

Treatment of ADHD with synbiotics (probiotics plus prebiotics)

Submission date 11/04/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 02/05/2019	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 03/03/2025	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The bacteria in the gut are known to influence the brain and behaviour in animal models. Gut symptoms are common in ADHD and autism. The study aim is to explore if a food supplement with anti-inflammatory lactic acid bacteria and fibers attenuates psychiatric symptoms and functioning in persons with ADHD.

Who can participate?

Those with an ADHD diagnosis and no autism diagnosis aged 5-55 years and understanding Swedish.

What does the study involve?

Nine weeks with daily intake of 10 g of food supplement or placebo, a 30 minutes interview with a research nurse on psychiatric health and answering questionnaires on psychiatric health, as well as sampling of blood, urine and feces at start and after the 9 weeks.

What are the possible benefits and risks of participating?

Benefits: the treatment may improve the symptoms and functioning. It is possible for anyone to continue the treatment after the trial since the food supplement is commercially publicly available. Risks: no side effects have been reported for this food supplement.

Where is the study run from?

Karolinska Institutet in Stockholm.

When is the study starting and how long is it expected to run for?

The study started in 2016 and the last sampling was done in August 2018.

Who is funding the study?

The Swedish Research Council, the Swedish Brain Foundation, Ekhaga Foundation and PRIMA child and adult psychiatry Stockholm AB.

Who is the main contact?
Associate Professor Catharina Lavebratt
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
BAMBA_1

Study information

Scientific Title
Randomized placebo-controlled trial in children and adults with ADHD of the effect of Synbiotic2000Forte on symptoms and function.

Acronym
BAMBA

Study objectives
Synbiotic2000Forte improves symptoms and/or function in ADHD

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/07/2015 and 23/02/2017, The Regional Review Board, Stockholm (The Swedish Review Board, Box 2110, 750 02 Uppsala; +4610-4750800; registrator@etikprovning.se), ref: 2015/884-31/1 and 2017/91-31.

Primary study design

Interventional

Study design

Interventional study, multicenter double-blinded parallel randomized placebo-controlled trial.

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Attention-deficit hyperactivity disorder

Interventions

Synbiotic2000 or placebo, 1 bag daily, 9 weeks treatment, follow-up for both treatments. Randomisation by external in blocks of 10 by external unit.

Active treatment: Synbiotic being is a composition of 4×10^{11} CFU per dose of three lactic acid bacteria *Pediococcus pentosaceus* 5-33:3/16:1 (Strain deposit number: LMG P20608), *Lactobacillus casei* ssp *paracasei* F19 (LMG P-17806), *Lactobacillus plantarum* 2362 (LMG P-20606), and 2.5 g of each of the fermentable fibers betaglucan, inulin, pectin and resistant starch.

Placebo 10 g

One dose per day oral intake on foods for 9 weeks

Intervention Type

Supplement

Primary outcome(s)

1. Symptoms of inattention, hyperactivity/impulsivity is measured using ASRS for adults and SNAP-IV for children at baseline and 12 weeks.
2. Symptoms of autism is measured using AQ for adults and SCQ for children at baseline and 12 weeks.
3. Function is measured using WFIRS at baseline and 12 weeks.

Key secondary outcome(s)

1. Emotional regulation is measured in adults using DERS-16 at baseline and 12 weeks.
2. Insomnia is measured using KSQ for adults and ISI for children at baseline and 12 weeks.
3. Well-being is measured in adults using the well-being scale at baseline and 12 weeks.
4. Gastrointestinal symptoms is measured using the Bristol Stool Scale and one pain question at baseline and 12 weeks.
5. Plasma immune activity markers is measured using multiplex immunoassays at baseline and 12 weeks.
6. Plasma bacterial metabolites e.g. short chain fatty acids is measured using LC-MS/MS at baseline and 12 weeks.
7. Feces microbiome is measured using shot gun sequencing at baseline and 12 weeks.

Completion date

24/08/2018

Eligibility

Key inclusion criteria

1. ADHD diagnosis
2. Swedish speaker
3. Aged 5-55 years old

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

Total final enrolment

182

Key exclusion criteria

1. Autism diagnosis
2. Gastrointestinal diagnosis other than IBS
3. Diabetes
4. Antibiotic drug treatment last six weeks

Date of first enrolment

10/01/2016

Date of final enrolment

20/08/2018

Locations

Countries of recruitment

Sweden

Study participating centre

PRIMA child adolescent and adult psychiatry

Götgatan 71

Stockholm

Sweden

11621

Sponsor information

Organisation

Karolinska Institutet

ROR

<https://ror.org/04hmgwg30>

Funder(s)

Funder type

Government

Funder Name

Vetenskapsrådet

Alternative Name(s)

Swedish Research Council, VR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Sweden

Funder Name

Hjärnfonden

Alternative Name(s)

Swedish Brain Foundation, Brain Foundation

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Sweden

Funder Name

Ekhaga Foundation

Funder Name

PRIMA psychiatry AB

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication after anonymisation.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Symptoms and daily functioning	01/10/2020	26/10/2020	Yes	No
Results article	Plasma immune activity markers and short-chain fatty acids	06/03/2023	14/06/2023	Yes	No
Results article	Bacterial gut microbiome	20/03/2023	03/03/2025	Yes	No
Results article	Plasma concentrations of short-chain fatty acids		03/03/2025	Yes	No
Results article	Proinflammatory mediators	01/06/2020	03/03/2025	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes