

# 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

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isfahan

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**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

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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**  
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Medical Engineering  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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**  
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