Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of neurofeedback, vitamin D3 and combined neurofeedback with vitamin D3 supplementation in children with ADHD: a randomized, double blind, Parallel-Group trial

Protocol summary

Study aim

The aim of this study is comparison of neurofeedback, vitamin D3 and combined neurofeedback with vitamin D3 supplementation in children with ADHD.

Design

This stydy is a randomized, double -blind, with parallel groups clinical trial. 90 patients with Attention-Deficit-Hyperactivity Disorder in four groups of 30 people in a phase III trial are assigned randomly.

Settings and conduct

Location is Fetros Comprehensive Health Center.120 patients are selected. 30 patients in control group, 30 patients in neurofeedback, 30 patients in vitamin D3 and 30 patients in combined neurofeedback and vitamin D3 are assigned randomly. In this double-blind study, the psychiatrist and data analyser were kept blind to the treatment. participants pick up envelopes inside the box randomly which are in an unspecified wrapper.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of attention-deficit-hyperactivity disorder based on diagnostic and Statistical Manual of Mental Disorders (DSM), No use of Vitamin D3 before the study, Lack of any psychotherapy during last 2 months, Insufficiency 12 to 20 ng/mL (30 to 50 nmol/L) or Deficiency < 12 ng/mL (< 30 nmol/L). Exclusion criteria: Parent's dissatisfaction to participate in study, Psychiatric comorbidities (except for oppositional defiant disorder), seizure, Systolic blood pressure over 12, Drug allergy

Intervention groups

Control group:Patients do not receive intervention during the 12 weeks. Intervention group1: Patients receive 1 30-minute neurofeedback training session every week for 12 weeks. Intervention group2: Patients take vitamin Pills (50,000 IU) weekly for 12 weeks. Intervention group2: Patients receive vitamin D3 Pills (50,000 IU) weekly in addition 30-minute neurofeedback training session during 12 weeks.

Main outcome variables

Hyperactivity symptoms, Attention deficit symptomd, impulsivity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190602043790N1**
Registration date: **2020-06-06, 1399/03/17**
Registration timing: **prospective**

Last update: **2020-06-06, 1399/03/17**
Update count: **0**

Registration date

2020-06-06, 1399/03/17

Registrant information

Name

Saba Hasanvandi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 66 3324 2643

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-07-22, 1399/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of neurofeedback, vitamin D3 and combined neurofeedback with vitamin D3 supplementation in children with ADHD: a randomized, double blind, Parallel-Group trial

Public title

Comparison of neurofeedback, vitamin D3 and combined neurofeedback with vitamin D3 supplementation in children with ADHD

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of attention-deficit-hyperactivity disorder based on diagnostic and Statistical Manual of Mental Disorders (DSM) No use of Vitamin D3 before the study Lack of any psychotherapy during last 2 months Insufficiency 12 to 20 ng/mL (30 to 50 nmol/L) or Deficiency < 12 ng/mL (< 30 nmol/L).

Exclusion criteria:

Parent's dissatisfaction to participate in study Psychiatric comorbidities (except for oppositional defiant disorder) seizure Systolic blood pressure over 12 Drug allergy

Age

From **5 years** old to **17 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Data analyser

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method is randomly blocks A, B, C, D. Patients fall into four categories, A, B, C or D depending on the order in which they study. Block A is the control group, Block B is neurofeedback, Block C vitamin D treatment and Block D combined neurofeedback and citamin D. Random allocation is done by the researcher and the clinical caregiver and data analyzer are not aware of the allocation of patients.

Blinding (investigator's opinion)

Double blinded

Blinding description

Treatment allocation was concealed from the psychiatrist and the data analyser who rated patients by using successively numbered, opaque, and sealed envelopes. participants pick up envelopes inside the box randomly which are in an unspecified wrapper. They are aware which experimental group they were assigned to.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Baqiyatallah University of Medical Science

Street address

Sheykhbahaie street, Molla Sadra street, Vanak square, Tehran

City

Tehran

Province

Tehran

Postal code

1435915371

Approval date

2020-01-14, 1398/10/24

Ethics committee reference number

IR.BMSU.BAQ.REC.1398.026

Health conditions studied

1

Description of health condition studied

Attention-Deficit Hyperactivity Disorder

ICD-10 code

F90.9

ICD-10 code description

Attention-deficit hyperactivity disorder, unspecified type

Primary outcomes

1

Description

Hyperactivity symptoms

Timepoint

Assessment of ADHD - attention deficit at the beginning of the study (before the intervention), weeks 4, 8 and 12 after the start of neurofeedback in intervention groups 2 and 4 and vitamin D3 consumption in intervention groups 3 and 4.

Method of measurement

Parent and Teacher ADHD-RS-IV

2

Description

Attention-Deficit symptoms

Timepoint
Assessment of ADHD - attention deficit at the beginning of the study (before the intervention), weeks 4, 8 and 12 after the start of neurofeedback in intervention groups 2 and 4 and vitamin D3 consumption in intervention groups 3 and 4.
Method of measurement
Parent and Teacher ADHD-RS-IV

3

Description
Impulsivity
Timepoint
Assessment of ADHD - attention deficit at the beginning of the study (before the intervention), weeks 4, 8 and 12 after the start of neurofeedback in intervention groups 2 and 4 and vitamin D3 consumption in intervention groups 3 and 4.
Method of measurement
Parent and Teacher ADHD-RS-IV

Secondary outcomes

empty

Intervention groups

1

Description
Control group:Patients do not receive any intervention during the 12 weeks.
Category
Behavior

2

Description
Intervention group: Patients receive 1 30-minute neurofeedback training session every week for 12 weeks.
Category
Treatment - Devices

3

Description
Intervention group: Patients take vitamin Pills (50,000 IU) weekly (manufactured by Poursina Pharmaceuticals) on a weekly basis for 12 weeks, depending on their weight.
Category
Treatment - Drugs

4

Description
Intervention group:Patients receive vitamin Pills (50,000 IU) weekly (manufactured by Poursina Pharmaceuticals) depending on their weight in addition 30-minute neurofeedback training session every 12 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Fetros Urban Comprehensive Center
Full name of responsible person
Dr Gholam Hossein Alishiri
Street address
Delfani Street, Enghelab Street, Khorram abad, Lorestan, Iran.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Dr Gholam Hossein Alishiri
Street address
Sheykhbahaie street, Molla Sadra street, Vanak square, Tehran
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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
Bagheiat-allah 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
Bagheiat-allah University of Medical Sciences

Full name of responsible person
Saba Hasanvandi

Position
Assistant professor

Latest degree
Ph.D.

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
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Only part of the data, such as information related to main outcome or like that , can be share.

When the data will become available and for how long
Start of access, 6 months after publishing the results

To whom data/document is available
Only people working in academic institutions could apply.

Under which criteria data/document could be used
People who are conducting clinical trials in this field could apply.

From where data/document is obtainable
By referring to the electronic address: s.hasanvandi@alzahra.ac.ir

What processes are involved for a request to access data/document
The applicant can receive information by registering the exact personal details.

Comments