

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

The effectiveness of Fine Motor Training on Language and Motor Skills in Children with Intellectual Disabilities

Protocol summary

Study aim

This study examines the effects of fine motor learning and changes in the motor, linguistic and cognitive systems of children with mental disabilities.

Design

Randomized Clinical trials, Double-blind, Random and hidden

Settings and conduct

This study will be conducted at Najaf Abad Mehr Rehabilitation Center in Isfahan. Children will be divided into intervention and control groups. Health workers (therapist, speech therapist, and psychologist) who evaluate the initial and final evaluation will also not be aware of the allocation of any children in the groups and will be required to accurately assess all the children participating (case and control) and The final allocation of these children will be done by the trainer. After the end of the interventions, the initial and final information of both groups will be collected by the educational instructor and the statistics expert will be presented for analysis and comparison of the results of the two groups.

Participants/Inclusion and exclusion criteria

The child is a Persian language and speaks only in Persian at home. The language age of the child is at the stage of the emerging or progress of the language. The child is a person with educable intellectual disabilities on the basis of an IQ of 50 to 70.

Intervention groups

In this study, children will be divided into intervention and control groups, which will receive the routine care center of the center as usual and in the intervention group, in addition to rehabilitation services, will receive special training in subtle motor skills based on the HOMA educational protocol and In the end, the results of the evaluations will be compared between the two groups.

Main outcome variables

Language skills, Gross and fine motor skills

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190309042983N1**

Registration date: **2019-04-30, 1398/02/10**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-30, 1398/02/10**

Update count: **0**

Registration date

2019-04-30, 1398/02/10

Registrant information

Name

Ehsan Hemmati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3881 3434

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-09, 1398/01/20

Expected recruitment end date

2019-11-11, 1398/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of Fine Motor Training on Language and Motor Skills in Children with Intellectual Disabilities

Public title

The effect of Fine Motor Training on linguistic and motor skills

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The child is a person with educable intellectual disabilities on the basis of an IQ of 50 to 70, and the Vineland Social Maturity Scale. The language age of the child is at the stage of the emerging or progress of the language, which is determined by the form of the PANA profile. The child is a Persian language and speaks only in Persian at home, which is based on the Persian language of the child's question of parents. The child's parents have literacy skills that can read and respond to checklist, which is obtained through parenting questions. According to a parent's report, the child has no hearing impairment. According to the parents of children who are blind or severely visually impaired is not.

Exclusion criteria:

If the examinations (pre-test or post-test) occupational therapy, speech therapy or psychology for children has not been done. The child's parents did not respond to more than half of the checklists questions. The child has autism diagnosis, which, if suspected, is evaluated by a psychiatrist.

Age

From **4 years** old to **14 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, case and control groups will be randomized through the stratified randomization so that in addition to the same sample size, variables such as IQ, linguistic and motor skills should be the same in the two groups. The results and final differences between the two groups can be understood as the effect of interventions in the case group. After applying these layers, homogeneous individuals in each layer will be randomly assigned to one of the case and control groups based on random numbers. Hiding in this study will be done by an instructor. Speech therapist, occupational therapist, psychologist and even parents of these children will be unaware of being or not taking each child in the case and control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants: From the parents, all participants (both case and control groups) received written consent for participation in the study, but consent will be made that the participating children will be randomly divided into two groups and only one intervention group, mean your baby will have 50 percent chance of receiving an intervention. The main researcher (Ehsan Hemmati) is not involved in sampling, and his colleague will conduct linguistic assessments. Health workers (therapist, speech therapist, and psychologist) who evaluate the initial and final evaluation will also not be aware of the allocation of any children in the groups and will be required to accurately assess all the children participating (case and control) and The final allocation of these children will be done by the trainer. After the end of the interventions, the initial and final information of both groups was collected by the educational instructor and the statistics expert will be presented for analysis and comparison of the results of the two groups (without specifying the case group from the control).

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University Medical Sciences, Hemmat freeway, next to Milad tower, Tehran

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1135617713

Approval date

2019-03-06, 1397/12/15

Ethics committee reference number

IR.IUMS.REC.1397.1163

Health conditions studied

1

Description of health condition studied

Intellectual Disabilities

ICD-10 code

F70
ICD-10 code description
Mild intellectual disabilities

Primary outcomes

1

Description

the language skills and gross and fine motor skills

Timepoint

At the beginning of the study and the end of the intervention

Method of measurement

Through questionnaires, checklists and record sample and speech analysis

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this study, the educational protocol of drawing (Homa design) as an intervention for fine motor training to the children of the intervention group is used. This protocol, which is designed to measure the ability of visual arts for people with special needs, determines the ability to draw these children. In this intervention, each child is trained individually, two sessions per week for six months. This intervention has been designed in five main attributes, including understanding the shape, understanding positioning, understanding the size, drawing power and the precision in drawing that is necessary for painting, which is arranged in 15 columns and in a single page. To run this test, the instructor will ask the child to draw the same box as the test form in the blank box of the same page and then score the child according to the scoring criterion. According to the score, the child will be placed in one of the six levels of the test, and according to his level, he will start specific training. The A level test is all about Blatter, and the person is able to draw complicated subjects with fit and perfect composition. Level B includes intricate topics with low detail, C level, simple threads with wide color surfaces with distinct and large detail, D level, simple threads with wide color surfaces with distinct, large and small detail, E Simple threads with wide color surfaces with distinct layouts, without the details, and level F, include lines, dots, and sprays of simple colors and incomplete levels. In this plan, sub-classes B to F is assigned classed exercises to obtain the ability to perform exercises. These exercises include point-related, line-related, color-related, and related-level exercises.

Category

Rehabilitation

2

Description

Control group: Routine care=

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Mehr rehabilitation center

Full name of responsible person

Alireza Aghaz

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Sponsors / Funding sources

1

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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

Iran University of Medical 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
Iran University of Medical Sciences
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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

Not applicable

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