ISRCTN57795429 https://doi.org/10.1186/ISRCTN57795429

Treatment of ADHD with synbiotics (probiotics plus prebiotics)

Submission date	Recruitment status
11/04/2019	No longer recruiting
Registration date	**Overall study status**
02/05/2019	Completed
Last Edited	**Condition category**
03/03/2025	Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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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Study website
via https://ki.se/en/people/catlav

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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.

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

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a participant information sheet.

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 4x10exp(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 measure

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.

Secondary outcome measures
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. Gastrointestional 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.

Overall study start date
20/08/2015

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

Age group
Mixed

Sex
Both

Target number of participants
248

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

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Sponsor type
University/education

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)
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

Publication and dissemination plan

Planned publications in high-impact peer-reviewed journal.

Intention to publish date
20/05/2019

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