

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of Montessori exercises on social adjustment and movement skills of primary school students

Protocol summary

Study aim

Determining the effect of Montessori exercises on social adjustment and movement skills of primary school students aged 7 to 10 in Shahrood

Design

The sample size of this research will be selected based on G*POWER software in the amount of 40 people (20 people in the test group) and (20 people in the control group). One district will be randomly selected from among all educational districts of Shahrood city, then two elementary schools from the desired district will be randomly selected as test and control groups

Settings and conduct

This study is a classical and double-blind experimental intervention study, which will be conducted with the aim of determining the effect of Montessori exercises on social adjustment and motor skills of primary school students in Shahrood city in 1401. The research environment of this study will be all primary schools in Shahrood city and the targeted community will be all male and female students of primary schools in Shahrood city in 1401. In this study, blinding will be done for the participants, the researcher and the clinical supervisor

Participants/Inclusion and exclusion criteria

Entry requirements: Willingness to participate in the study Education in selected primary schools of Shahrood city The age range is at least 6 years and at most 12 years and 11 months; Conditions of non-entry: unwillingness to continue cooperation in the study

Intervention groups

In this study, the test group will be trained in the Montessori method for 12 weeks and 3 sessions of 45 minutes each week, while the control group will be trained in the normal way

Main outcome variables

social adjustment score in Dakhanchi's social adjustment questionnaire; Motor skills score in the Lincoln Ozertsky Motor Skills Questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221214056811N1**

Registration date: **2023-01-24, 1401/11/04**

Registration timing: **retrospective**

Last update: **2023-01-24, 1401/11/04**

Update count: **0**

Registration date

2023-01-24, 1401/11/04

Registrant information

Name

Mahdia Sadat Habibi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3237 3785

Email address

13711374mh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2022-12-21, 1401/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Montessori exercises on social adjustment and movement skills of primary school students

Public title

The effect of Montessori exercises on social adjustment and movement skills of primary school students aged 7 to 10 in Shahrood

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to participate in the study studying in selected primary schools of Shahrood city age range of at least 6 years and at most 12 years and 11 months

Exclusion criteria:

Unwillingness to continue cooperation in the study

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The sampling method in this research is a random cluster method that will be done in a multi-stage manner. First, one district will be randomly selected from all the educational districts of Shahrood city, then two schools in the primary school will be randomly selected as the test and control groups (one school of the test group and one school of the control group)

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 Islamic Azad University, Aliabad Katul branch

Street address

Next to Iran Insurance, between Shahid Madani 2 and 4, Shahid Madani St., Shahrood city

City

Shahrood

Province

Semnan

Postal code

۳۶۱۴۶۴۷۵۵۳

Approval date

2022-09-12, 1401/06/21

Ethics committee reference number

IR.IAU.AK.REC.1401.001

Health conditions studied

1

Description of health condition studied

Social adjustment

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Motor skills

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Social adjustment score in Dakhanchi's social adjustment questionnaire

Timepoint

Measuring social adjustment at the beginning of the study and 3 months after starting Montessori exercises

Method of measurement

Smoker's social adjustment questionnaire

Secondary outcomes

1

Description

Motor skills score in the Lincoln Ozertsy Motor Skills Questionnaire

Timepoint

Measurement of movement skills at the beginning of the study and 3 months after starting the Monte exercises

Method of measurement

Lincoln Ozertsy Motor Skills Questionnaire

Intervention groups

1

Description

"Intervention group:" 20 students in the intervention group receive selected Montessori exercises for three 45-minute sessions per week for twelve weeks. The first session: coloring and painting, the second session: putting together a puzzle and writing without dots, the

third session: cutting with scissors and gluing the pieces

Category

N/A

2

Description

"Control group:" 20 students of the control group will receive only regular school education during twelve weeks at the same time as the test group

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Sajjad Primary School (AS)

Full name of responsible person

Mahdia Sadat Habibi

Street address

Next to Iran Insurance, between Shahid Madani 2 and 4, Shahid Madani St., Shahrood city

City

Shahrood

Province

Semnan

Postal code

۳۶۱۴۶۴۷۵۵۳

Phone

+98 901 144 1963

Email

mahdiyehhabibi6@gmail.com

2

Recruitment center

Name of recruitment center

Imam Hadi Primary School(A.S.)

Full name of responsible person

Mahdia Sadat Habibi

Street address

Next to Iran Insurance, between Shahid Madani 2 and 4, Shahid Madani St., Shahrood city

City

Shahrood

Province

Semnan

Postal code

۳۶۱۴۶۴۷۵۵۳

Phone

+98 901 144 1963

Email

mahdiyehhabibi6@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Salman Amir Khan

Street address

Next to Iran Insurance, between Shahid Madani 2 and 4, Shahid Madani St., Shahrood city

City

Shahrood

Province

Semnan

Postal code

۳۶۱۴۶۴۷۵۵۳

Phone

+98 901 144 1963

Email

mahdiyehhabibi6@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mahdia Sadat Habibi

Position

Master's student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Next to Iran Insurance, between Shahid Madani 2 and 4, Shahid Madani St., Shahrood city

City

Shahrood

Province

Semnan

Postal code

۳۶۱۴۶۴۷۵۵۳

Phone

+98 23 3237 3785

Email

mahdiyehhabibi6@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mahdia Sadat Habibi

Position

Master's student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Next to Iran Insurance, between Shahid Madani 2 and 4, Shahid Madani St., Shahrood city

City

Shahrood

Province

Semnan

Postal code

۳۶۱۴۶۴۷۵۵۳

Phone

+98 23 3237 3785

Email

mahdiyehhabibi6@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mahdia Sadat Habibi

Position

Master's student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Next to Iran Insurance, between Shahid Madani 2 and 4, Shahid Madani St., Shahrood city

City

Shahrood

Province

Semnan

Postal code

۳۶۱۴۶۴۷۵۵۳

Phone

+98 23 3237 3785

Email

mahdiyehhabibi6@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available