Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 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 witch contains two group 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 person for each group.

Settings and conduct

Interventions will take place in Iran Autism Association and autism schools in Tehran. They will last for 12 session, 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 choosen in the beginning of each session accidental by 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 in 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)

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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

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Phone

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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

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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

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Person responsible for scientific inquiries

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Associate Professor

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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
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 witch 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 witch are needed, they will be accessible in one week.

Comments