Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

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

Protocol summary

Study aim

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

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 Scinces, 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- Hasteei 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
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9192264462
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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
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91961264714
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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
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Psychology
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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