Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Sep 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)
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+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,
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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
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6714414971
Phone
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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
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Nasrin Shahbazi
Position
PhD student
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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