

# 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

##### Street address

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

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##### Phone

+98 81 3821 8164

##### Email

hnaderifar121@gmail.com

## 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

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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

Ph.D.

##### Other areas of specialty/work

Sport Medicine

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

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## Person responsible for scientific inquiries

#### Contact

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Researcher  
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## Person responsible for updating data

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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**