Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

sogand.shahwar@iau.ir

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
Khouzestan
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

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

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Province

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Pejman Taghipour Birgani
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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
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
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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
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@aui.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