

# 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.

<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Werving gestart
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Interventie onderzoek

## Samenvatting

### ID

NL-OMON27864

### Bron

Nationaal Trial Register

### 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).

## Onderzoeksopzet

### Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	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