The effect of Galacto-oligosaccharides (GOS) on self-perceived stress in apparently healthy but stressed Dutch women: randomized controlled study

Published: 31-01-2022
Last updated: 05-04-2024

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

Summary

ID

NL-OMON51276

Source
ToetsingOnline

Brief title
Prebiotics and stress reduction in women

Condition

- Other condition

Synonym
self-perceived stress, stress

Health condition

Stress

Research involving

Human

Sponsors and support

Primary sponsor: FrieslandCampina
Source(s) of monetary or material Support: door FrieslandCampina zelf

Intervention

Keyword: females, mental-welbeing, prebiotics, stress

Outcome measures

Primary outcome

To assess the effect of 28-days consumption of GOSplus on the DASS42 derived stress sub-score in a population of healthy Dutch women (25-45 years), who perceive stress on a regular basis, compared to a placebo (maltodextrin).

Secondary outcome

To assess the effect of 14 days consumption of GOSplus on the DASS42 derived stress sub-score, compared to a placebo (maltodextrin).

To assess the effect of 28- and 14-days consumption of GOSplus on the DASS42 derived anxiety sub-score, compared to a placebo (maltodextrin).

To assess the effect of 28 days consumption of GOSplus on early morning cortisol levels in saliva, compared to placebo (maltodextrin).

To assess the effect of 28- and 14-days consumption of GOSplus, or maltodextrin, on the changes (baseline versus endline) in DASS42 derived stress and anxiety sub-score, and early morning cortisol levels in saliva.

Study description

Background summary

In modern life, many people state to experience stress. Women compared to men report more and higher levels of stress. Recent research found that supplementation of galactose-oligosaccharides (GOS) resulted in reduced anxiety levels in British female students with higher anxiety scores at baseline in self-reported trait anxiety. Moreover, supplementation of probiotics in germ-free rodents resulted in reduced levels of circulating corticosterone (cortisol in humans). These findings illustrate the potential of prebiotic supplementation, through the microbiota-gut-brain (MGB) axis, to improve mental health and wellbeing.
The present study aims to study the effect of GOS and 2'-FL on self-perceived stress.

Study objective

The main objective of this study is to assess the effect of GOS in combination with 2*-FL on perceived stress. The secondary objective is to assess the effect of GOS in combination with 2-FL on saliva cortisol levels, as well as on perceived anxiety .

Study design

The study is double-blind randomized placebo controlled.

Intervention

The participants will consume GOSplus (5.0 g BiotisTMGOS + 0.5 g 2*-FL) or a placebo (5.5 g maltodextrin) daily during the first consumption moment of the day (preferably in the morning) for 28 days.

Study burden and risks

The risk for the present study is limited. The burden (filling in questionnaires and taking saliva) is very acceptable. On the other hand, if a positive effect is shown, this is a simple way to improve feelings of stress through food.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

* Apparently healthy women (based on lifestyle questionnaire)
* Moderate or high stress level; DASS42 stress sub-score *19
* Age between 25 and 45 years
* Body mass index (BMI) between 18.5 and 30 kg/m2
* Access to internet and a smart phone, and willing to install an app

Exclusion criteria

* Any metabolic, gastrointestinal, inflammatory or chronic disease
* History of gastro-intestinal surgery or having (serious) gastrointestinal discomfort
* Use of supplement to relief stress during or within 2 weeks prior to the start of the study
* Use of pre- and/or probiotics during the study (except for the study product) or within 4 weeks prior to the start of the study
* Use of medication that may influence the study results, such as laxatives
* Self-reported and/or clinical lactose intolerance
* Self-reported and/or active cow*s milk protein allergy
* Pregnant or lactating (or having the wish to become pregnant during the study period, self-reported)
* Having used antibiotics in the 6 months prior to the start of the study

* Being an employee of FrieslandCampina

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-02-2022
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	31-01-2022
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL80003.028.21

Study results

Date completed:	18-06-2022
Actual enrolment:	125