

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Effects of transcranial direct current stimulation with cognitive orientation to daily occupational performance versus neurodevelopmental treatment on motor based occupational performance of upper extremity in children with cerebral hemiplegia: a randomized clinical trial

Protocol summary

Study aim

Assessing the effect of transcranial direct current stimulation with cognitive orientation to daily occupational performance versus neurodevelopmental treatment on motor based occupational performance of upper extremity in children with cerebral hemiplegia

Design

This a randomized clinical trial, in which 36 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible children with cerebral hemiplegia who will refer to University of Welfare and Rehabilitation Sciences during the study period will be enrolled in the trial

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 7 to 12 years Cerebral hemiplegia The ability to establish verbal communication Medium to high intelligence Exclusion criteria: A history of CO_OP treatment A history of surgery or botulinum toxin injection in the last three months Blindness Deafness Seizure

Intervention groups

Intervention group: Transcranial direct current stimulation with severity of 0.5 to 2 mA for 15 min plus cognitive orientation 10 sessions, each session for 45 min. Control group: Transcranial direct current stimulation with severity of 0.5 to 2 mA for 15 min plus neurodevelopmental treatment 10 sessions, each session for 45 min

Main outcome variables

Primary outcome: Assessing the occupational performance two weeks after treatment through physical examination Assessing the performance of upper extremity two weeks after treatment through physical

examination

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N220**

Registration date: **2018-05-16, 1397/02/26**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-16, 1397/02/26**

Update count: **0**

Registration date

2018-05-16, 1397/02/26

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-10, 1397/02/20

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of transcranial direct current stimulation with cognitive orientation to daily occupational performance versus neurodevelopmental treatment on motor based occupational performance of upper extremity in children with cerebral hemiplegia: a randomized clinical trial

Public title

Effects transcranial direct current stimulation with cognitive orientation to daily occupational performance versus neurodevelopmental treatment on motor based occupational performance of upper extremity in children with cerebral hemiplegia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 7 to 12 years Cerebral hemiplegia The ability to establish verbal communication Medium to high intelligence

Exclusion criteria:

A history of CO_OP treatment A history of surgery or botulinum toxin injection in the last three months Blindness Deafness Seizure

Age

From **7 years** old to **12 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the patients to the intervention and control groups through drawing of lots

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of University of Welfare and Rehabilitation Sciences

Street address

University of Welfare and Rehabilitation Sciences, Student Blvd, Velenjak,

City

Tehran

Province

Tehran

Postal code

1985713834

Approval date

2018-03-11, 1396/12/20

Ethics committee reference number

IR.USWR.REC.1396.307

Health conditions studied

1

Description of health condition studied

Cerebral hemiplegia

ICD-10 code

G81.0

ICD-10 code description

Flaccid hemiplegia

Primary outcomes

1

Description

Assessing the occupational performance

Timepoint

Two weeks after treatment

Method of measurement

Through physical examination

2

Description

Assessing the performance of upper extremity

Timepoint

Two weeks after treatment

Method of measurement

Through physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Transcranial direct current stimulation with severity of 0.5 to 2 mA for 15 min plus cognitive orientation 10 sessions, each session for 45 min.

Category

Treatment - Other

2

Description

Control group: Transcranial direct current stimulation with severity of 0.5 to 2 mA for 15 min plus neurodevelopmental treatment 10 sessions, each session for 45 min

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

University of Welfare and Rehabilitation Sciences

Full name of responsible person

Sahar Johari

Street address

University of Welfare and Rehabilitation Sciences,
Student Blvd, Velenjak,

City

Tehran

Province

Tehran

Postal code

1985713834

Phone

+98 21 2218 0083

Email

saharjohari85@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Dr Amir Masood Arab

Street address

University of Welfare and Rehabilitation Sciences,
Student Blvd, Velenjak,

City

Tehran

Province

Tehran

Postal code

1985713834

Phone

+98 21 2218 0083

Email

rd@uswr.ac.ir

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

Sahar Johari

Position

Student of Occupational Therapy

Latest degree

Master

Other areas of specialty/work

Occupational Medicine

Street address

University of Welfare and Rehabilitation Sciences,
Student Blvd, Velenjak,

City

Tehran

Province

Tehran

Postal code

1985713834

Phone

+98 21 2218 0083

Email

saharjohari85@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Hojatolah Haghgoo

Position

Occupational Therapy Specialist

Latest degree

Medical doctor

Other areas of specialty/work

Occupational Medicine

Street address

University of Welfare and Rehabilitation Sciences,

Student Blvd, Velenjak,
City
Tehran
Province
Tehran
Postal code
1985713834
Phone
+98 21 2218 0083
Email
h.haghgoo@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr Jalal Poorolajal
Position
Professor of Epidemiology
Latest degree
Ph.D.
Other areas of specialty/work
Epidemiology
Street address
School of Public Health, Hamadan University of
Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Province

Hamadan
Postal code
6517838695
Phone
+98 81 3838 0090
Email
poorolajal@umsha.ac.ir

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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available