Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
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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 Questionnsire (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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No. 2, Shahid Fahmideh Blvd., Ghaem Ave., Hamadan town, Hamedan, Iran
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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
Street address
No. 2, Shahid Fahmideh Blvd., Ghaem Ave., Hamadan town, Hamedan, Iran
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Email
Webda@umsha.ac.ir
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
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Other areas of specialty/work
Sport Medicine
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Person responsible for scientific inquiries

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Person responsible for updating data

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Position
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Ph.D.

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Sport Medicine

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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