

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Investigating the Impact of 8 Weeks of Virtual Reality Training on Motor Proficiency and Executive Function in Children with Developmental Coordination Disorder

#### Protocol summary

##### Study aim

The general objective of this study is to investigate the effect of 8 weeks of virtual reality training on motor competence and executive function in children with developmental coordination disorder.

##### Design

The study has a control group, an intervention group, is triple-blinded, targeted based on a score lower than 16 on the MABC test, randomized using a lottery program, and is single-phase on 30 patients.

##### Settings and conduct

The exercises in this study will be conducted in the sports hall of schools in Hamadan and will be free of any distracting visual and auditory stimuli. The children's exercise coach will be blind to the existence and level of visual impairment in the children, and in each training session, they will exercise with the children for 45 minutes, including specific warm-up and cool-down exercises.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. DCD diagnosis based on (DSM-5) 2. Age 7 to 9 years Exclusion criteria: 1. Children who did not wish to continue participating in the research process. 2. Children who were required to use a specific medication.

##### Intervention groups

Virtual Reality Group: Received specific exercises using virtual reality headsets for two months. Control Group: Received normal school instruction during this time.

##### Main outcome variables

Motor competence, inhibition, working memory, attention, hot executive function

#### General information

##### Reason for update

##### Acronym

DCD

##### IRCT registration information

IRCT registration number: **IRCT20250122064475N1**

Registration date: **2025-07-26, 1404/05/04**

Registration timing: **retrospective**

Last update: **2025-07-26, 1404/05/04**

Update count: **0**

##### Registration date

2025-07-26, 1404/05/04

##### Registrant information

###### Name

Maryam Khoshniat

###### Name of organization / entity

The University of Abu Ali Sina

###### Country

Iran (Islamic Republic of)

###### Phone

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###### Email address

khoshniat.basu.ac.ir@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2025-04-05, 1404/01/16

##### Expected recruitment end date

2025-05-22, 1404/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the Impact of 8 Weeks of Virtual Reality Training on Motor Proficiency and Executive Function in Children with Developmental Coordination Disorder

#### Public title

Examining the effect of virtual reality training on children with developmental coordination disorder

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Achieving a standard score on the DCD-Q (15 to 46 for 7-year-olds and 15 to 55 for 8 to 9-year-olds) Age 7 to 9 years Diagnosis of DCD based on (DSM-V) using the Movement Assessment Battery for Children-2 (MABC-2): a score less than or equal to the 16th percentile, (DSM-5, Criterion A); motor deficits severely and persistently interfere with a person's daily activities (Criterion B, DSM-5); parents of children confirm the onset of motor problems from early developmental periods (Criterion C). Children should not have any pathological damage. They should have the ability to understand and collaborate with the researcher. Be able to attend the intervention program regularly throughout the study period. Be able to walk independently without assistance. Have no prior experience participating in a virtual reality based program. Have normal or corrected-to-normal vision. Do not use psychiatric medication. All participants and their supervisors must provide written consent. They are right-handed.

##### Exclusion criteria:

Children who are absent for more than 3 training sessions during the study. Children who are forced to use a specific medication. Children who do not wish to continue participating in the research process.

#### Age

From **7 years** old to **9 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

- Outcome assessor
- Data analyser

#### Sample size

Target sample size: **30**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

After identifying 30 eligible participants, they were randomly divided into two groups, intervention and control (15 people in each group), using a simple random method through a draw. The names of the participants were written on identical cards and placed in an opaque container. To conceal the grouping, a person outside the research team drew the cards by lot. As soon as each card was drawn, the participant was assigned to one of the two groups, intervention or control; the first card drawn was placed in the intervention group, the second card in the control group, and this process continued until the last card. The results were immediately placed

in sealed envelopes. The unit of allocation was the individual. Given the limited sample size and the homogeneity of the study population (in terms of age and severity of disorder), stratification was not used. The grouping sequence was also generated by a person outside the research team and recorded and kept in a separate document. The screening team remained unaware of the groups until the end of the grouping process.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

Blinding in this study was applied at the level of outcome assessment and data analysis. Due to the nature of the intervention, blinding of participants is not possible, as the virtual reality-based exercises and their implementation differ between the two groups, which participants will notice. However, to prevent bias in data collection and evaluation, outcome assessors will be unaware of group allocation to ensure data is collected independently and without conscious influence.

Furthermore, data analysts will be unaware of group allocation until the final processing is complete to avoid bias in the review of results. If necessary, allocation concealment methods, such as randomization lists and the use of data processing systems, will be used to maintain impartiality in the analysis. This level of control in allocation and data processing increases the validity of the results and prevents side effects caused by bias.

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

This study will be conducted by designing exercises for 12 sports, from simple to complex, with specialized warm-ups and 3 sessions of 45 minutes per week.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee in Biomedical Research

##### Street address

Boulevard Ahmadinejad

##### City

Hamadan

##### Province

Hamadan

##### Postal code

6517683819

#### Approval date

2025-03-03, 1403/12/13

#### Ethics committee reference number

IR.BASU.REC.1403.042

## Health conditions studied

### 1

#### Description of health condition studied

Developmental Coordination Disorder

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Motor Proficiency

#### Timepoint

7 days before the study

#### Method of measurement

Movement Assessment Battery for Children- Second Edition

## Secondary outcomes

### 1

#### Description

Motor Competence

#### Timepoint

Before the intervention and 24 sessions after the start of the intervention

#### Method of measurement

MABC-2 Test

### 2

#### Description

executive functions

#### Timepoint

Before the intervention and 24 sessions after the start of the intervention

#### Method of measurement

Stroop, go/no-go, n-back, hungry donkey tests

### 3

#### Description

Impact of virtual reality training

#### Timepoint

24 sessions after the start of the intervention

#### Method of measurement

The extent of progress in cognitive and motor functions

## Intervention groups

### 1

#### Description

Warm-up for 10 minutes, exercise for 30 minutes, cool-down for 5 minutes. Week 1, Session 1, Warm-up: running, shoulder rotations, stretching the arm, forearm, triceps muscles, wrist rotations, rope skipping, boxing shadow boxing. Exercises: darts, boxing. Cool-down:

overhead stretch, down, left and right. Session 2, Warm-up: running, shoulder rotations, stretching the arm, forearm, triceps muscles, wrist rotations, rope skipping, boxing shadow boxing. Exercises: darts, boxing. Cool-down: hip flexion, triceps stretch, shoulder stretch. Session 3, Warm-up: running, shoulder rotations, stretching the arm, forearm, triceps muscles, wrist rotations, rope skipping, boxing shadow boxing. Exercises: darts, boxing. Cool-down: bending forward as much as possible, neck stretch. Week 2, Session 1: running, lateral lunge with inner thigh stretch, arm rotations, knee-to-chest jumps, ankle circles, stationary dribbling, stretching back and waist muscles, ball release exercise, stretching shoulders and triceps, wrists and forearms - basketball, bowling - overhead stretch, down, left and right. Session 2: running, lateral lunge with inner thigh stretch, arm rotations, knee-to-chest jumps, ankle circles, stationary dribbling, stretching back and waist muscles, ball release exercise, stretching shoulders and triceps, wrists and forearms - basketball, bowling - hip flexion, triceps stretch, shoulder stretch. Session 3: running, lateral lunge with inner thigh stretch, arm rotations, knee-to-chest jumps, ankle circles, stationary dribbling, stretching back and waist muscles, ball release exercise, stretching shoulders and triceps, wrists and forearms - basketball, bowling - bending forward as much as possible, neck stretch. Week 3: Session 1: rope skipping, boxing shadow boxing, paw boxing, short runs with change of direction, trunk rotation with racket, leg and hamstring stretches, service practice without ball, zigzag jumping - boxing, clay tennis - overhead stretch, down, left and right. Session 2: rope skipping, boxing shadow boxing, paw boxing, short runs with change of direction, trunk rotation with racket, leg and hamstring stretches, service practice without ball, zigzag jumping - boxing, clay tennis - hip flexion, triceps stretch, shoulder stretch. Session 3: rope skipping, boxing shadow boxing, paw boxing, short runs with change of direction, trunk rotation with racket, leg and hamstring stretches, service practice without ball, zigzag jumping - boxing, clay tennis - bending forward as much as possible, neck stretch. Week 4, Session 1: jogging in place, stretching back and shoulders, neck and shoulder rotations, deep breathing exercise, wrist and forearm stretches, fast lateral movement, wrist rotation with racket, ball dribbling with racket - archery, table tennis - overhead stretch, down, left and right. Session 2: jogging in place, stretching back and shoulders, neck and shoulder rotations, deep breathing exercise, wrist and forearm stretches, fast lateral movement, wrist rotation with racket, ball dribbling with racket - archery, table tennis - hip flexion, triceps stretch, shoulder stretch. Session 3: jogging in place, stretching back and shoulders, neck and shoulder rotations, deep breathing exercise, wrist and forearm stretches, fast lateral movement, wrist rotation with racket, ball dribbling with racket - archery, table tennis - bending forward as much as possible, neck stretch. Week 5 Session 1: Lateral movements with speed, dynamic lunges with change of direction, shoulder and arm rotation, wrist exercises with racket, vertical jumps, hitting the ball in the air Badminton, Golf Stretching overhead, down, left and right. Session 2: Lateral

movements with speed, dynamic lunges with change of direction, shoulder and arm rotation, wrist exercises with racket, vertical jumps, hitting the ball in the air - Badminton, Golf - Hip flexion, triceps stretch, shoulder stretch. Session 3 Lateral movements with speed, dynamic lunges with change of direction, shoulder and arm rotation, wrist exercises with racket, vertical jumps, hitting the ball in the air Badminton, Golf Bending forward as much as possible, stretching the neck and head. Week 6: Session 1: Running, multi-directional lunge movements, footwork training with agility ladder, torso rotation with racket, dynamic stretches for shoulder and wrist, vertical jumps, fast lateral movements, shoulder and arm rotations, stretching triceps and wrist Squash, Volleyball Stretching overhead, down, left and right. Session 2 Running, multi-directional lunge movements, footwork training with agility ladder, torso rotation with racket, dynamic stretches for shoulder and wrist, vertical jumps, fast lateral movements, shoulder and arm rotations, stretching triceps and wrist-Squash, Volleyball-Hip flexion, triceps stretch, shoulder stretch. Session 3: Running, multi-directional lunge movements, footwork training with agility ladder, torso rotation with racket, dynamic stretches for shoulder and wrist, vertical jumps, fast lateral movements, shoulder and arm rotations, stretching triceps and wrist Squash, Volleyball Bending forward as much as possible, stretching the neck and head Week 7. Session 1 Short runs with change of direction, torso rotation with racket, leg and hamstring stretches, serving practice without ball, zigzag jumping, stretching back and lumbar muscles, ball release practice, stretching shoulders and triceps, wrists and forearms - Clay court tennis, Bowling - Stretching overhead, down, left and right. Session 2: Short runs with change of direction, torso rotation with racket, leg and hamstring stretches, serving practice without ball, zigzag jumping, stretching back and lumbar muscles, ball release practice, stretching shoulders and triceps, wrists and forearms - Clay court tennis, Bowling - Hip flexion, triceps stretch, shoulder stretch Session 3: Short runs with change of direction, torso rotation with racket, leg and hamstring stretches, serving practice without ball, zigzag jumping, stretching back and lumbar muscles, ball release practice, stretching shoulders and triceps, wrists and forearms - Clay court tennis, Bowling - Bending forward as much as possible, stretching the neck and head. Week 8: Session 1: Running, multi-directional lunge movements, footwork training with agility ladder, torso rotation with racket, dynamic stretches for shoulder and wrist, vertical jumps, fast lateral movements, shoulder and arm rotations, stretching triceps and wrist - Volleyball, Squash - Stretching overhead, down, left and right. Session 2: Running, multi-directional lunge movements, footwork training with agility ladder, torso rotation with racket, dynamic stretches for shoulder and wrist, vertical jumps, fast lateral movements, shoulder and arm rotations, stretching triceps and wrist - Volleyball, Squash - Hip flexion, triceps stretch, shoulder stretch Session 3 Running, multi-directional lunge movements, footwork training with agility ladder, torso rotation with racket, dynamic stretches for shoulder and wrist, vertical jumps, fast lateral movements, shoulder

and arm rotations, stretching triceps and wrist - Volleyball, Squash - Bending forward as much as possible, stretching the neck and head.

**Category**

Behavior

**2**

**Description**

Control group: This group will continue their normal life routine throughout the study and will only participate in school programs that are the same for everyone.

**Category**

Behavior

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

General Directorate of Education of Hamadan Province

**Full name of responsible person**

Rasul Sheydayi

**Street address**

Taleghani Street, Farhang Street

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**Province**

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**Postal code**

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**Phone**

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**Email**

hamedan.medu.gov.ir@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

non

**Full name of responsible person**

non

**Street address**

non

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khoshniat.basu.ac.ir@gmail.com

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor**

**organization/entity?**

No

**Title of funding source**

non

**Proportion provided by this source**

1

**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**

Other

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

Bu-Ali Sina University

**Full name of responsible person**

Maryam Khoshniat

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Motor behavior

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

Bu-Ali Sina university

**Full name of responsible person**

Seyedeh Manizheh Arabi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Motor development

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**Other areas of specialty/work**

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**Web page address****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**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is 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**

Yes - There is a plan to make this available

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

The data will be shared after individuals are anonymized.

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

The course starts with 6 months access after the publication of the article.

**To whom data/document is available**

Researchers of academic institutions

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

In review studies

**From where data/document is obtainable**

People can contact Maryam Khoshniat at the email

address [khoshniat.basu.ac.ir@gmail.com](mailto:khoshniat.basu.ac.ir@gmail.com)

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

In a letter, provide a complete introduction of yourself

and your resume, stating your purpose and how you intend to use it, and email it to Ms. Khoshniyat. She will announce the result to you within a 6-month timeframe.

**Comments**