

Probiotics, Brain & Behavior

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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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27864

Bron

NTR

Verkorte titel

Probiotics

Aandoening

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

Ondersteuning

Primaire sponsor: Radboud UMC Nijmegen

Overige ondersteuning: TKI LSH, Winclove Probiotics B.V.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Neurocognitive measures of emotion and executive functioning.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

E. Aarts
[default]
The Netherlands

Wetenschappelijk

E. Aarts
[default]
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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;

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksofzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-04-2016
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	02-05-2016

Soort:

Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 43866

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten