

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 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 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
City
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

Kermanshah
Postal code
6714733587
Phone
+98 83 3823 5149
Email
ravakermanshah@medu.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Razi University
Full name of responsible person
Dr. Mustafa Mostafaei
Street address
University St, Taq-e-Bostan
City
Kermanshah
Province
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

City
Kermanshah
Province
Kermanshah
Postal code
6714414971
Phone
+98 83 3845 8428
Email
n_shahbazi_69@yahoo.com

Person responsible for scientific 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
City
Kermanshah
Province
Kermanshah
Postal code
6714414971
Phone
+98 83 3845 8428
Email
n_shahbazi_69@yahoo.com

Person responsible for updating data

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
City
Kermanshah
Province
Kermanshah
Postal code

6714414971

Phone

+98 83 3845 8428

Email

n_shahbazi_69@yahoo.com

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