

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

The effects of home-based Yoga program on physical quality of life, Social behavior and Sleep Habits in children and adolescents with autism spectrum disorder and their parents(international study)

Protocol summary

Study aim

The effects of home-based Yoga program on quality of life, Social behavior and Sleep Habits in children and adolescents with autism spectrum disorder and their parents

Design

In this study, all the children who met the inclusion criteria, and who visited the autism spectrum disorders research center located in Hamedan, Iran are considered. Then, they are randomly divided into two groups (intervention and control). A block randomization method with a block size of four was used to randomize participants. The design will be parallel.

Settings and conduct

We will recruit children with autism syndrome aged 6-12 years from an autism spectrum disorders research center located in Hamedan, Iran. Then the participants will be randomly divided into two intervention and control groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: a) having a child diagnosed with Autism syndrome, b) agreeing to participate in the study voluntarily and c) having an active WhatsApp account

Intervention groups

The intervention group will receive Yoga training for 8 weeks—3 times per week and 40 minutes each session. The control group will participate in their usual daily activity levels, without additional exercise.

Main outcome variables

Quality of life, Social behavior and Sleep Habits in children and adolescents with autism spectrum disorder and their parents

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170114031921N4**

Registration date: **2023-06-26, 1402/04/05**

Registration timing: **registered_while_recruiting**

Last update: **2023-06-26, 1402/04/05**

Update count: **0**

Registration date

2023-06-26, 1402/04/05

Registrant information

Name

homa naderifar

Name of organization / entity

Tehran

Country

Iran (Islamic Republic of)

Phone

+98 21 5541 6134

Email address

homa.naderifar@ut.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-20, 1402/03/30

Expected recruitment end date

2023-12-21, 1402/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of home-based Yoga program on physical

quality of life, Social behavior and Sleep Habits in children and adolescents with autism spectrum disorder and their parents(international study)

Public title

effects of home-based Yoga program on quality of life, Social behavior and Sleep Habits in children and adolescents

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Having a child diagnosed with Autism syndrome
Agreeing to participate in the study voluntarily having an active WhatsApp account.

Exclusion criteria:

Children who demonstrated comorbidities, including genetic syndromes
Children who have severe medical limitations or illness

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: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

A block randomization method with a block size of four was used to randomize participants. For this purpose, four sheets of paper were prepared. On two sheets letter C (Control group), and on two sheets letter I (Intervention group) was written. The sheets were mixed together and then randomly drawn out one at a time for each participant without replacement until all four sheets were drawn. This method is repeated until all participants were randomized.

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 Hamadan University of Medical Sciences

Street address

No. 2, Shahid Fahmideh Blvd., Ghaem Ave., Hamadan town, Hamedan, Iran

City

Hamadan

Province

Hamadan

Postal code

۶۵۱۷۸۳۸۷۳۶

Approval date

2023-03-04, 1401/12/13

Ethics committee reference number

IR.UMSHA.REC.1401.1044

Health conditions studied

1

Description of health condition studied

autism spectrum disorder

ICD-10 code

F84.0

ICD-10 code description

Autistic disorder

Primary outcomes

1

Description

Children's quality of life

Timepoint

Before the intervention and after the intervention

Method of measurement

Peds-Quality of life for children

2

Description

Social behavior

Timepoint

Before the intervention and after the intervention

Method of measurement

Behavior Checklist

3

Description

Sleep Habits

Timepoint

Before the intervention and after the intervention

Method of measurement

Childrens Sleep Habit Questionnaire (CSHQ)

4

Description

Quality of life of parents

Timepoint

Before the intervention and after the intervention

Method of measurement

World Health Organization Quality of Life (Brief) for

parents

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Participants in the intervention group will receive yoga training for 8 weeks (3 times a week and each session is 40 minutes).Yoga program will involve pranayamas (yoga breathing techniques), loosening exercises, asanas (physical postures), chanting and yoga relaxation techniques .

Category

Rehabilitation

2

Description

Control group: People in this group have their routine daily activities.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Autism Research Center

Full name of responsible person

Homa Naderifar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Reza Shokoohi

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Homa Naderifar

Position

Consultant

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

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Person responsible for scientific inquiries

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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
No - There is not a plan to make this available
Clinical Study Report
Yes - There is 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
Not applicable
Title and more details about the data/document
All data is potentially shareable after de-identifying individuals
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
It will be available for researchers working in academic and scientific institutions
Under which criteria data/document could be used
Analysis is not allowed
From where data/document is obtainable
Sending an email to the corresponding author
What processes are involved for a request to access data/document
Sending an email to the corresponding author
Comments