

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### The effect of physical exercise on controlling balance among the visually impaired elderly using auditory vibratory alarming feedback device.

#### Protocol summary

##### Study aim

The aim of the current research is to study the effect of physical exercise on controlling balance among the visually impaired elderly using auditory vibratory alarming feedback device

##### Design

This is an experimental and randomized trial that includes aged 65 to 74 years old volunteering volunteers who were living in Mahabad. According to the information on physical and motor health records, 30 were selected, which consisted of two groups of 15 visually impaired people.

##### Settings and conduct

The Center for Educational Rehabilitation was used in Mahabad, where special mattresses used in taekwondo sport were embedded. The instrument was to detect the interaction of the subjects using a Stabilometer balance device. Subjects were then divided into two groups of 15, who performed balance exercises in 12 sessions.

##### Participants/Inclusion and exclusion criteria

visually impaired elderly with healthy from the nerve and skeletal aspect.

##### Intervention groups

A group performed only physical exercises that caused various sensation to be balanced and the other group performed the physical exercises with the use of the biofeedback device.

##### Main outcome variables

The balance

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190107042265N1**

Registration date: **2019-07-07, 1398/04/16**

Registration timing: **retrospective**

Last update: **2019-07-07, 1398/04/16**

Update count: **0**

##### Registration date

2019-07-07, 1398/04/16

##### Registrant information

###### Name

Hadi Gevorki

###### Name of organization / entity

The University of Shahid Beheshti Tehran

###### Country

Iran (Islamic Republic of)

###### Phone

+98 44 4222 7439

###### Email address

hadigevorki@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-04-21, 1397/02/01

##### Expected recruitment end date

2018-04-30, 1397/02/10

##### Actual recruitment start date

2018-04-30, 1397/02/10

##### Actual recruitment end date

2018-04-30, 1397/02/10

##### Trial completion date

2018-07-01, 1397/04/10

##### Scientific title

The effect of physical exercise on controlling balance among the visually impaired elderly using auditory vibratory alarming feedback device.

##### Public title

using auditory-vibratory alarming feedback device on balance

##### Purpose

Prevention

## **Inclusion/Exclusion criteria**

### **Inclusion criteria:**

the visually impaired elderly

### **Exclusion criteria:**

developing neurological disease having a history of a skeletal disease

## **Age**

From **65 years** old to **74 years** old

## **Gender**

Male

## **Phase**

N/A

## **Groups that have been masked**

*No information*

## **Sample size**

Target sample size: **30**

Actual sample size reached: **30**

## **Randomization (investigator's opinion)**

Randomized

## **Randomization description**

In this study, a randomized random method was used, so that individuals are divided into two groups of physical exercise and physical training group along with the use of biofeedback device.

## **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**

Ethics committee of Shahid Beheshti University of Tehran

##### **Street address**

Shahid Beheshti University of Tehran

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1983969411

#### **Approval date**

2018-12-01, 1397/09/10

#### **Ethics committee reference number**

IR.SBU.ICBS.97/1035

## **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**

Change the score slightly balance

#### **Timepoint**

after 6 weeks of training.

#### **Method of measurement**

balance measurement device Stabilometer

## **Secondary outcomes**

### 1

#### **Description**

Change the score slightly balance

#### **Timepoint**

Before the intervention and 45 days after the start of the training.

#### **Method of measurement**

balance test stabilometer device

## **Intervention groups**

### 1

#### **Description**

Intervention group 1: only did the physical training provided by examiner to change the balance score.

#### **Category**

Rehabilitation

### 2

#### **Description**

Intervention group: They performed the physical exercise provided by the examiner, and received an equilibrium warning from the feedback device attached to the subjects waist, including vibration and sound through the headphones.

#### **Category**

Rehabilitation

## **Recruitment centers**

### 1

#### **Recruitment center**

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

Mahabad elderly center

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

Hadi Gevorki

**Street address**

No.34, Esteghlal Square, 24 meters street to the hospital.

**City**

Mahabad

**Province**

West Azarbaijan

**Postal code**

5916957854

**Phone**

+98 44 4222 7439

**Email**

hadigevorki@yahoo.com

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

The university of shahid Beheshty

**Full name of responsible person**

Morteza Rezaei Zadeh

**Street address**

Shahid Chamran highway, Yemen street, Shahid Shahriari Square.

**City**

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**Postal code**

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**Phone**

+98 21 2990 5305

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+98 21 2243 1919

**Email**

mortaza\_rezaee@yahoo.com

**Grant name**

Morteza Rezaei Zadeh

**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

The university of shahid Beheshty

**Proportion provided by this source**

100

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

Persons

**Person responsible for general inquiries****Contact****Name of organization / entity**

The University of Shahid Beheshty

**Full name of responsible person**

Hadi Gevorki

**Position**

student

**Latest degree**

Ph.D.

**Other areas of specialty/work**

motor behavior

**Street address**

No.34, Esteghlal Alley , street 24 letters to hospital.

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

The University of Shahid Beheshti Tehran

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student

**Latest degree**

Ph.D.

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Motor Behavior

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Street 24 Meters to Hospital

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**Person responsible for updating data****Contact****Name of organization / entity**

The University of Shahid Beheshti

**Full name of responsible person**

Hadi Gevorki

**Position**

PhD student

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Motor Behavioral (Motor control)

**Street address**

The University of Shahid Beheshti

**City**

Tehran

**Province**

Tehran

**Postal code**

5916957854

**Phone**

+98 44 4222 7439

**Email**

hadigevorki@yahoo.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

In the form of an ethical commitment, both participants are assured that their data will be serialized.

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available