

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effectiveness of probiotic supplement as an adjunctive therapy on executive functions and the severity of symptoms of inattention, hyperactivity and impulsivity in children with attention deficit hyperactivity disorder: A randomized, double-blind, placebo-controlled trial

Protocol summary

Study aim

To determine the effectiveness of probiotic supplement as adjunctive therapy on executive functions (behavior regulation skills and metacognition skills) and symptom severity (inattention, hyperactivity and impulsivity) in children with attention deficit hyperactivity disorder

Design

randomized, double-blind, placebo-controlled trial. 44 patients in each group

Settings and conduct

The study will be performed in Shafa Hospital in Rasht. The experimental group (n = 44) received bioflora probiotic supplement for 2 months (n = 60), and the control group (n = 44) received placebo for 2 months (n = 60). The evaluation will be implemented again after the intervention is terminated and also two months later, to gather post-test and follow-up data.

Participants/Inclusion and exclusion criteria

Inclusion criteria include having attention deficit hyperactivity disorder (ADHD), age group 7 to 12 years and being treated with Ritalin. exclusion criteria include Comorbid with other severe psychiatric and medical disorders, drug interactions, and concomitant use of similar supplements.

Intervention groups

Intervention group: Bioflora capsules, produced by Tak Zhen Zist Pharmaceutical Company; for two months (one per day), 1.8×10^9 CFU/Capsule, and Control group: Placebo consumption for two months (one per day), Placebo is produced by Tak Zhen Zist Pharmaceutical Company and is quite similar to a probiotic supplement in shape, color, size and packaging, even the available fillers or excipients (Magnesium stearate, Maltodextrin). The only difference is the absence of

strains in placebo.

Main outcome variables

executive functions, inattention, hyperactivity and impulsivity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210531051454N2**

Registration date: **2022-07-02, 1401/04/11**

Registration timing: **prospective**

Last update: **2022-07-02, 1401/04/11**

Update count: **0**

Registration date

2022-07-02, 1401/04/11

Registrant information

Name

Fatemeh Rabipour

Name of organization / entity

Tabriz Azad University

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-16, 1401/04/25
Expected recruitment end date
 2022-10-17, 1401/07/25
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 The effectiveness of probiotic supplement as an adjunctive therapy on executive functions and the severity of symptoms of inattention, hyperactivity and impulsivity in children with attention deficit hyperactivity disorder: A randomized, double-blind, placebo-controlled trial

Public title
 The role of probiotic supplements in the recovery of children with attention deficit hyperactivity disorder

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Diagnosis of attention deficit- hyperactivity disorder 7-12 years old having informed consent to participate in research having normal IQ rate (85 to 115) children under standard treatment with Ritalin Body mass less than +2 standard deviation
Exclusion criteria:
 Having Psychiatric and medical comorbid disorders simultaneous use of supplements or drugs that interfere with treatment

Age
 From **7 years** old to **12 years** old

Gender
 Both

Phase
 3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
 Target sample size: **88**

Randomization (investigator's opinion)
 Randomized

Randomization description
 88 people will be selected based on the inclusion criteria and will be assigned by web-based randomization method (<https://www.randomizer.org>) as experimental and control groups (each group 44 people). Allocation concealment will be done using sequentially numbered, opaque sealed envelopes (SNOSE). Based on the research sample size, several aluminum envelopes will be prepared; each random sequence will be recorded on a card and the cards will be placed into the separate envelopes respectively. To maintain the random sequence, the envelopes will be numbered in the same way on their outer surface. In the end, the flaps of

envelopes will be glued and orderly placed in a box. At the beginning of the intervention, the envelopes will be opened in order and the assigned group of the relevant participants will be revealed.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, each step will be performed by one of the team researchers without informing the other members of the research team. In the first stage, participants will be interviewed by a psychiatrist and then the names of the participants (without further information) will be presented to the person responsible for randomization and assessment. Assessor will not know about the participants characteristics and how they are allocated. In addition, the participants will not know whether they are positioned as an experimental group or a control group; Because placebo is quite similar to a probiotic supplement in shape, color, size and packaging and participants will not be aware of the type of intervention received. Finally, the statistical analyst will be selected outside the research team and will not have any information about the details of the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Guilan University of Medical Sciences

Street address

Ethics Committee of Guilan University of Medical Sciences, In front of Shahrivar 17 hospital, Shahid Siadati Street, Namjoo Street

City

Rasht

Province

Guilan

Postal code

4185733411

Approval date

2022-02-23, 1400/12/04

Ethics committee reference number

IR.GUMS.REC.1400.582

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**

Executive functions

Timepoint

Before intervention, after intervention, two months after intervention

Method of measurement

BRIEF' Executive Function Questionnaire (parent form)

2**Description**

attention deficit

Timepoint

Before intervention, after intervention, two months after intervention

Method of measurement

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

3**Description**

hyperactivity

Timepoint

Before intervention, after intervention, two months after intervention

Method of measurement

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

4**Description**

Impulsivity

Timepoint

Before intervention, after intervention, two months after intervention

Method of measurement

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

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Bioflora capsules (Active substance: lactobacillus acidophilus, bifidobacterium bifidum, bifidobacterium lactis, bifidobacterium longum and other ingredients: Magnesium stearate, Maltodextrin), produced by Tak Zhen Zist Pharmaceutical Company; for two months (one per day), 1.8 × 10⁹ CFU/Capsule

Category

Treatment - Other

2**Description**

Control group: Placebo consumption is intended for two months (one per day) for each participant. Placebo is produced by Tak Zhen Zist Pharmaceutical Company and is quite similar to a probiotic supplement in shape, color, size and packaging, even the available fillers or excipients (Magnesium stearate, Maltodextrin). The only difference is the absence of lactobacillus acidophilus, bifidobacterium bifidum, bifidobacterium lactis, bifidobacterium longum strains in placebo.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shafa Educational & Remedial Center

Full name of responsible person

Dr. Seyedeh Maryam Zavar Mousavi

Street address

Shafa Educational & Remedial Center (Children and adolescents' section), next to Dr Heshmat Hospital, 15 Khordad St, Imam Khomeini Blvd.

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Guilan University of Medical Sciences, Vice-Chancellor for Research & Technology

Full name of responsible person

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Grant name

Grant code / Reference number

3353

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Guilan University of Medical Sciences, Vice-Chancellor for Research & Technology

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

Fatemeh Rabipour

Position

PhD candidate

Latest degree

Master

Other areas of specialty/work

Psychology

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Latest degree

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Due to the decision to further research in this area

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

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

No - There is not a plan to make this available

Data Dictionary

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

Title and more details about the data/document

There is not a plan to make this available

When the data will become available and for how long

There is not a plan to make this available

To whom data/document is available

There is not a plan to make this available

Under which criteria data/document could be used

There is not a plan to make this available

From where data/document is obtainable

There is not a plan to make this available

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

There is not a plan to make this available

Comments