

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the Effectiveness of Neurofeedback and Yoga on Enhancing Concentration, Attention, and Reducing Anxiety in Children Aged 6 to 11 with Attention-Deficit/Hyperactivity Disorder (ADHD)

Protocol summary

Study aim

Determining the Comparative Effectiveness of Neurofeedback and Yoga on Enhancing Concentration, Attention, and Reducing Anxiety in Children Aged 6 to 11 with Attention-Deficit/Hyperactivity Disorder (ADHD) in Ahvaz.

Design

A clinical trial with an intervention group and a control group, with parallel groups, unblinded, randomized, with pre-test and post-test, on 50 people, Drawing lots will be used for randomization.

Settings and conduct

The study was conducted at a girls' elementary school in Ahvaz. The study population consisted of 50 participants. In this study, blinding was not performed.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Having a confirmed diagnosis of Attention-Deficit/Hyperactivity Disorder (ADHD) by the school counselor, as well as through ADHD questionnaires. Children aged between 6 and 11 years. Having an Intelligence Quotient (IQ) within the normal range (typically 90-110 or higher), as measured by the Wechsler Intelligence Scale for Children (WISC-IV).
Exclusion Criteria: Presence of severe comorbid psychiatric disorders or serious comorbid conditions such as psychotic disorders, severe major depressive disorder, bipolar disorder, or autism spectrum disorders. Presence of neurophysiological disorders such as a history of epilepsy, seizures, severe head trauma, or any known neurological condition that may affect brain function and EEG. Regular participation in other psychotherapy sessions (e.g., play therapy, art therapy) or any other interventions that directly affect attention and anxiety during the study period.

Intervention groups

The intervention group receives cognitive behavioral therapy. The control group receives no intervention.

Main outcome variables

Anxiety in Children, Attention-Deficit/Hyperactivity Disorder (ADHD)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250906067136N1**

Registration date: **2025-09-09, 1404/06/18**

Registration timing: **prospective**

Last update: **2025-09-09, 1404/06/18**

Update count: **0**

Registration date

2025-09-09, 1404/06/18

Registrant information

Name

Sogand Shahwar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3228 3679

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-23, 1404/07/01

Expected recruitment end date

2025-11-22, 1404/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of Neurofeedback and Yoga on Enhancing Concentration, Attention, and Reducing Anxiety in Children Aged 6 to 11 with Attention-Deficit/Hyperactivity Disorder (ADHD)

Public title

Comparison of the Effectiveness of Neurofeedback and Yoga on Enhancing Concentration, Attention, and Reducing Anxiety in Children Aged 6 to 11 with Attention-Deficit/Hyperactivity Disorder (ADHD)

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Having a confirmed diagnosis of Attention-Deficit/Hyperactivity Disorder (ADHD) by the school counselor as well as through ADHD questionnaires. The child's age should be between 6 and 11 years (completed). Having an Intelligence Quotient (IQ) within the normal range (typically 90-110 or higher), as measured by the Wechsler Intelligence Scale for Children (WISC-IV). No use of psychiatric medications during the past three months. Obtaining written informed consent from the child's parents for participation in the study.

Exclusion criteria:

Presence of severe comorbid psychiatric disorders or serious comorbid conditions such as psychotic disorders, severe major depressive disorder, bipolar disorder, or autism spectrum disorders. Presence of neurophysiological disorders such as a history of epilepsy, seizures, severe head trauma, or any known neurological condition that may affect brain function and EEG. Regular participation of the child in other psychotherapy sessions (such as play therapy, art therapy) or any other interventions that directly affect attention and anxiety during the study period. Presence of severe sensory (blindness, deafness) or motor impairments that make participation in yoga sessions or sitting still during neurofeedback sessions impossible. Lack of willingness of the child or family to consistently comply with the research protocol (regular attendance at sessions, completing questionnaires) or their request to withdraw from the study at any stage.

Age

From **6 years** old to **11 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

A simple randomization method will be used. According to this method, the names of all selected participants will be written on pieces of paper and placed in a box for a lottery draw. Then, the pieces of paper will be drawn one by one, with the first 25 participants (1-25) assigned to the experimental group and the next 25 participants (26-50) drawn from the box assigned to 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**

The Ethics Committee in Research of Islamic Azad University - Ahvaz Branch

Street address

South Kargar Boulevard, Farhang Shahr, Golestan Highway

City

Ahvaz

Province

Khuzestan

Postal code

6134937333

Approval date

2025-09-03, 1404/06/12

Ethics committee reference number

IR.IAU.AHVAZ.REC.1404.423

Health conditions studied**1****Description of health condition studied**

Attention-Deficit/Hyperactivity Disorder

ICD-10 code

F90.0

ICD-10 code description

Attention-deficit hyperactivity disorder, predominantly inattentive type

Primary outcomes**1****Description**

Attention-Deficit/Hyperactivity

Timepoint

Measurements will be conducted at pre-test, post-test, and three-month follow-up after the post-test

Method of measurement

Integrated Visual and Auditory Continuous Performance Test

2

Description

Children's Anxiety

Timepoint

Measurements will be conducted at pre-test, post-test, and three-month follow-up after the post-test

Method of measurement

Spence Children's Anxiety Scale - SCAS

3

Description

Attention-Deficit/Hyperactivity

Timepoint

Measurements will be conducted at pre-test, post-test, and three-month follow-up after the post-test

Method of measurement

Swanson, Nolan, and Pelham Rating Scale - Fourth Edition (SNAP-IV)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group will participate in a 24-session training program, each session lasting 60 minutes (30 minutes of neurofeedback + 30 minutes of yoga), conducted three times per week. 1. Sessions 1-3: Introduction and Initial AssessmentGoal: Reduce initial anxiety, familiarize children with the treatment process, and enhance

motivation.Content:Neurofeedback: Baseline EEG assessment, introduction to the device, and simple games.Yoga: Introduction to yoga in child-friendly language, practice of abdominal breathing, and simple stretches.Homework: Daily 3-minute abdominal breathing exercise with parents. 2. Sessions 4-6: Beginning Basic TrainingGoal: Strengthen sustained attention and increase body awareness.Content:Neurofeedback: Implementation of SMR protocol (12-15 Hz), simple visual games.Yoga: Cat-cow, tree pose, and basic arm-leg stretches combined with calm breathing.Homework: Daily practice of the tree pose or a simple stretch at home. 3. Sessions 7-9: Stabilization and RelaxationGoal: Improve mental and physical self-regulation.Content:Neurofeedback: Continuation of SMR training with calm breathing before each session.Yoga: Focus on breathing and simple seated-standing movements.Homework: Daily 5-minute calm breathing practice with parents. 4. Sessions 10-12: Enhancing Selective AttentionGoal: Improve processing

speed and focus on specific stimuli.Content:Neurofeedback: Introduction of low beta protocol (15-18 Hz), intermediate-level games.Yoga: Animal poses (frog, snake, bird) combined with storytelling.Homework: Practice one animal yoga pose at home and perform it for parents. 5. Sessions 13-15: Strengthening Sustained AttentionGoal: Enhance accuracy and mind-body control.Content:Neurofeedback: Combined SMR + beta protocol, more engaging games.Yoga: Balance exercises (tree pose, warrior, standing on one foot).Homework: Daily one-leg balance for 20 seconds. 6. Sessions 16-18: Training in Simulated ConditionsGoal: Generalize learned skills to real-life situations.Content:Neurofeedback: Practice with distracting stimuli (additional sounds or images).Yoga: Guided relaxation (simple body scan, lying down, and breathing).Homework: Relaxation practice before bedtime (lying down and calm breathing). 7. Sessions 19-21: Review and IntegrationGoal: Automate attention and integrate mind-body skills.Content:Neurofeedback: Advanced-level games, focusing under more difficult conditions.Yoga: Integration of breathing, stretches, animal poses, and balance exercises.Homework: Short yoga session at home (5 minutes breathing + 2 simple poses). 8. Sessions 22-24: Final ConsolidationGoal: Consolidate achievements and transfer skills into daily life.Content:Neurofeedback: Final review and training, reassessment of changes.Yoga: Review of learned movements, final playful yoga session.Homework: Continue daily practice (5 minutes breathing + one focus activity or yoga pose).

Category

Behavior

2

Description

Control group: They receive no training.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Bahar Andisheh Girls' Primary School

Full name of responsible person

Zahra Mohammadi

Street address

No. 35, Shahid Azadi Street, Saadi Neighborhood, Golestan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Pejman Taghipour Birgani

Street address

South Kargar Boulevard, Farhang Shahr District;
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Province

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6134937333

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info@iauahvaz.ac.ir

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

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

Islamic Azad University

Full name of responsible person

Sogand Shahwar

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

Street address

No. 26, Arad 6 Building, Mehregan 4, Sepidar

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Rahmatollah Khanmohammadi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Only part of the data, such as information related to the primary outcome or similar, can be shared.

When the data will become available and for how long

Access period begins 6 months after publication of results.

To whom data/document is available

The data will only be accessible to researchers affiliated with academic or scientific institutions.

Under which criteria data/document could be used

Any type of analysis is permitted on the delivered data.

From where data/document is obtainable

Via email: sogand.shahwar@au.i.ir

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

The data will be sent after emailing sogand shahwar and receiving approval from the research team members.

Comments