Probiotics, Brain & Behavior

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27864

Source
NTR

Brief title
Probiotics

Health condition

Emotion processing and executive functioning in a healthy population.
Probiotics, Nervous System, Stress and Emotions

Sponsors and support

Primary sponsor: Radboud UMC Nijmegen
Source(s) of monetary or material Support: TKI LSH, Winclove Probiotics B.V.

Intervention

Outcome measures

Primary outcome

Neurocognitive measures of emotion and executive functioning.

Secondary outcome

Neuropsychological (questionnaires), physiological, and fecal measures.

Study description

Background summary

Changes in microbiota-gut- brain axis have been linked to alterations in emotional-cognitive behavior

consistent with some anxiety and depressive symptoms. Recently, a growing body of animal studies

proves evidences for effects of probiotics on gut microblome composition and functions. Accordingly,

the present fMRI study aims to define the effects of probiotics supplementation on emotion, executive

functioning and brain activity in a double-blind, placebo controlled design. Short term effects will be

investigated after four weeks of supplementation with probiotics from the baseline in a Healthy human

population.

Study objective

The aim of the present study is to investigate the effects of probiotic supplementation with Ecologic®Barrier on emotion processing and executive functioning in human subjects by using fMRI.

Study design

First scanning session before starting probiotic supplementation (T0) and second scanning session within a week after the end of the intervention (T1).

Intervention

28 days of 2g multi-species probiotic (Ecologic-®Barrier)/Placebo supplementation (1x daily)

Contacts

Public
E. Aarts

[default]
The Netherlands
Scientific
E. Aarts
[default]
The Netherlands

Eligibility criteria

Inclusion criteria

Inclusion criteria:

- Females taking hormonal contraceptives;

- Age: 18-40 years old;

- Dutch as a mother tongue or fluent in Dutch;

- Right-handed;

- BMI range between 18–25;

Exclusion criteria

Exclusion criteria:

- Previous or current neurological, psychiatric, gastrointestinal or endocrine disorders, or other relevant medical history;

- Current or recent (<3 months) regular medication use;

- Previous or current substance/alcohol dependence or abuse within the last 3 months;

- Regular tobacco use (>5 cigarettes/day);

- Moderate alcohol use (>10 glasses a week);

- Antibiotic use 3 months prior to the study;

- Regular use of pre- and probiotics (and within 3 months prior to the study);

- Lactose Intolerance;

- Vegan Diet;

- Diet changed drastically over the last 3 months, or planning/willing to change diet drastically in the near future;
- MRI incompatibility (unremovable metal objects in body [plates, screws, serrefines, dental plates (pontics), metal splinters, piercings or medical plasters], active implant [e.g. pacemaker, neuro stimulator, insulin pump and/or hearing aid], head operation, epilepsy, claustrophobia).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2016
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date:	02-05-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 43866
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5693
NTR-old	NTR5845
CCMO	NL55406.091.15
OMON	NL-OMON43866

Study results