

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jun 2026

### Evaluation of the effectiveness of the enhanced Brain Port device on visual field observation, detection of black and white color contrast and sharpness of the visually impaired and blind

#### Protocol summary

##### Study aim

Evaluation of the effectiveness of the enhanced Brain Port device on visual field observation, detection of black and white color contrast and sharpness of the visually impaired and blind

##### Design

Clinical trial with control group, with parallel groups, not blinded, on 30 patients

##### Settings and conduct

Patients who will come for eye examination will be referred to Heshmatieh Sabzevar Hospital, and then a list of visually impaired people who were between 20 and 50 years of age and who referred to Sabzevar Hospital in 2022 will be prepared. The criteria for diagnosing low vision will be an ophthalmologist. Their numbers will be contacted

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Failure to receive psychological treatment Patient consent to participate in the study - Lack of vision in a person is congenital Exclusion criteria: Oral lesions or cleft palate Structural and neurological disorders of the tongue -smoking -MR (mental retardation) The dissatisfaction of the person continuing the research

##### Intervention groups

There will be two groups (15 controls) and (15 experiments). Patients were introduced to the features of the BrainPort vision device, including turning the device on and off, field of view / zoom features, light intensity control, and inversion controls. We also showed maintenance issues such as how to replace the battery, how to take care of the device and troubleshooting solutions. The limitations of this technology were discussed, such as lack of color, lack of 3D depth perception, and that the stimulus is primarily a tactile perception. At the end of the sessions, due to ethical issues, 5 sessions of treatment will be performed on the

control group. The next session of the informed consent form and pre-test will be performed.

##### Main outcome variables

Field of vision, black and white color contrast detection

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20101130005280N56**

Registration date: **2022-07-09, 1401/04/18**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-07-09, 1401/04/18**

Update count: **0**

##### Registration date

2022-07-09, 1401/04/18

##### Registrant information

##### Name

Raheleh Nejati

##### Name of organization / entity

Mashhad University of Medical Sciences, Ibn-e- Sina Psychiatric Hospital

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3711 2540

##### Email address

nejatir2@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-06-22, 1401/04/01

##### Expected recruitment end date

2022-08-23, 1401/06/01  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty  
**Scientific title**  
Evaluation of the effectiveness of the enhanced Brain Pert device on visual field observation, detection of black and white color contrast and sharpness of the visually impaired and blind  
**Public title**  
Evaluation of the effectiveness of amplified Brain Pert device on visual field observation  
**Purpose**  
Treatment  
**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Low vision on both sides and one side Having congenital low vision Disorders of the eyes or nerves of the visual pathway Failure to receive psychological treatment before entering the study Patient consent to participate in the research and to sign a written consent Low vision is not congenital  
**Exclusion criteria:**  
Low vision is not congenital Oral lesions or cleft palate Structural and neurological disorders of the tongue smoking MR (mental retardation) Individual dissatisfaction with continuing research  
**Age**  
From **20 years** old to **50 years** old  
**Gender**  
Both  
**Phase**  
N/A  
**Groups that have been masked**  
*No information*  
**Sample size**  
Target sample size: **30**  
**Randomization (investigator's opinion)**  
Not randomized  
**Randomization description**  
**Blinding (investigator's opinion)**  
Not blinded  
**Blinding description**  
**Placebo**  
Not used  
**Assignment**  
Parallel  
**Other design features**

## Secondary Ids

empty

## Ethics committees

1

### Ethics committee

#### Name of ethics committee

Sabzevar University of Medical Sciences

#### Street address

Shohaday-e- Hastei Blvd.

#### City

Sabzevar

#### Province

Razavi Khorasan

#### Postal code

9617913112

#### Approval date

2022-03-15, 1400/12/24

#### Ethics committee reference number

IR.MEDSAB.REC.1400.190

## Health conditions studied

1

### Description of health condition studied

Low vision

#### ICD-10 code

H54.50

#### ICD-10 code description

Low vision, one eye, unspecified eye

## Primary outcomes

1

### Description

Field of vision

#### Timepoint

Baseline- end of treatment

#### Method of measurement

score of the FrACT questionnaire.

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: First, a briefing session will be held for them and the purpose of the research and how to work with the device will be explained to him. Patients were introduced to the features of the BrainPort vision device, including turning the device on and off, field of view / zoom features, light intensity control, and inversion controls. We also showed maintenance issues such as how to replace the battery, how to take care of the device and troubleshooting solutions. The limitations of this technology were discussed, such as lack of color, lack of 3D depth perception, and that the stimulus is primarily a tactile perception.

#### Category

Treatment - Other

**2**

**Description**

Control group: At the end of the sessions, due to ethical issues, 5 sessions of treatment will be performed on the control group.

**Category**

Treatment - Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Sabzevar Heshmatieh Hospital

**Full name of responsible person**

Ebrahim Shirzad

**Street address**

Sabzevar Heshmatieh Hospital

**City**

Sabzevar

**Province**

Razavi Khorasan

**Postal code**

9192264462

**Phone**

+98 903 926 4520

**Email**

raikaravan@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Sabzevar University of Medical Sciences

**Full name of responsible person**

Alireza Moslem

**Street address**

Address: Sabzevar - Sabzevar University of Medical Sciences - Vice Chancellor for Research and Technology

**City**

Sabzevar

**Province**

Razavi Khorasan

**Postal code**

91961264714

**Phone**

+98 51 4401 1004

**Email**

raikaravan@gmail.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Sabzevar 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**

Sabzevar University of Medical Sciences

**Full name of responsible person**

Ebrahim Shirzad

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Psychology

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**Person responsible for scientific inquiries**

**Contact**

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**Email**

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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