

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Neuropsychological Interventions on low vision children

Protocol summary

Study aim

Evaluation of Neuropsychological Interventions on visual function in low vision children: A single arm clinical trial

Design

The single arm clinical trial was conducted with a 5-person group of visually impaired children. The method has the following three features: 1. Repeated measurements during a trial of the dependent variable. 2. Run multiple test situations for each participant (for example, each person is in both the trial (intervention) and baseline (control) positions. 3. Each participant is considered as a basis for comparing effectiveness of experimental situation. The reason for choosing such a plan is that each person can be in both a control and an intervention position, while being repeatedly measured in each position to ensure consistency in the individual's score and readiness to move to the next position.

Settings and conduct

The single arm clinical trial applied on 5 children with low vision in dark room of Tavakol rehabilitation center. All 5 low vision children were initially given 4 sessions in baseline (control), then 8 sessions in experimental (intervention) and 4 sessions in baseline (control) again, at the end of each session was measured their visual function.

Participants/Inclusion and exclusion criteria

1. age : 4 between 6
2. exclude other sensitive defect
3. exclude autism
4. exclude ADHD

Intervention groups

Intervention involves training and rehabilitation on a group of 5 visually impaired children by applying rehabilitation exercises implemented on the optical stimulus system.

Main outcome variables

Upgrading the subjects in the following variables: 1. Light Detection 2. Color Perception 3. Color Recognition 4. Shape Recognition 5. Shape Recognition from background 6. Detail Recognition 7. Visual Tracking 8. Visual Memory and sequence of Visual Memory 9. Eye-hand coordination 10. Depth Detection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190620043955N1**

Registration date: **2019-12-08, 1398/09/17**

Registration timing: **retrospective**

Last update: **2019-12-08, 1398/09/17**

Update count: **0**

Registration date

2019-12-08, 1398/09/17

Registrant information

Name

Elaheh Moazeni

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3230 0141

Email address

moazeni.bme@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-20, 1397/10/30

Expected recruitment end date

2019-02-18, 1397/11/29

Actual recruitment start date

2019-01-20, 1397/10/30

Actual recruitment end date

2019-02-18, 1397/11/29

Trial completion date

2019-03-19, 1397/12/28

Scientific title

Neuropsychological Interventions on low vision children

Public title

The effect of educational and visual rehabilitation exercises on the visual function of low vision children

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Having a defect in eyesight- Being visually impaired
Having aged 4-6 years

Exclusion criteria:

Lack of ADHD Lack of Autism Lack of defect in other senses

Age

From **4 years** old to **6 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **5**

Actual sample size reached: **5**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar Jerib street, Isfahan, Iran

City

isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2018-03-03, 1396/12/12

Ethics committee reference number

IR.MUI.REC.1396.3.961

Health conditions studied

1

Description of health condition studied

Low vision

ICD-10 code

H54.2

ICD-10 code description

Low vision, both eyes

Primary outcomes

1

Description

1. Light Detection

Timepoint

Total number of sessions: 16, 4 session per week, 1 hour for every session (4 sessions before intervention, 8 sessions intervention and 4 sessions after intervention)

Method of measurement

complete case report form based on Likert scale

2

Description

2. Color Perception

Timepoint

Total number of sessions: 16, 4 session per week, 1 hour for every session (4 sessions before intervention, 8 sessions intervention and 4 sessions after intervention)

Method of measurement

complete case report form based on Likert scale

3

Description

3. Color Recognition

Timepoint

Total number of sessions: 16, 4 session per week, 1 hour for every session (4 sessions before intervention, 8 sessions intervention and 4 sessions after intervention)

Method of measurement

complete case report form based on Likert scale

4

Description

4. Shape Recognition

Timepoint

Total number of sessions: 16, 4 session per week, 1 hour for every session (4 sessions before intervention, 8 sessions intervention and 4 sessions after intervention)

Method of measurement

complete case report form based on Likert scale

5

Description

5. Shape Recognition from background

Timepoint

Total number of sessions: 16, 4 session per week, 1

hour for every session (4 sessions before intervention, 8 sessions intervention and 4 sessions after intervention)

Method of measurement

complete case report form based on Likert scale

6

Description

6. Detail Recognition

Timepoint

Total number of sessions: 16, 4 session per week, 1 hour for every session (4 sessions before intervention, 8 sessions intervention and 4 sessions after intervention)

Method of measurement

complete case report form based on Likert scale

7

Description

7. Visual Tracking

Timepoint

Total number of sessions: 16, 4 session per week, 1 hour for every session (4 sessions before intervention, 8 sessions intervention and 4 sessions after intervention)

Method of measurement

complete case report form based on Likert scale

8

Description

8. Visual Memory and sequence of Visual Memory

Timepoint

Total number of sessions: 16, 4 session per week, 1 hour for every session (4 sessions before intervention, 8 sessions intervention and 4 sessions after intervention)

Method of measurement

complete case report form based on Likert scale

9

Description

9. Eye-hand coordination

Timepoint

Total number of sessions: 16, 4 session per week, 1 hour for every session (4 sessions before intervention, 8 sessions intervention and 4 sessions after intervention)

Method of measurement

complete case report form based on Likert scale

10

Description

10. Depth Detection

Timepoint

Total number of sessions: 16, 4 session per week, 1 hour for every session (4 sessions before intervention, 8 sessions intervention and 4 sessions after intervention)

Method of measurement

complete case report form based on Likert scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention involves training and rehabilitation on a group of 5 visually impaired children by applying rehabilitation exercises implemented on the optical stimulus system. The clinical trial applied in dark room of Tavakol rehabilitation center. All 5 low vision children were initially given 4 sessions in baseline (control), then 8 sessions in experimental (intervention) and 4 sessions in baseline (control) again, at the end of each session was measured their visual function.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Tavakol Rehabilitation Center of Family and Low Vision and Blindness Children

Full name of responsible person

Fateme Tavakolli

Street address

No. 27, 22 Bahman Alley, Falatory Ave, Isfahan, Iran

City

isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3568 6202

Email

markazetavakol@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellery for Research and Technology of Isfahan University of Medical Sciences

Full name of responsible person

Dr.ShaghayeghHaghjoo Javanmard

Street address

Hezar Jerib street, Isfahan

City

Isfahan

Province

Isfahan

Postal code

73461-81746

Phone

+98 31 3792 3071

Email

research@mui.ac.ir

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-Chancellery for Research and Technology of Isfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Saeed Kermani
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Engineering
Street address
Hezar Jerib street, Isfahan, Iran
City
Isfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 3792 3861
Email
kermani@med.mui.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Saeed Kermani
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Engineering
Street address

Hezar Jerib street, Isfahan, Iran
City
Isfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 3792 3861
Email
kermani@med.mui.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Saeed Kermani
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Engineering
Street address
Hezar Jerib street, Isfahan, Iran
City
Isfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 3792 3861
Email
kermani@med.mui.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