

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 2026

### The Effects of Dual-task and Single-task Exercises on Functional Balance in Children with Autism Spectrum Disorder

#### Protocol summary

##### Study aim

To study the effects of dual-task exercises and single-task exercises on functional balance in children with autism spectrum disorder

##### Design

This will be a single blind clinical trial which contains two groups of single-task and dual-task. The simple method (Non blocked) will be used as randomization method and the sealed envelope method will be used. By means of a specific formula, sample size was determined 20 persons for each group.

##### Settings and conduct

Interventions will take place in Iran Autism Association and autism schools in Tehran. They will last for 12 sessions, 3 days a week and maximum 45 minutes each session. Participants in single\_task group will perform only balance exercises and participants in dual-task group will do the same balance exercises concurrent with cognitive exercises. Cognitive tasks will be chosen in the beginning of each session according to the participant.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Children diagnosed with Autism spectrum disorder aged 9 to 14, Educable children (IQ above 50), Exclusion criteria: Being able to stand on one foot for 30 seconds, Having the history of seizure, epilepsy, neurological disorders, orthopedic disorders, Using drugs which affects balance.

##### Intervention groups

In this research participants will divide into single-task and dual-task groups. Participants in single-task group will only perform the balance exercises and the participants in dual-task group will perform balance exercises and cognitive exercises concurrently. The cognitive tasks for each session, will be chosen by the participant at the beginning of the session.

##### Main outcome variables

Berg balance scale and Mini-BESTEST will be done to study functional balance. Timed up and go test will be

done to study dynamic balance. Because Gait speed test were used to determine sample size, this test will be done in dual-task and single-task.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181014041341N1**

Registration date: **2019-02-09, 1397/11/20**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-02-09, 1397/11/20**

Update count: **0**

##### Registration date

2019-02-09, 1397/11/20

##### Registrant information

##### Name

Maryam Yaghoubi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7753 8798

##### Email address

m-yaghoubi@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-12-22, 1397/10/01

##### Expected recruitment end date

2019-04-20, 1398/01/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
The Effects of Dual-task and Single-task Exercises on Functional Balance in Children with Autism Spectrum Disorder

**Public title**  
The Effects of Dual-task and Single-task Exercises on Functional Balance in Children with Autism Spectrum Disorder

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Children with autism spectrum disorder 9 to 14 years old  
Educable children (IQ above 50)  
**Exclusion criteria:**  
Being able to stand on one leg for 30 seconds Having a history of seizure, epilepsy, neurological disease, orthopedic disease Using medicines that have side effects on balance

**Age**  
From **9 years** old to **14 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**  
Target sample size: **40**

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

**Randomization description**  
In this study, the simple method (non blocked) will be used as randomization method and the sealed envelope method will be used. The number will be selected in Excel randomly and will be written on papers and the papers will be inserted in the envelopes and the envelopes will be sealed. A person who is not take part in the trial will select the numbers. The even numbers indicate the sample will be in Single-task group and the odd numbers indicate the sample will be in Dual-task group.

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

**Blinding description**  
In this study the participants will be unaware of the group witch they have been allocated in.The final assessments will be done by an assessor who does not know about the group of the samples.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

##### Street address

Tehran University of Medical Sciences School of Rehabilitation, Pich-e-Shemiran, Enghelab St

##### City

Tehran

##### Province

Tehran

##### Postal code

۱۱۴۸۹۵۶۱۱۱

#### Approval date

2018-08-29, 1397/06/07

#### Ethics committee reference number

IR.TUMS.FNM.REC.1397.086

## Health conditions studied

### 1

#### Description of health condition studied

Autism Spectrum Disorders

#### ICD-10 code

F84.0

#### ICD-10 code description

Childhood Autism

### 2

#### Description of health condition studied

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Dynamic Balance

#### Timepoint

Before the onset of interventions, After 6th session of intervention, After the termination of interventions

#### Method of measurement

Gait Speed Test (Dual-task and Single-task)

## Secondary outcomes

### 1

#### Description

Functional Balance

#### Timepoint

Before the onset of interventions, After 6th session of interventions, After the termination of interventions

#### Method of measurement

Pediatric Berg Balance Scale; Mini-BESTEST; Timed Up and Go test

## Intervention groups

### 1

#### Description

Intervention group No1: Participants in this group will perform single-task exercises based on Silsupadol's protocol (2009). Balance exercises in this group is just like balance exercises in Dual-task group. The exercises will perform in 12 sessions, maximum 45 minutes, for 3 days a week for 4 weeks.

#### Category

Rehabilitation

### 2

#### Description

Intervention group No2: Participants in this group will perform dual-task exercises based on Silsupadol's protocol (2009). This group will perform balance exercises and cognitive exercises (counting/ reverse counting/ auditory memory/ mention fruits, animals, foods, seasons, months, week days/ objects application, Raven test) concurrently. The exercises will perform in 12 sessions, maximum 45 minutes, for 3 days a week for 4 weeks.

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Iran Autism Association

##### Full name of responsible person

Saede Ghafari

##### Street address

No 8. Lale Blvd. After Hemmat Bridge. South Sattari Autobahn

##### City

Tehran

##### Province

Tehran

##### Postal code

114896111

##### Phone

+98 21 4442 2525

##### Email

ERR@irautism.org

##### Web page address

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Parvin Pasalar

##### Street address

No 56, Corner of Italia Street, Vesal-e-shirazi Street, keshavarz Blvd

##### City

Tehran

##### Province

Tehran

##### Postal code

1417755331

##### Phone

+98 21 8898 9161

##### Email

ssrc@tums.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Tehran University of Medical Sciences

#### 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

Tehran University of Medical Sciences

##### Full name of responsible person

Maryam Yaghoubi

##### Position

Master of Science Student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Occupational Therapy

##### Street address

Pich-e-shemiran, Enghelab Street

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1148965111

##### Phone

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Parvin Raji

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Occupational Therapy

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Pich-e-Shemiran, Enghelab Street

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## Person responsible for updating data

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**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

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**Position**

Master of Science Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Occupational Therapy

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**Phone**

+98 21 7753 3939

**Email**

m.yaghoubi1994@gmail.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**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

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

Data related to main end will be published

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

Data will be accessible after the essay publication

**To whom data/document is available**

Investigators who work in university and academic institutions

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

Investigators who are occupational therapist and other fields which are related to children with autism spectrum disorder

**From where data/document is obtainable**

Maryam Yaghoubi m.yaghoubi1994@gmail.com m-yaghoubi@razi.tums.ac.ir Dr. Parvi Raji parvin.raji@gmail.com

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

Applicant can connect researchers by means of Email, after studying the data which are needed, they will be accessible in one week.

**Comments**