Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

Effect of Computerized Visual Games on Handwriting, Visual Perception and Visual Motor Integration in the Children with Spastic Cerebral Palsy in the second and third grades of elementary schools.

Protocol summary

Study aim

The effect of computerized visual games on handwriting, visual perception skills and visual-motor integration in children with spastic cerebral palsy in second and third grades of elementary school.

Design

A clinical trial with a control group, parallel groups, single blind, randomized, on 30 children. A stratified permuted block randomization method will be used.

Settings and conduct

The study population is spastic cerebral palsy. Interventions are in the field of handwriting, visual perception and motor visual integrity. Interventions in occupational therapy clinics or exceptional schools in Tehran. Interventions will be computeized visual games (20 sessions . Interventions are for individual children. Games will be played on the computer and the child will play these games with the mouse in a quiet environment). After the end of interventions, final evaluation and then data analysis will be carried out. The study is a blind type that will be a blind statistical analyzer. The statistical analyzer who does not know the participants will perform these analyses.)

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children with spastic cerebral palsy diagnosed by pediatric neuroscience Exit Criteria: People who do not want to participate in the study at any stage of the study

Intervention groups

One of the intervention groups will receive the visual perception game alongside traditional handwriting exercises. The other intervention group will receive the visual-motor integration game in addition to traditional handwriting exercises, while the third group, serving as the control group, will not receive any of these games and will only perform traditional handwriting exercises.

Main outcome variables

Handwriting; visual perception; visual-motor integration

General information

Reason for update

Update of randomization method, recruitment status, and further clarification of interventions to ensure consistency with the final study protocol and in response to journal requirements.

Acronym

IRCT registration information

IRCT registration number: **IRCT20230219057447N1**
Registration date: **2023-05-25, 1402/03/04**
Registration timing: **prospective**

Last update: **2025-09-23, 1404/07/01**
Update count: **2**

Registration date

2023-05-25, 1402/03/04

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-12-21, 1403/10/01

Expected recruitment end date

2025-12-22, 1404/10/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Computerized Visual Games on Handwriting, Visual Perception and Visual Motor Integration in the Children with Spastic Cerebral Palsy in the second and third grades of elementary schools.

Public title
The Effect of Computer Vision Games on Handwriting, Visual Perception and Visual Motor Integrity
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Children with cerebral palsy participating, second and third grade of primary school Children diagnosed with spastic cerebral palsy by pediatric neuroscience specialty Children in the gross movement classification system (GMFCS E&R) at levels I, II, III Children in manual abilities classification system (MACS) at levels I, II, III Children have the ability to write with pencil Children with cognitive scores above 70 Children who do not achieve complete scores according to legibility criteria according to Persian Handwriting Test (PHAT) Children who have difficulty in the Visual Perception Skills Test (TVPS-R), i.e. obtain scores below the defined average Children who do not achieve complete scores by age in the Visual-Motor Integrity Test (DTVMI)
Exclusion criteria:
Children with modified visual acuity with glasses less than 0.8 in close vision Children with obvious eye deviation (strabismus) Children with any kind of orthopedic anomalies, upper extremity surgeries in the last six months or botulinum injections in the last three months
Age
From **8 years** old
Gender
Both

Phase
3
Groups that have been masked

- Data analyser

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
A stratified permuted block randomization method will be used in this trial. Participants will first be stratified based on the type of spastic cerebral palsy into three strata: hemiplegia, diplegia, and quadriplegia. Within each stratum, participants will be randomly assigned to one of the three study groups: Group A (visual-motor integration intervention), Group B (visual perception intervention), and Group C (control group). Thus, randomization will be performed separately within each CP subtype to ensure balance across groups. To achieve allocation concealment, we will use sealed, opaque envelopes made with foil and carbon paper to prevent any visibility of group assignment. Since we are not certain about the exact number of participants in each CP subtype in advance, and to follow recommendations from similar studies (e.g., Doig et al., 2005), we will prepare more than the planned 30 envelopes specifically, 81 envelopes in total, consisting of 27 for each group (A, B, and C). These envelopes will be distributed across three Tupperware-style containers, each labeled according to the CP subtype (hemiplegia, diplegia, quadriplegia). In each container, 9 envelopes from each group (A, B, and C) will be placed (totaling 27 envelopes per stratum). These envelopes will not be mixed between strata. Within each stratum, random blocks of size 3 and 6 will be created, and envelopes will be shuffled within each block. To determine the sequence of blocks, a coin-flipping method will be used: if the coin lands on heads, a block of size 3 will be selected; if tails, a block of size 6. This process will be repeated until a complete block sequence is generated for each stratum. Once the block order is finalized, it will remain fixed. Subsequently, envelopes within each stratum will be numbered sequentially: H1–H27 for hemiplegia, D1–D27 for diplegia, and Q1–Q27 for quadriplegia. As each participant enters the trial, after being classified by CP subtype, the next available envelope in that stratum will be assigned to them in sequence. Importantly, this entire randomization and allocation process will be performed by an independent researcher who is not involved in recruitment, intervention delivery, or outcome assessments, in order to minimize potential bias 54.
Blinding (investigator's opinion)
Single blinded
Blinding description
Given that all relevant information is included in the informed consent form, participants in this study will be fully aware of the group to which they are assigned after allocation. Specifically, participants in the intervention groups will receive computerized games, whereas participants in the control group will not receive any intervention from the therapist during the study. Therefore, blinding of participants is not possible. In this study, only the data analysts will be blinded to allow for a single-blind design. The principal investigator will conduct both the baseline assessments and the interventions, as well as the post-intervention evaluations, and will be fully aware of the entire study process.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences
Street address
Tehran Medical Sciences Girls' Dormitory, north kargar. amir abad. tehran
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Province
Tehran
Postal code
1439955975
Approval date
2023-04-30, 1402/02/10
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1402.057

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
handwriting
Timepoint
Before the study and after the end of the study (the interval between pre-test and post-test will be 10 weeks)
Method of measurement
Persian Handwriting Assessment Tool (PHAT)

Secondary outcomes

1

Description
Visual-motor integrity
Timepoint
Before the start of the intervention and after the end of the intervention (10 weeks gap between pre-test and post-test)
Method of measurement
the Beery Bactenica visual Motor Integrity Development Test

2

Description
visual percetion
Timepoint
Before the start of the intervention and after the end of the intervention (10 weeks gap between pre-test and post-test)
Method of measurement
Visual Perception Skills Test TVPS-R

3

Description
Cognitive Ability
Timepoint
At the time of determining the entry criteria (before the beginning of the intervention)
Method of measurement
With Sparkle Form

4

Description
Gross Motor Function
Timepoint
At the time of determining the entry criteria (before the beginning of the intervention)
Method of measurement
Gross Movement Classification System GMFCS

5

Description
Ability of the hand
Timepoint
At the time of determining the entry criteria (before the beginning of the intervention)
Method of measurement
Manual Ability Classification System MACS

6

Description
Visual acuity
Timepoint
At the time of determining the entry criteria (before the beginning of the intervention)
Method of measurement
With the Snellen Vision Chart

Intervention groups

1

Description
First intervention group: This group, consisting of 10 children, will receive a computerized visual perception game intervention for 20 sessions. The visual perception games target skills related to visual processing and progress from easy to difficult levels. The games consist of a series of cards adapted from exercise books and designed as games. These cards were suggested by

occupational therapists, optometrists, educators, learning specialists, and other health professionals, and aim to train skills such as figure-ground discrimination, visual discrimination, visual form constancy, visual closure, visual sequential memory, visuospatial relations, and visual memory in children who need improvement in these areas. In each session, a specific number of exercises will be assigned to the child, who will play the games on the researcher's computer and receive guidance from the therapist if errors occur. Each session will last 45 minutes, with two sessions per week, totaling 20 sessions over 10 weeks. In addition to this intervention, traditional handwriting exercises (including sensory-motor activities and paper-and-pencil tasks) will be provided to these children by occupational therapists from the same schools and clinics.

Category

Rehabilitation

2

Description

Second intervention group: This group, consisting of 10 children with cerebral palsy, will receive a computerized visual-motor integration game intervention for 20 sessions. The games are designed based on the German software CogPack and include nine different modules aimed at training visual-motor integration skills. The names of these games are: Visual-Motor, Flying Saucers, Ball, Falling Stars, Maze, Board and Cake Division, Navigation, and Mirror, each with multiple difficulty levels. A specific number of these modules will be completed in each session. Each session will last 45 minutes, conducted on the researcher's computer by the child, with two sessions per week over a total of 10 weeks. In addition to this intervention, traditional handwriting exercises (including sensory-motor activities and paper-and-pencil tasks) will be provided to these children by occupational therapists from the same schools and clinics.

Category

Rehabilitation

3

Description

Control group: This group, consisting of 10 children with cerebral palsy, will not receive any intervention from the researcher during the study. They will only participate in traditional handwriting exercises (including sensory-motor activities and paper-and-pencil tasks) provided by occupational therapists from the same schools and clinics.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Hasti occupational clinic

Full name of responsible person

Mehdi Bigham

Street address

Sattar Khan. Baqer Khan Street. No. 92.

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2

Recruitment center

Name of recruitment center

Haami occupational clinic

Full name of responsible person

Ghodrat khavari

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Pasdaran. Daoud Eslami Street.Corner of West Gulzar

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3

Recruitment center

Name of recruitment center

Tavanyab center

Full name of responsible person

Khosro Mansourian

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4

Recruitment center

Name of recruitment center

Occupational Therapy Clinic

Full name of responsible person

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5

Recruitment center
Name of recruitment center
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Full name of responsible person
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Recruitment center
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7

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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
1
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
Tehran University of Medical Sciences
Full name of responsible person
Aida Kazemnazhand Asl
Position
Student
Latest degree

Bachelor

Other areas of specialty/work
Occupational Therapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is 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

Title and more details about the data/document
Data related to the variables will be made available to the Occupational Therapy Education Research Department and, upon request by the corresponding author, will be provided to them for use in meta-analysis studies.

When the data will become available and for how long
The first part, concerning the provision of data to the Occupational Therapy Education group, will be carried out after the article is published. For the second part, data will be sent whenever an official request is received from the authors of meta-analysis studies.

To whom data/document is available
For researchers working in academic and scientific institutions

Under which criteria data/document could be used
For further studies in this field, based on the recommendations provided in the article.

From where data/document is obtainable
corresponding author (Dr. Hamid Dalvand)

What processes are involved for a request to access data/document
First, a message regarding the purpose of data usage, along with sufficient information about the researcher's name and contact details, will be emailed to the researcher. If the details are reviewed and the procedures are verified, it will be sent within a short period of time.

Comments