

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

The Effect of Physical Activity in Outdoor and Indoor Space on Motor, Perceptual and Social Development among Preschool Children

Protocol summary

The effect of two different learning environments on children's motor, perceptual and social development

Study aim

Investigating the effect of indoor and outdoor physical activity on motor, cognitive and social development of preschool children

Design

After selecting two groups of children from 4.5 to 6.5 years old based on the conditions of entry into the study, from the two spaces mentioned above, the two groups will be homogeneous according to the scores obtained from the dependent variables in order to select two homogeneous groups of 15 persons.

Settings and conduct

First, parents will receive a written consent to measure their motor, cognitive, and social development. At the beginning of the work, both groups will be taken as a pretest, tests related to the dependent variables of research. The first group of outdoor physical activities will conduct their activities in the natural outdoor school open space for 12 sessions of 4 hours in a month. Nature school activities include various activities such as sand play, equestrian games, water play, interaction with animals, coloring and painting in a natural. The second group will also carry out activities in indoor indoor daycare for 12 sessions of 4 hours in painting, teaching and children's games.

Participants/Inclusion and exclusion criteria

condition of entry: healthy children among 4.5-6.5 years old
condition of no-entry: having physical damaging, having behavioral and cognitive disorders.

Intervention groups

The statistical sample of this study will consist of preschool children aged 4.5-6.5 years old in Tabriz in two groups. The first group includes 15 registered students of the nature school of Tabriz University as an outdoor physical activity group and the second group includes 15 children, which will be called in a kindergarten and will be considered as a physical activity group in the indoor environment.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190207042649N1**

Registration date: **2019-04-29, 1398/02/09**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-29, 1398/02/09**

Update count: **0**

Registration date

2019-04-29, 1398/02/09

Registrant information

Name

Zahra Fathirezaie

Name of organization / entity

The university of Tabriz

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-16, 1397/12/25

Expected recruitment end date

2019-05-18, 1398/02/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The Effect of Physical Activity in Outdoor and Indoor Space on Motor, Perceptual and Social Development among Preschool Children

Public title
The Effect of Physical Activity in Outdoor and Indoor Space on Motor, Perceptual and Social Development among Preschool Children

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
healthy children among 4.5-6.5 years old
Exclusion criteria:
having physical damaging having behavioral and cognitive disorders

Age
From **54 months** old to **78 months** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

29 bahman Blvd, University of Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166616471

Approval date

2019-03-12, 1397/12/21

Ethics committee reference number

IR.TBZMED.REC.1397.1019

Health conditions studied

1

Description of health condition studied

There was not

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

"motor development"

Timepoint

pre test and post test (practical period in 30 days)

Method of measurement

" Bruininks-oseretsky Test of Motor Proficiency"

2

Description

"perceptual development"

Timepoint

pre test and post test (practical period in 30 days)

Method of measurement

"Visual-Motor Integration"

3

Description

"social development"

Timepoint

pre test and post test (practical period in 30 days)

Method of measurement

"vineland social maturity scale"

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: activity in outdoor space. Outdoor activities were that children played in a green garden for 12 session, each session was 4 hour for one month. The garden, which was called the Nature School, includes parts for children's play, including water games, playing soil, animal interactions, planting, balancing games, Carpentry, and so on.

Category

Lifestyle

2

Description

control group: activity in outdoor space. This group includes children registered in kindergarten. They also carried out 12 sessions of activities such as painting, manual work, etc. in an indoor environment.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

University of Tabriz

Full name of responsible person

Kosar Abbaspour

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29 Bahman Blvd, University of Tabriz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Tabriz

Full name of responsible person

Asghar Asgari

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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

University of Tabriz

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

University of Tabriz

Full name of responsible person

Kosar Abbaspour

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

University of Tabriz

Full name of responsible person

zahra Fathirezaie

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

motor behavior

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Person responsible for updating data

Contact

Name of organization / entity

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Assistant Professor

Latest degree

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Other areas of specialty/work

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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

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

All data is available after being unidentifiable

When the data will become available and for how long

6 month

To whom data/document is available

researchers and Enthusiasts

Under which criteria data/document could be used

demanding with email

From where data/document is obtainable

Kosar Abbaspour

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

demanding via email from Kosar Abbaspour

Comments