

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jun 2026

### Investigation the Effect of Active Vision Therapy on visual skills using Vision Therapy System 4 (VTS4) in children with Bilateral Refractive Amblyopia ages 5-13

#### Protocol summary

##### Study aim

General objectives: Determining the effect of active vision therapy(AVT) using vision therapy system version 4 in children with bilateral refractive amblyopia(BRA)

##### Design

Clinical trial with control group, with parallel groups, double-blind, randomized, on 40 patients. (Block randomization )

##### Settings and conduct

Selection of bilateral refractive amblyopia patient, aged 5-13 years, as available in Postachi clinic They will be referred to the Soroosh optometry center for full examination( VA, SA, CS, AI) Program for treatment group will be three 30-minute sessions AVT per week with patching. The control group will have patch and placebo vision therapy sessions. Difference consideration: at least one line improvement in VA. patients and optometrists who check before and after test will be blinded.

##### Participants/Inclusion and exclusion criteria

inclusion criteria: age between 5 - 13 years Astigmatism or hyperopia in each eye or a mix hyperopia-astigmatism Maximom VA 20/40 and Minimum VA 20/100 in each eye exclusion criteria: weak follow-up for treatment. The existence of pathological and structural problems of the eyes History of eye surgeries strabismus, microtropia or eccentric fixation

##### Intervention groups

AVT for the treatment group and patching for control group. for Treatment group active vision exercises and patching, for control group, patching and placebo training

##### Main outcome variables

Improvement of visual acuity, stereacuity, contrast sensitivity and facility of accommodation.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230823059229N1**

Registration date: **2024-02-28, 1402/12/09**

Registration timing: **prospective**

Last update: **2024-02-28, 1402/12/09**

Update count: **0**

##### Registration date

2024-02-28, 1402/12/09

##### Registrant information

##### Name

Saeedeh Hosseinmenni

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7756 1721

##### Email address

s.hoseiny2021@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2025-03-05, 1403/12/15

##### Expected recruitment end date

2025-11-21, 1404/08/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Investigation the Effect of Active Vision Therapy on visual skills using Vision Therapy System 4 (VTS4) in children with Bilateral Refractive Amblyopia ages 5-13

## Public title

Investigation the Effect of Active Vision Therapy Using Vision Therapy System 4 (VTS4) in Bilateral Refractive Amblyopia

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Full patient consent to participate in the study The minimum age is 5 and the maximum is 13 years Bilateral refractive amblyopes Astigmatism more than 1.5 diopters and hyperopia more than 3.00 diopters in each eye or a mix hyperopia-stigmatism Maximum vision 20/40 and minimum vision 20/100 in each eye (moderate amblyopia)

### Exclusion criteria:

Children who do not cooperate to perform the tests Children who experience diplopia or nausea while using liquid crystal glasses The presence of uncompensated phoria Children who do not have the necessary follow-up for treatment. The existence of pathological and structural problems of the eye History of eye surgeries The presence of nystagmus strabismus, microtropia or eccentric fixation

## Age

From **5 years** old to **13 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant
- Care provider

## Sample size

Target sample size: **40**

## Randomization (investigator's opinion)

Randomized

## Randomization description

patient divide in two control and active treatment groups. Block Randomization is used for this. Blocks of couple of four are created in which, randomly, half of the people in each group are placed in one block and the others in the other group. Using blocks of couple of four, we will place 40 people in two control and treatment groups. First, we determine all the four states in which group. We consider the treatment group as A and the control group as B. 1-AABB 2-ABBA 3-ABAB 4-BBAA 5-BABA 6-BAAB Then, we will randomly select 8 blocks of four and write their combination one after the other, in fact, we will sample 8 times from this 6-member society, that is, a random number between 1 and 6 will be selected 8 times. In this way, the type of treatment will be determined for 40 patients.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

It will be made in a double-blind manner. In order for the researcher not to know whether the examinee is in the active or inactive vision therapy group, vision therapy will be performed by one person and the main researcher will perform other examinations. In order to blind the participants, we will also consider sessions to perform placebo vision therapy exercises in the office for the patching group.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shahid Beheshti university of medical sciences

##### Street address

floor. 13, flat A, he central headquarters of the Ministry of Health, Simayr Iran street, Shahrak Ghods, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1467664961

#### Approval date

2023-11-26, 1402/09/05

#### Ethics committee reference number

IR.SBMU.RETECH.REC.1402.513

## Health conditions studied

### 1

#### Description of health condition studied

amblyopia, lazy eye

#### ICD-10 code

H53.023

#### ICD-10 code description

Refractive amblyopia, bilateral,

## Primary outcomes

### 1

#### Description

visual acuity

#### Timepoint

before and after

#### Method of measurement

snellen vision chart LCD chart vision (model,

HDC-9000N/PF, made in South Korea) Howitz company

## 2

### **Description**

stereoacuity

### **Timepoint**

before and after

### **Method of measurement**

Randot & Vectogram Registered trade marks of Stereo Optical Co., Inc and Stereo Fly Stereotest of Stereo Optical Company Inc

## 3

### **Description**

contrast sensitivity

### **Timepoint**

before and after

### **Method of measurement**

Freiburg contrast sensitivity test, made in Germany, designed by Michael Bach, 2011 version

## 4

### **Description**

Infacility of Accommodation

### **Timepoint**

Before and after

### **Method of measurement**

flipper lens and snellen near chart

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

"Intervention group:" Patching and Vision therapy exercises in three sessions of 30 minutes a week with the Vision Therapy System version 4 (an American software (HTS Inc., Gold Canyon, AZ, USA)), consisting of a 50-inch monitor, a case, a gamepad and a pair of liquid crystal glasses and patching eye

#### **Category**

Rehabilitation

### 2

#### **Description**

"Control group:" 1-2 hours patching each eye every day and placebo training

#### **Category**

Rehabilitation

## **Recruitment centers**

### 1

#### **Recruitment center**

#### **Name of recruitment center**

Poostchi clinic

#### **Full name of responsible person**

Dr Mohammadreza Talennejad

#### **Street address**

Karimkhan Zand Blvd., Shiraz

#### **City**

Shiraz

#### **Province**

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#### **Email**

poostchi@sums.ac.ir

#### **Web page address**

<https://poostchi.sums.ac.ir/>

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Shahid Beheshti University of Medical Sciences

##### **Full name of responsible person**

Dr Saeed Rahmani

##### **Street address**

In front of Bo Ali Hospital, Damavand Street, Imam Hossein Square, Tehran

##### **City**

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##### **Province**

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##### **Postal code**

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##### **Phone**

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rehab.sbm@gmail.com

##### **Web page address**

<https://rehab.sbm.ac.ir/>

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

No

#### **Title of funding source**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Saeedeh Hosseinmenni

**Position**

PhD candidate

**Latest degree**

Master

**Other areas of specialty/work**

Optometry

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## Person responsible for scientific inquiries

### Contact

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**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Optometry

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Saeedeh Hosseinmenni

**Position**

PhD Candidate

**Latest degree**

Master

**Other areas of specialty/work**

Optometry

**Street address**

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**Web page address**

<https://rehab.sbmu.ac.ir/>

## 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**

Yes - There is 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**

Information about the primary outcome measure can be shared.

**When the data will become available and for how long**

starting 6 months after publication

**To whom data/document is available**

available for people working in academic institutions and people working in businesses can apply to receive it.

**Under which criteria data/document could be used**

without limitation

**From where data/document is obtainable**

Saeedeh Hosseinmenni, researcher of the study:

s.hoseiny2021@gmail .com

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

Two months after application

**Comments**