Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The Effectiveness of Treatment with Probiotic Supplements Added to the Usual Treatment (Medical Treatment for Children with Parenting Training Sessions for Parents) in Children Suffering from Attention Deficit-Hyperactivity Disorder Referred to Specialized Treatment Centers for Child and Adolescent Psychiatry

Protocol summary

Study aim
The effectiveness of treatment with probiotic supplements added to the usual treatment in children with attention deficit-hyperactivity disorder

Design
A clinical trial with a control group, with a parallel group, double-blind, randomized on 80 patients

Settings and conduct
Study is conducted in psychiatric clinics and on children aged 6 to 12 With attention deficit-hyperactivity disorder. Children will be given medicine and placebo in two groups. Questionnaires will be filled by the before, during and after the study. The presenter, parents and children will not know about the child's group.

Participants/Inclusion and exclusion criteria
Inclusion criteria 1- 6 to 12 years old children with ADHD . 2- Not change in their treatment regimen in the last two months. Non-entry criteria: 1- Who take antidepressant, anti psychotic and mood stabilizer drugs. 2- Who have anxiety according to Hamilton questionnaire and have depression according to children depression inventory.

Intervention groups
Before and after the parenting training session, a test (questionnaire) will be taken from both groups. Then, we ask the intervention group to take 200 mg probiotic capsules for 1 and a half months in addition to their usual treatment, and then they will be tested again. In the control group, 200 mg placebo capsules were prescribed in addition to their usual treatment, and they were tested again after 1 and a half months.

Main outcome variables
Attention deficit-hyperactivity disorder status.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211004052670N6**
Registration date: **2024-01-20, 1402/10/30**
Registration timing: **registered_while_recruiting**

Last update: **2024-01-20, 1402/10/30**
Update count: **0**

Registration date
2024-01-20, 1402/10/30

Registrant information

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afsaneh karbasi amel

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-22, 1402/10/01

Expected recruitment end date
2024-12-21, 1403/10/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Treatment with Probiotic Supplements Added to the Usual Treatment (Medical Treatment for Children with Parenting Training Sessions for Parents) in Children Suffering from Attention Deficit-Hyperactivity Disorder Referred to Specialized Treatment Centers for Child and Adolescent Psychiatry

Public title

The Effectiveness of Probiotic Supplements in Attention Deficit-Hyperactivity Disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children with Attention Deficit-Hyperactive Disorder with 6 to 12 years old. No change in treatment regimen during the last two months. Consent to participate in the study.

Exclusion criteria:

Taking anti-depressant drugs, anti-psychotic drugs and mood stabilizers. Children with anxiety (based on Hamilton Rating Scale for Depression) and with depression (based on Children Depression Inventory). Children with Inflammatory Bowel Disease, Celiac disease and Irritable bowel syndrome. Children with Diabetes.

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 80 eligible patients are randomly selected. For this, the letter A written on 40 sheets, the letter B written on 40 sheets, and each of them is placed in an envelope. Each patients is then asked to choose one of the envelopes. Depending on the selected envelope, the patient is assigned to one of two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to observe blindness, the drugs (medicine and placebo) are prepared in the same shape before the intervention and are coded and given to the physician. They prescribe them without knowing the type of each drug. Therefore, the patient,the person recording the clinical and baseline information of the patients as well as the statistical analyst will not be aware of the type of intervention.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Isfahan University of Medical Sciences

Street address

Ibn Sina Street, Amin Hospital, Isfahan, Iran

City

Isfahan

Province

Isfehan

Postal code

8148653141

Approval date

2023-07-14, 1402/04/23

Ethics committee reference number

IR.MUI.MED.REC.1402.150

Health conditions studied

1

Description of health condition studied

Attention deficit-hyperactivity disorder

ICD-10 code

F90.2

ICD-10 code description

Attention-deficit hyperactivity disorder, combined type

Primary outcomes

1

Description

Attention deficit-hyperactivity scale in attention deficit-hyperactivity rating scale

Timepoint

The questionnaire is filled in at the baseline visit and after 15 days of participating in parent training sessions (before the start of the intervention) and then 45 days later and after the end of taking the drug.

Method of measurement

Attention deficit-hyperactivity rating scale.

2

Description

Attention deficit-hyperactivity scale in Connors

questionnaire.

Timepoint

The questionnaire is filled in at the baseline visit and after 15 days of participating in parent training sessions (before the start of the intervention) and then 45 days later and after the end of taking the drug.

Method of measurement

Connors questionnaire

3

Description

Quality of life score in Pediatric's Quality of Life Questionnaire.

Timepoint

The questionnaire is filled in at the baseline visit and after 15 days of participating in parent training sessions (before the start of the intervention) and then 45 days later and after the end of taking the drug.

Method of measurement

Pediatric's Quality of Life Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Control groupThe control group was instructed to administer a capsule (contains placebo) once daily for a duration of 1.5 months concurrently with their routine medication. Drug utilization was communicated through a telephonic announcement, adhering to the guidelines provided by the pharmaceutical manufacturer (Amin Lab) and informed by extant research. Preceding the intervention, parent management training sessions were conducted for the participating parents.

Category

Placebo

2

Description

Intervention group: The intervention group was instructed to administer a capsule (probiotics capsule 200 mg) once daily for a duration of 1.5 months concurrently with their routine medication. Drug utilization was communicated through a telephonic announcement, adhering to the guidelines provided by the pharmaceutical manufacturer (Amin Lab) and informed by extant research. Preceding the intervention, parent management training sessions were conducted for the participating parents.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amin Hospital

Full name of responsible person

Karbasi Amel Afsaneh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

غلامرضا عسگری

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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

Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Afsaneh Karbasi Amel

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Psychiatrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available