Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effects of Sensorimotor Training on hand function of children with spastic hemiplegia 4-12 years

Protocol summary

Summary

Objectives: In children with spastic hemiplegia, sensorimotor disorder cause inability to do many manual skills, followed by the restriction on doing daily activities and assignments. Because of the important role of manual skills in children’s adaptation to the environment and independence in daily life activities, development of these skills is of great importance. The present research aimed to study the effect of sensorimotor training on improving hand function in children with spastic hemiplegia. Experimental design: The present research is a single-blind experimental study. Participants: 40 children with cerebral palsy (spastic hemiplegia) aged 4-12. In the control group, 20 children spastic hemiplegia will receive conventional training on hand function including stretching, strengthening muscles, and fine movements of hands 3 sessions a week for 4 weeks. In the intervention group, 20 other children with spastic hemiplegia, in addition to conventional training on hand function, will perform sensorimotor exercises 3 sessions a week for 4 weeks (each session will last 1 hour). Treatment will be based on the principles of sensory retraining and further use hands. However, unlike the traditional retraining methods in which hands are mainly passive during the intervention, this training requires active and exploratory movements of hands. It should be noted that the sense of sight will be eliminated in order to further stimulate the sensory function of hands. These exercises include detection of objects and their weight, texture, and temperature, manipulation, and subtle movements. Participants of both groups will be evaluated before and after the intervention and a follow-up measurement will be performed in the intervention group one month after the intervention. primary and secondary assessment is Stereognosis, Proprioceptive, Purdue pegboard, MAS, Nine Hole Peg Test.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016030626926N1**
Registration date: **2016-12-09, 1395/09/19**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-12-09, 1395/09/19

Registrant information

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Recruitment status

Recruitment complete

Funding source

Neuromuscular rehabilitation research center

Expected recruitment start date

2016-06-11, 1395/03/22

Expected recruitment end date

2017-02-10, 1395/11/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effects of Sensorimotor Training on hand function of children with spastic hemiplegia 4-12 years

Public title
study of hand function in cerebral palsy
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria: Medical diagnosis of children with spastic hemiplegia; being aged 4-12; the ability to communicate in order to perform tests; mild to moderate spasticity based on the Modified Ashworth Scale, and having a sense of protection in the palm of the hand (the minimum monofilament No. 6.65 and 33 grams). Exclusion criteria: Lack of cooperation during the intervention or parent’s request for stopping the intervention; orthopedic problems such as fixed deformity in hand; impairment of attention and concentration; and significant hearing and vision problems.
Age
From **4 years** old to **12 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Semnan University of Medical Sciences Ethics Committee
Street address
No.47,Semnan university of medical sciences, Basij Blvd, Semnan, Iran
City
Semnan
Postal code
Approval date
2016-05-25, 1395/03/05
Ethics committee reference number
Ir.semums.rec.1395.22

Health conditions studied

1

Description of health condition studied
Spastic hemiplegic cerebral palsy
ICD-10 code
G80.2, G81
ICD-10 code description
G80.2 Spastic hemiplegic cerebral palsy G81.1 Spastic hemiplegia

Primary outcomes

1

Description
hand fine movement
Timepoint
Before intervention, The end of each 4 treatment sessions, end of intervention and 1 month after the end of intervention
Method of measurement
purdopegboard, Nine Hole Peg Test

Secondary outcomes

1

Description
sensory of hand function
Timepoint
Before intervention,The end of each 4 treatment sessions, end of intervention and 1 month after the end of intervention
Method of measurement
sterognosis and Proprioceptive

Intervention groups

1

Description
Intervention group:In the intervention group, in addition to conventional occupational therapy training on hand function, will perform sensorimotor exercises 3 sessions a week for 4 weeks (each session will last 1 hour).
Category
Rehabilitation

2

Description
control group:In the control group, patients will receive conventional occupational therapy training on hand function including stretching, strengthening muscles, and fine movements of hands 3 sessions a week for 4 weeks

(each session will last 1 hour).

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Neruromuscular rehabilitation research center

Full name of responsible person

Karim Ayoubi Avaz

Street address

No.24, Neuromuscular Rehabilitation Research Center, Ghods Blvd, Mashahir square, Semnan, Iran

City

Semnan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Semnan University of Medical Sciences

Full name of responsible person

Dr Ali Rashidipour

Street address

No.47,Semnan university of medical sciences, Basij Blvd, Semnan, Iran

City

Semnan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Semnan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Karim Ayoubi Avaz

Position

Master of siences / Faculty member

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty