

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 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)

##### Phone

+98 51 5224 0355

##### Email address

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**

feisal jabbary

**Street address**

piroozy

**City**

tehran

**Province**

Tehran

**Postal code**

1765677435

**Phone**

+98 21 7775 1494

**Email**

kardarmaninovin@gmail.com

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

University of social welfare and rehabilitation sciences

**Full name of responsible person**

University of Social Welfare and rehabilitation sciences

**Street address**

Student Boulevard, Koodakyar Ave

**City**

tehran

**Province**

Tehran

**Postal code**

1985713871

**Phone**

+98 21 2218 0083

**Email**

pr@USWR.ac.ir

**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

**Street address**

gharahni street. gharahni 5. No13

**City**  
torbat heydariyeh  
**Province**  
Razavi Khorasan  
**Postal code**  
9518943400  
**Phone**  
+98 51 5222 8297  
**Email**  
sajadsss1375@gmail.com

## Person responsible for scientific 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  
**Street address**  
garahni street. gahrani 5. No13  
**City**  
torbat heydariyeh  
**Province**  
Razavi Khorasan  
**Postal code**  
9518943400  
**Phone**  
+98 51 5222 8297  
**Email**  
sajadsss1375@gmail.com

## Person responsible for updating data

### 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  
**Street address**  
gharahni street. gharahni 5.No 13  
**City**  
Torbati heydariyeh  
**Province**  
Razavi Khorasan  
**Postal code**  
9518943400  
**Phone**  
+98 51 5222 8297  
**Email**  
sajadsss1375@gmail.com

## 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