

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

The effect of eye exercises with and without active movements on motor skills in children with amblyopia

Protocol summary

Study aim

the aim of the present research was to analyze the effect of eye exercises with and without active movements on motor skills in children with amblyopia.

Design

A randomized controlled clinical trial, 4 Amblyopia children with parallel groups, randomized, Triple blind

Settings and conduct

At first, general descriptions of the type of interventions were given to the subjects and their parents, and the parents of the children signed informed consent to participate in the study. Then, all subjects in the four groups received visual perception and motor skills as pre-test. Each of the experimental groups underwent individually designed 30-minute sessions of individually designed 3-minute sessions for four weeks. The control group subjects performed their daily activities and did not perform any specific exercise. All subjects took post-test two days after the last training session. It should be noted that the intervention, pre-test and post-test groups were trained in a part of a gym equipped for this purpose. Subjects did not know the interventions group exercises and that the subjects in the four groups had no knowledge of the type of exercises and how to perform them in other groups; the principal investigator selected one Individual examiners and practitioners were blinded to each group and data analyst by providing statistical corrections through predefined codes.

Participants/Inclusion and exclusion criteria

A group of 40 children aged 5-8 years with amblyopia

Intervention groups

Three groups: eye exercises without active movements, eye exercises with active movements (ocular, ocular and manual, and displacement), and control(They did their daily activities and did not do any of the interventions).

Main outcome variables

motor skills

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191112045425N1**

Registration date: **2019-12-27, 1398/10/06**

Registration timing: **retrospective**

Last update: **2019-12-27, 1398/10/06**

Update count: **0**

Registration date

2019-12-27, 1398/10/06

Registrant information

Name

Mohammad Reza Shahabi Kaseb

Name of organization / entity

Hakim sabzevari university

Country

Iran (Islamic Republic of)

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+98 51 4441 4160

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mr.shahabi@hsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-01-21, 1396/11/01

Actual recruitment start date

2017-12-31, 1396/10/10

Actual recruitment end date

2018-01-30, 1396/11/10

Trial completion date

2018-01-30, 1396/11/10

Scientific title

The effect of eye exercises with and without active movements on motor skills in children with amblyopia

Public title

The effect of eye exercises on children with amblyopia

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Children with amblyopia (caused by refractive errors)

Exclusion criteria:

Age

From **5 years** old to **8 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Subjects were randomly assigned to one of four groups by simple random method (ball and bowl). The groups were randomly assigned to experimental and control groups

Blinding (investigator's opinion)

Triple blinded

Blinding description

Attendees at different times to intervene Supplementary Description: Before the subjects were included in the study, a general introduction to the research objectives for the subject and their parents was made. So they knew the whole point. Subjects were present at the training site at different times to observe the "independence of observations". Using an evaluator that was not part of the research group Use statistics expert

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic Azad University of Sabzevar

Street address

خراسان رضوی ، سبزوار ، توحید شهر، پردیس دانشگاه حکیم سبزواری

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Postal code

9617976487

Approval date

2017-12-05, 1396/09/14

Ethics committee reference number

IR.IAU.S.REC.1395.7

Health conditions studied

1

Description of health condition studied

amblyopia

ICD-10 code

H00-H59

ICD-10 code description

Diseases of the eye and adnexa

Primary outcomes

1

Description

Motor Skills

Timepoint

Before the intervention and two days after the last training session (after the intervention)

Method of measurement

Lincoln Oseretsky's test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: First. Exercise-Free Vision Training Group (Exercise Vision-Free Bodybuilding). The subjects in this group sat in a stationary and immobilized position and performed dynamic sharpening exercises, field-based perception, depth-perception, and eye-tracking using movement only. The eyes did. Subjects performed three 30-minute sessions of exercise for four weeks each week.

Category

Prevention

2

Description

Intervention group: Second. The group with active low vision exercises consisted of hands-on visual exercises

(visual-manual exercises). Field perception, depth perception, and visual pursuit were performed with hand movement. Subjects performed three 30-minute sessions of exercise for four weeks each week.

Category

Prevention

3**Description**

Intervention group: Third. High-intensity, active-motion visual exercises that included whole-body visual training (visual-movement exercises). Subjects performed visual-displacement exercises, dynamic sharpening exercises, field form perception, depth perception, and visual pursuit along with whole-body displacement. Subjects performed three 30-minute sessions of exercise for four weeks each week.

Category

Prevention

4**Description**

Control group: The control group subjects did their daily activities and did not perform any extra exercises. Only participated in pre-test and post-test

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

بهزیستی

Full name of responsible person

Marziee Kasraee far

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Campus of Hakim University of Sabzevari, Tohid Shahr, Sabzevar, Khorasan Razavi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Hakim Sabzevar University

Full name of responsible person

Ahmad Farzaneh Kord

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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

Hakim Sabzevar University

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**

Hakim Sabzevari University

Full name of responsible person

Mohammad Reza Shahabi Kaseb

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Motor Behavior

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Person responsible for scientific

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Contact

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Full name of responsible person

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Motor skills scores can be shared.

When the data will become available and for how long

Start of access period 6 months after printing results

To whom data/document is available

participants

Under which criteria data/document could be used

Data and documentation are available for use in welfare centers.

From where data/document is obtainable

Apply to mr.shahabi@hsu.ac.ir

What processes are involved for a request to access data/document

Results will be announced a week after the application is submitted

Comments