The impact of EcologicBarrier on neurocognitive measures of emotion & executive functioning

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To investigate the impact of the multispecies probiotic product Ecologic*Barrier on neurocognitive measures of emotion and executive functioning.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON43866

Source
ToetsingOnline

Brief title
Probiotics and Behavior

Condition

- Other condition
- Mood disorders and disturbances NEC

Synonym
not applicable

Health condition

fundamenteel onderzoek (gezonde volwassenen)

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Winclove Probiotics

Intervention

Keyword: emotion, fMRI, gut-brain axis, Probiotics

Outcome measures

Primary outcome

The effect of the intervention will be tested in terms of BOLD signal measured with functional magnetic resonance imaging (fMRI) as well as response times on the cognitive tasks during fMRI.

Secondary outcome

Secondarily, the effects of the intervention will be tested in terms of paper-and-pencil neuropsychological tests and subjective measurements (i.e. self-report questionnaires and visual analog scales), physiological measures (blood pressure and heart rate), anthropomorphic measures (BMI and waist-hip ratio), cortisol and alpha-amylase (from saliva), and relative abundance of gut microbes (from stool sample).

Study description

Background summary

Different probiotic products have been shown to be effective in different animal models of depression and anxiety. Recent human studies show that consumption of probiotics modulated brain activity, regulated cognitive reactivity, alleviated psychological distress and altered urinary cortisol levels in healthy volunteers. It becomes increasingly clear that gut microorganisms and the intestinal barrier function play an important role in gut-brain communications, which are also associated with psychiatric disorders.

Gut-brain communication seems to be an important working mechanism for probiotics. However, the effects of probiotics on neural and cognitive functioning in humans are still unclear.

Study objective

To investigate the impact of the multispecies probiotic product Ecologic*Barrier on neurocognitive measures of emotion and executive functioning.

Study design

We will use a double blind, randomized, placebo-controlled, between-subject study design. Subjects will be tested twice using fMRI, once before and once after four weeks of Ecologic*Barrier supplementation or placebo.

Intervention

For a 4-week period, subjects will receive either one daily dose of 2 grams of the multispecies probiotic product Ecologic® Barrier (Bifidobacterium bifidum W23, Bifidobacterium lactis W52, Lactobacillus acidophilus W37,Lactobacillus brevis W63, Lactobacillus casei W56,Lactobacillus salivarius W24, Lactococcus lactis W19,Lactococcus lactis W58, with a total cell count of 2.5 x 109 colony forming units (cfu) per gram, blended on a carrier material consisting of maize starch, maltodextrin, vegetable protein and a mineral mix) or 2 grams of the placebo, containing only the carrier material.

Study burden and risks

MRI does not involve any risks when precaution is taken (e.g. no pacemaker, no metal objects, etc.), which will be done by an extensive screening. The probiotic EcologicBarrier is freely available to consumers and research has shown that the risks of taking the probiotic and placebo are negligible (i.e. excellent EFSA profile).
The burden of participation consists of 2 lab visits, with 4 weeks in between: 3 hours per visit, of which 1 hour fMRI (including 30 minutes tasks) that will be followed by neuropsychological tests and questionnaires. We will also take saliva samples (5 per visit) and fecal samples (2 in total). During the intervention time period, subjects have to adhere to some simple restrictions with respect to the consumption of Ecologic*Barrier.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Females taking oral contraceptives (We will test participants in the weeks they take the pill, i.e. not in the stop week. This way, we will ensure that hormone levels are similar between the two test sessions)
• Age: 18-40 years old
• Dutch as a mother tongue
• Right-handed
• Willing to perform tasks in the MRI scanner, to come to the centre on two occasions, consuming Ecologic*Barrier (or a placebo) and willing to perform the written tests and questionnaires.
• BMI range between 18-25

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)
• Mild alcohol use (>5 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).
• regular use of supplements 3 months prior or during the to the study

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-04-2016
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	18-02-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	18-05-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 27864
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL55406.091.15
OMON	NL-OMON27864