

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effectiveness of Leap Motion controller on the functionality of the upper limb in children with bilateral spastic cerebral palsy: Randomized controlled trial

Protocol summary

Study aim

Effectiveness of common occupational therapy interventions based on Leap motion to increase the power of hand perception of bilateral spastic cerebral palsy. Effectiveness of common occupational therapy interventions based on Leap motion on improving the manual skills of children with bilateral spastic cerebral palsy.

Design

Clinical trial with control group, single blind, randomized. Even and odd numbers are used for randomization.

Settings and conduct

The control and intervention groups are identified randomly and single blind. Initially, one assessment is taken from the two groups. The intervention group receives 12 weeks of treatment using Leap Motion in addition to conventional occupational therapy, and the control group receives only conventional occupational therapy. At the end of 12 weeks, the evaluation is done again. And after 4 weeks the two groups are reevaluated.

Participants/Inclusion and exclusion criteria

1. Age category 5 to 8 years. 2. Ability to understand and follow simple verbal commands. 3. Diagnosis of bilateral spastic cerebral palsy by a neurologist. 4. Level one or two or three manual ability classification system. 5. Level one or two or three systems of gross motor function. 6. No history of Botox injections, surgery and upper limb fractures during the last 6 months. 7. Grade 2 or less spastic tone based on the modified Ashworth scale in the flexor muscle of the wrist and elbow. 8. Absence of severe visual impairment. 9. Not participating in research using Leap Motion for the past six months. 10. Absence of obvious and noticeable deformity in the upper limbs based on clinical examination.

Intervention groups

The child puts his hands on the "Leap Motion" sensor and performs types of grips and pinch, and at the same time

sees his hands on the laptop, and according to the visual feedback received, his movement corrects.

Main outcome variables

Hand skill, hand and finger strength

General information

Reason for update

Acronym

LMC

IRCT registration information

IRCT registration number: **IRCT20210616051599N2**

Registration date: **2022-05-08, 1401/02/18**

Registration timing: **prospective**

Last update: **2022-05-08, 1401/02/18**

Update count: **0**

Registration date

2022-05-08, 1401/02/18

Registrant information

Name

Sajad Sabbaghi siuki

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 5224 0355

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-26, 1401/03/05

Expected recruitment end date

2022-06-05, 1401/03/15

Actual recruitment start date

2022-06-06, 1401/03/16

Actual recruitment end date

2022-10-08, 1401/07/16

Trial completion date

2022-10-08, 1401/07/16

Scientific title

Effectiveness of Leap Motion controller on the functionality of the upper limb in children with bilateral spastic cerebral palsy: Randomized controlled trial

Public title

Effectiveness of Leap Motion on hand function in children with cerebral palsy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age category 5 to 8 years. Ability to understand and follow simple verbal commands. Diagnosis of bilateral spastic cerebral palsy by a neurologist based on medical records. Level one or two or three manual ability classification system. Level one or two or three systems of gross motor function. No history of Botox injections, surgery and upper limb fractures during the last 6 months, according to a family report. Grade 2 or less spastic tone based on the modified Ashworth scale in the flexor muscle group of the wrist and elbow joints. Absence of obvious and noticeable deformity in the upper limbs based on clinical examination. Non-participation in research using "Leap motion" during the last six months. Absence of severe visual impairment.

Exclusion criteria:

Reluctance / ability of the child and family to continue participating in the research.

Age

From **5 years** old to **8 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **20**

Actual sample size reached: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the randomization method is simple. It is an individual randomization unit and its tool is using even and odd numbers that are provided to families in the envelope and those who choose odd numbers in the control group and people who choose even numbers in the intervention group Placed.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, occupational therapy graduates who were unaware of the division of children into control and

intervention groups were used for evaluation.

Placebo

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

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

ethics committee of university of social welfare and rehabilitation sciences

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kodakyar Ave, Daneshjo Blvd, Evin

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Postal code

1985713871

Approval date

2021-06-09, 1400/03/19

Ethics committee reference number

IR.USWR.REC. 1400.063

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

Cerebral palsy

ICD-10 code

G80

ICD-10 code description

Cerebral palsy

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

Manual skill score in QUEST questionnaire

Timepoint

At the beginning of the study and in the 12th and 16th weeks after the start of the study

Method of measurement

QUEST questionnaire

Secondary outcomes**1****Description**

power grip

Timepoint

At the beginning of the study and at weeks 12 and 16 after the start of the study

Method of measurement

Dynamometer device

2**Description**

lateral pinch, palmar pinch

Timepoint

At the beginning of the study and at weeks 12 and 16 after the start of the study

Method of measurement

pinch gauge device

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

Intervention group: In this study, the intervention will be a clinical trial in two groups of intervention and control. At the beginning of the intervention phase, an assessment is made of the individuals. Then 12 weeks of intervention is performed by Leap Motion. The intervention is that the child performs all kinds of grip and pinch on the device and receives visual feedback and corrects it if necessary. At the end of 12 weeks, the evaluation is done again. Children are re-evaluated 4 weeks after the end of the intervention period.

Category

Treatment - Devices

2**Description**

Control group: In this study, the control group receives common occupational therapy interventions. At the beginning of the research, this group is evaluated. This evaluation will be performed again after 12 weeks. At 16 weeks, the third evaluation is performed.

Category

Rehabilitation

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

Neghah Novin Occupational Therapy Clinic

Full name of responsible person

feisal jabbary

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

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Web page address**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

University of social welfare and rehabilitation sciences

Proportion provided by this source

100

Public or private sector

Public

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 social welfare and rehabilitation sciences

Full name of responsible person

sajjad sabbaghi siuki

Position

Master student

Latest degree

Master

Other areas of specialty/work

Occupational Therapy

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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

The principle of confidentiality and moral principles

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available