Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

Phone

+98 51 5224 0355

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sajadsss1375@gmail.com

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
Street address
kodakyar Ave, Daneshjo Blvd, Evin
City
Tehran
Province
Tehran
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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of social welfare and rehabilitation sciences
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University of Social Welfare and rehabilitation sciences
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Email
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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
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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