

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Evaluation The effect of Probiotics in Reducing Behavioral Symptoms and Severity of Autism in Children and Adolescents with Autism Spectrum Disorder

#### Protocol summary

##### Study aim

The effect of probiotics on the symptoms and severity of autism disorder will be evaluated.

##### Design

A one-way clinical trial of 70 autistic children 3 to 18 years of age who are conveniently available to participate in the study.

##### Settings and conduct

70 children with autism spectrum disorder between the ages of three to 18 years old who is referred to the children and adolescent psychiatric clinic of Imam Hossein Hospital in Tehran or Iran's Autism Association will be selected. This sample will first be evaluated using two CARS and ATEC questionnaires to examine the symptoms and determine the severity of the disorder. Then all participants will be treated once a day for four weeks with Kidilact probiotics. At the end of the month, children will be evaluated again by the CARS and ATEC questionnaires, and the symptoms and response rates will be reviewed. The results will be analyzed statistically and will be compared with the beginning of the study.

##### Participants/Inclusion and exclusion criteria

Children from 3 to 18 year old with Autism Spectrum Disorder who do not have chronic infectious disease and AIDS without taking antifungal medication, antibiotic, anti-inflammatory drugs, corticosteroids and anti-diarrheal drugs, enrolled in the study after receiving consent from their parent or caretaker.

##### Intervention groups

After four weeks, the effect of Kid Lakt on the symptoms and severity of autism in children is evaluated.

##### Main outcome variables

Changes in the number of symptoms of autism in response to probiotics; changes in the severity of autism in response to probiotics

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130504013215N2**

Registration date: **2018-05-14, 1397/02/24**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-05-14, 1397/02/24**

Update count: **0**

##### Registration date

2018-05-14, 1397/02/24

##### Registrant information

##### Name

Katayoon Razjouyan

##### Name of organization / entity

Behavioral Sciences Research Center, Shahid Beheshti University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7755 1023

##### Email address

k\_razjouyan@sbm.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-09-23, 1396/07/01

##### Expected recruitment end date

2018-09-23, 1397/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Evaluation The effect of Probiotics in Reducing Behavioral Symptoms and Severity of Autism in Children and Adolescents with Autism Spectrum Disorder

**Public title**

Probiotics Effect in Reducing Behavioral Symptoms and Severity of Autism

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

All patients with autism between 3 and 18 years of age

**Exclusion criteria:**

Suffering from chronic infectious diseases Congenital metabolic disorders HIV and Congenital Immunodeficiency Disorder Under treatment with anti-fungal drugs, antibiotics, anti-inflammatory drugs, corticosteroids, anti-diarrheal compounds, chemotherapy

**Age**

From **3 years** old to **18 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **70**

**Randomization (investigator's opinion)**

N/A

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Single

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Beheshty University of Medical Sciences

**Street address**

Imam Hossein Hospital, Madani st.

**City**

Tehran

**Province**

Tehran

**Postal code**

16117763141

**Approval date**

2016-11-13, 1395/08/23

**Ethics committee reference number**

IR.SBMU.RETECH.REC.1395.548

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

Autism Spectrum Disorder

**ICD-10 code**

F84.0

**ICD-10 code description**

Childhood autism

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

Change in symptoms of autism disorder in the CARS questionnaire

**Timepoint**

When entering the study and 8 weeks after starting treatment

**Method of measurement**

CARS questionnaire at the beginning and the end of the study

**2****Description**

Change in severity of autism disorder in the ATEC questionnaire

**Timepoint**

When entering the study and 8 weeks after starting treatment

**Method of measurement**

ATEC questionnaire at the beginning and the end of the study

**Secondary outcomes**

empty

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

Intervention group: Children with autism disorder are treated with Kidilact probiotics Sache for four weeks. Before entering the study, they filled out the CARS and ATEC questionnaires to measure the symptoms and severity of the disorder. Kidilact Sache is specific for children over 2 years of age that contains high levels of seven beneficial bacterial strains, including the specific strain of children "Bifidobacterium infantis" along with probiotic fructooligosaccharide (contributing to the

growth and activity of probiotics). Its formula is specially designed for children to eat it easily. It is consumed by a sachet a day. After 4 weeks, the effect of the drug on the reduction of symptoms and severity of autism disorder is measured by the CARS and ATEC questionnaires.

**Category**

Treatment - Drugs

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

Imam Hossein Hospital- Autism Society of Iran

**Full name of responsible person**

Katayoon Razjouyan

**Street address**

Shahid Madani Street

**City**

Tehran

**Province**

Tehran

**Postal code**

1617763141

**Phone**

+98 21 7755 1023

**Email**

k\_razjouyan@sbmu.ac.ir

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

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Katayoon Razjouyan

**Street address**

Imam Hossein Hospital- Madani Street

**City**

Tehran

**Province**

Tehran

**Postal code**

1617763141

**Phone**

+98 21 7755 1023

**Email**

k\_razjouyan@sbmu.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shahid Beheshti University of Medical Sciences

**Proportion provided by this source**

30

**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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Katayoon Razjouyan

**Position**

Assistant Professor of Child and Adolescent Psychiatry

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Psychiatrics

**Street address**

Shahid Madani Street

**City**

Tehran

**Province**

Tehran

**Postal code**

1617763141

**Phone**

+98 21 7755 1023

**Fax**

+98 21 7755 1023

**Email**

k\_razjouyan@sbmu.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Katayoon Razjouyan

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Psychiatrics

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Katayoon Razjouyan

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Psychiatrics

**Street address**

Shahid Medani street

**City**

Tehran

**Province**

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**Postal code**

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**Email**

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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**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Demographic information such as gender and age, without mentioning the name is shared.

**When the data will become available and for how long**

The access period starts from 2019.

**To whom data/document is available**

Researchers on Autism Spectrum Disorders

**Under which criteria data/document could be used**

For use in similar studies on children with developmental disorders

**From where data/document is obtainable**

Use the responsible person's email

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

After the presentation of evidence from well-known research centers to conduct a similar study, files will be available up to one month.

**Comments**