Inclusion and exclusion criteria

8-16 years old cognitive children with spastic cerebral palsy having Knee flexor and extensors grade 3 and above according to manual muscle testing.

Intervention groups

hold- relax peripheral neuromuscular facilitation technique along with conventional physical therapy. The exercise program included: o Dynamic stretching utilizing the principles of hold relax peripheral neuromuscular facilitation. Keeping the knee straight, the patient was asked to lift the leg for 7 seconds while the therapist held the leg from moving. The muscles were relaxed for 2 seconds while holding the new position. The process was repeated five times and the whole set was done 66 times with a 2-minute rest between each set. o Conventional static stretching was done at the start of the protocol for 5 minutes.

Main outcome variables

- knee torque.
- motor function
- functional capability
- spasticity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240530061952N1**

Registration date: **2024-06-15, 1403/03/26**

Registration timing: **retrospective**

Last update: **2024-06-15, 1403/03/26**

Update count: **0**

Registration date

2024-06-15, 1403/03/26

Registrant information

Name

Azka Zulfiqar

Name of organization / entity

University of Lahore

Country

Pakistan

Phone

+92 308 0529889

Email address

azka286@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-05, 1402/09/14

Expected recruitment end date

2024-01-10, 1402/10/20

Actual recruitment start date

2023-12-15, 1402/09/24

Actual recruitment end date

2024-01-12, 1402/10/22

Trial completion date

2024-04-18, 1403/01/30

Scientific title

COMPARATIVE EFFECT OF HOLD-RELAX PERIPHERAL NEUROMUSCULAR FACILITATION TECHNIQUE WITH AND WITHOUT CONVENTIONAL PHYSICAL THERAPY ON KNEE TORQUE AND MOTOR FUNCTION IN CHILDREN WITH SPASTIC CEREBRAL PALSY

Public title

Effect of hold relax technique on knee movement of children with cerebral palsy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 8-16 years Ambulatory patient Normal vision, as well as hearing, and the ability to follow instructions Knee flexor and extensors grade 3 and above according to manual muscle testing

Exclusion criteria:

The patient was unable to respond physically or mentally Subjects with Gross Motor Functional Classification levels 4 and 5 Fixed contractures or deformities of the spine or extremities History of surgical interference of the spine or lower extremities within 1 year

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **53**

Actual sample size reached: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

participants were randomly allocated to different groups using the sealed enveloped method Non-probability, purposive sampling. A single-blind randomized controlled trial was performed. The assessor was not aware of the treatment given to either group

Blinding (investigator's opinion)

Single blinded

Blinding description

A single-blind randomized controlled trial was performed. The outcome assessor (senior physiotherapist) was not aware of the treatment given to either group

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research Ethics Committee (REC) Faculty of Allied Health Sciences The University of Lahore

Street address

University of Lahore Defence Road Campus, 1-Km, DefenceRoad, 10-Km, LahoreRoad, Off Bhotatian Chowk, Lahore.

City

Lahore

Postal code

54792

Approval date

2023-09-28, 1402/07/06

Ethics committee reference number

REC-UOL-537-09-2023

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

Cerebral Palsy

ICD-10 code

G80.9

ICD-10 code description

Cerebral palsy, unspecified

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

Knee torque

Timepoint

Baseline, 6,12 weeks

Method of measurement

Dynamometer

2**Description**

Motor function

Timepoint

Before intervention ,6,12 weeks

Method of measurement

Gross motor function scale

3**Description**

Functional capability

Timepoint

Before intervention, 6, 12 weeks

Method of measurement

Sit and reach test

4

Description

Spasticity

Timepoint

Before intervention, 6, 12 weeks

Method of measurement

Modified Tardieu Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The children in the experimental group received a hold-relax peripheral neuromuscular facilitation technique along with conventional physical therapy. The exercise program included: Dynamic stretching utilizing the principles of hold relax peripheral neuromuscular facilitation. Keeping the knee straight, the patient was asked to lift the leg for 7 seconds while the therapist held the leg from moving. The muscles were relaxed for 2 seconds while holding the new position. The process was repeated five times and the whole set was done 66 times with a 2 minute rest between each set. Conventional static stretching was done at the start of the protocol for 5 minutes.

Category

Rehabilitation

2

Description

Control group: All children in this group underwent an especially designed Conventional Physical Therapy Program for 40 minutes, 3 times per week for 12 successive weeks. The exercise program included the following: Static Stretching at the knee, ankle, and hip. Knee isometrics for knee strengthening.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Rehab Care School for special children

Full name of responsible person

Dr. Khushbakht

Street address

176, block Q1, Wapda Town, Phase 2, Lahore

City

Lahore

Postal code

54770

Phone

+92 333 1048076

Email

admin@rehabcare.pk

Web page address

https://rehabcare.com.pk/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Lahore

Full name of responsible person

Umair Ahmed

Street address

University of Lahore, Defence road Campus, 1 km off Bhoobtian road, Lahore

City

Lahore

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53700

Phone

+92 42 35322501

Email

info@uol.edu.pk

Web page address

https://uol.edu.pk/

Grant name

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

Azka Zulfiqar

Position

MS- PT student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
No - There is not a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Collection data set for knee torque CP
When the data will become available and for how long
Data can be provided within 6 months of publication
To whom data/document is available
Supporting documents can be provided on request to academic institutions
Under which criteria data/document could be used
Academic institutions can use the data for further research
From where data/document is obtainable
Documents are available on request on azka286@gmail.com
What processes are involved for a request to access data/document
Documents are available on request on azka286@gmail.com
Comments
For additional information contact on azka286@gmail.com