

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effects of virtual reality intervention with and without transcranial direct current stimulation on motor and cognitive performances in sedentary adolescent girls

#### Protocol summary

##### Study aim

The effects of 4 weeks of virtual reality training with and without transcranial direct current stimulation on motor performance (motor coordination, balance) and cognitive (reaction time, working memory, cognitive flexibility) of sedentary adolescent girls.

##### Design

A single-blind clinical trial with a control group and parallel groups, and randomized in a block method on 36 sedentary adolescent girls. The website [www.randomization.com](http://www.randomization.com) will be used for randomization.

##### Settings and conduct

This research will be carried out in Razi University. First, the research variables will be measured, Then, 3 groups participating in the research will receive the desired interventions. After completing the interventions, the research variables will be measured again. In this research, the participants and the main research team will be blinded.

##### Participants/Inclusion and exclusion criteria

Being right-handed; having physical health; lack of physical activity; having normal vision or corrected vision; having an age range of 15 to 18 years old; no history of head injury, previous seizures; lack of brain implants, heart battery; no drug addiction; not suffering from severe diabetes, asthma; not simultaneously participating in another study

##### Intervention groups

1- Virtual reality group + real transcranial direct current stimulation  
2- Virtual reality group + sham direct current stimulation  
3- The control group did not participate in virtual reality exercises and did not receive direct brain current stimulation

##### Main outcome variables

Change in hand-eye coordination; bimanual coordination; static balance; dynamic balance; simple reaction time; selective reaction time; working memory; cognitive

flexibility

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221124056598N1**

Registration date: **2022-12-10, 1401/09/19**

Registration timing: **prospective**

Last update: **2022-12-10, 1401/09/19**

Update count: **0**

##### Registration date

2022-12-10, 1401/09/19

##### Registrant information

##### Name

Nasrin Shahbazi

##### Name of organization / entity

Razi University of Kermanshah

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 4238 2214

##### Email address

n\_shahbazi\_69@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-12-21, 1401/09/30

##### Expected recruitment end date

2022-12-31, 1401/10/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
The effects of virtual reality intervention with and without transcranial direct current stimulation on motor and cognitive performances in sedentary adolescent girls

**Public title**  
Effect of virtual reality with and without transcranial direct current stimulation in adolescent girls

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Sedentary girls based on physical activity questionnaire  
Compliance with the age range of 15 to 18 years  
Right-handedness of subjects  
Having normal or corrected vision  
**Exclusion criteria:**  
Having a history of neurological disease  
Having cardiovascular disease  
Having any kind of metal implant in the brain  
History of balance disorder and frequent positional vertigo and fear of electrical stimulation of the brain  
Any physical weakness or injury  
Inability to complete test and practice sessions  
Any dissatisfaction with doing assignments during the exam  
Concurrent participation in another study

**Age**  
From **15 years** old to **18 years** old

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**  

- Participant

**Sample size**  
Target sample size: **36**

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

**Randomization description**  
In this study, permuted block randomization via the [www.randomization.com](http://www.randomization.com) website will be used. To do so, first, a unique number will be allocated to each subject as the identifier code and, a 36-digit sequence (equal to sample size) will be created. Then, treatment labels including: 1 (virtual reality group + real trans cranial direct current stimulation, 2 (virtual reality group + sham trans cranial direct current stimulation); 3 (The control group: will be defined in the relevant section on the website). After defining the treatment groups and to avoid potential problems associated with equal block sizes, permuted block randomization with different block sizes will be applied. In this case, by knowing the sample size, the block sizes will be unequal and a multiple of the number of treatment groups (for example, block sizes of 2, 4, 6, or 8). The website has the ability to randomly specify the sequence of blocks with different sizes. In the final step and upon performing the 'Generate Plan' on the website, all subjects will be randomly assigned to

blocks of different sizes that already have a random sequence. Finally, by using the number (code) assigned to each subject and checking the blocks, the group of each subject will be determined.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
The present study is a single-blind study, in which participants are blinded about receiving real or sham stimulation while, based on the nature of virtual reality, there will be no blinding for virtual reality interventions. In order to blind the two groups receiving brain stimulation, they do not know the settings of the device whether it is real or sham. Both groups will receive stimulation (sham or real) for 20 minutes.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**  
**1**  
**Ethics committee**  
**Name of ethics committee**  
Research Ethics Committees of Kermanshah Razi University  
**Street address**  
Ddeputy of research, Razi University, University St., Taq-e-bostan, Kermanshah, Iran  
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Kermanshah  
**Province**  
Kermanshah  
**Postal code**  
6714414874  
**Approval date**  
2022-08-03, 1401/05/12  
**Ethics committee reference number**  
IR.RAZI.REC.1401.058

**Health conditions studied**  
**1**  
**Description of health condition studied**  
Sedentary adolescent girls  
**ICD-10 code**  
**ICD-10 code description**

**Primary outcomes**  
**1**  
**Description**  
Change in hand-eye coordination

## **Timepoint**

before the starting the intervention, 2 weeks after the starting the intervention, 4 weeks after the starting the intervention, 2 weeks after the end of the intervention

## **Method of measurement**

Lafayette Instrument Automatic Mirror Trace

## **2**

### **Description**

Bimanual coordination

### **Timepoint**

Before the starting the intervention, 2 weeks after the starting the intervention, 4 weeks after the starting the intervention, 2 weeks after the end of the intervention

### **Method of measurement**

Lafayette Instrument Two-Arm Coordination Test

## **3**

### **Description**

Static balance

### **Timepoint**

Before the starting the intervention, 2 weeks after the starting the intervention, 4 weeks after the starting the intervention, 2 weeks after the end of the intervention

### **Method of measurement**

Stork Balance Stand Test

## **4**

### **Description**

Dynamic balance

### **Timepoint**

Before the starting the intervention, 2 weeks after the starting the intervention, 4 weeks after the starting the intervention, 2 weeks after the end of the intervention

### **Method of measurement**

Y Balance Test

## **5**

### **Description**

Reaction time

### **Timepoint**

Before the starting the intervention, 2 weeks after the starting the intervention, 4 weeks after the starting the intervention, 2 weeks after the end of the intervention

### **Method of measurement**

Reaction time software

## **6**

### **Description**

Working memory

### **Timepoint**

Before the starting the intervention, 2 weeks after the starting the intervention, 4 weeks after the starting the intervention, 2 weeks after the end of the intervention

### **Method of measurement**

Nback software

## **7**

### **Description**

Cognitive flexibility

### **Timepoint**

before the starting the intervention, 2 weeks after the starting the intervention, 4 weeks after the starting the intervention, 2 weeks after the end of the intervention

### **Method of measurement**

Cognitive flexibility questionnaire

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Intervention group: Virtual reality training combined with real transcranial direct current stimulation for 4 weeks. The exercises will be 3 sessions per week, 20 minutes of real direct current stimulation and one hour of virtual reality exercises.

#### **Category**

Other

### **2**

#### **Description**

Intervention group: Virtual reality exercises combined with sham transcranial direct current stimulation for 4 weeks. The exercises will be 3 sessions a week, 20 minutes of direct current sham stimulation and one hour of virtual reality exercises.

#### **Category**

Other

### **3**

#### **Description**

Control group: This group had a normal life routine for 4 weeks and did not participate in any sports activities during this time.

#### **Category**

Other

## **Recruitment centers**

### **1**

#### **Recruitment center**

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

education of Kermanshah

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

Salman Mohammadi

##### **Street address**

The beginning of Farhangian Boulevard, phase one, Shahid Mostafa Emami Street,

##### **City**

Kermanshah

##### **Province**

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6714733587  
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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Razi University  
**Full name of responsible person**  
Dr. Mustafa Mostafaei  
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University St, Taq-e-Bostan  
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Kermanshah  
**Postal code**  
6714414971  
**Phone**  
+98 83 3427 4515  
**Email**  
bouck58@yahoo.com  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Razi 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**  
Razi University  
**Full name of responsible person**  
Nasrin Shahbazi  
**Position**  
PhD student  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Others  
**Street address**

Faculty of Sport Sciences, Razi University, Taq-e-Bostan, University St., Kermanshah, Iran

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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

#### Contact

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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**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be 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**

Not applicable

**Title and more details about the data/document**

All data are shared after the de-identification of the participants

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

3 months after publication

**To whom data/document is available**

All individuals upon formal request

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

Data sharing requests are accepted for any purposes

**From where data/document is obtainable**

To obtain any data/document, please send an e-mail to nasrin shahbazi , a PhD student at Razi University, through the following e-mail address:  
n\_shahbazi\_69@yahoo.com

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

Upon formal request, mentioning due reasons, and providing full personality details, data will be sent after 72 h via e-mail.

**Comments**