The effect of galacto-oligosaccharides on gut complaints without medical diagnosis (e.g. bloating, constipation, diarrhea) in adult women

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to assess the effect of 21 days of consumption of 5.5 g GOS powder on the gut comfort component score (based on 5 questions), as compared to a control group receiving maltodextrin (control product).

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal conditions NEC
Study type	Interventional

Summary

ID

NL-OMON50012

Source
ToetsingOnline

Brief title
Darmboost

Condition

- Gastrointestinal conditions NEC

Synonym
gut complaints

Research involving
Human

Sponsors and support

Primary sponsor: Campina

Source(s) of monetary or material Support: Frieslandcampina

Intervention

Keyword: Galacto-oligosacharides, Gastrointestinal complaints, Prebiotic

Outcome measures

Primary outcome

The primary parameter is a component score of gut comfort feelings based on 5 questions regarding bloating, flatulence, stomach ache, constipation and diarrhea of the past 7 days (each answer ranging from 0 -3; thus component score can range from 0-15).

Secondary outcome

The secondary objectives are to assess the effects of GOS on the component score of gut comfort at days 4 and 14 and the shifts in microbial composition after 21 days.

Study description

Background summary

Prebiotics are important in steering the intestinal microbiota composition, and by doing so they can play an important role in the relief of *general* gut complaints (not linked to a specific disease). Galacto-oligosaccharides (GOS) is a lactose derived prebiotic and fermented in particular by, and thus stimulating, bifidobacteria and lactobacilli. Besides a possible effect on gut complaints, emerging evidence finds a link between microbiota and brain function, known as the microbiome-gut-brain axis, affecting the regulation of the stress hormone cortisol and sleep quality. Limited studies of GOS on general gut complaints have been performed in humans, whereas the combination of gut complaints, stress and sleep probably is unique.

Study objective

to assess the effect of 21 days of consumption of 5.5 g GOS powder on the gut

comfort component score (based on 5 questions), as compared to a control group receiving maltodextrin (control product).

Study design

Double-blind placebo controlled intervention study

Intervention

The intervention group receives 5.5 g GOS in powder form. The control group receives the same amount of maltodextrin powder. Both groups need to use these powder supplements, portion packed in sachets, daily for 21 days. The powders can be added to a dairy product (e.g. yogurt, quark) or to a glass of water, tea or coffee, and have to be consumed with the first meal of the day.

Study burden and risks

The risks involved in participating in this experiment are low. The GOS and maltodextrin powders are food-grade and will be produced under Good Manufacturing Practices in certified facilities and using approved and commercially available ingredients, in amounts that have been used more often without difficulties. Next to using the powders for 21 days in their normal dietary pattern, participants are asked to fill out four times an online questionnaire each taking about 15 minutes and to collect a faecal sample at the start and at the end of the study. The total burden of these activities is low and results in important information necessary to answer our research question on self-perceived health benefits.

Contacts

Public
Campina

Bronland 20
Wageningen 6708 WH
NL
Scientific
Campina

Bronland 20
Wageningen 6708 WH
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Female
- 25 - 45 years of age
- Component (summed) score for gut complaints * 6 (based on bloating, flatulence, stomach ache, constipation, diarrhea)

Exclusion criteria

- Any medical diagnosed disease underlying gut-related complaints, including Irritable Bowel Syndrome, celiac disease, Crohn*s disease, colitis, haemorrhoids, cancer, and/or any other disease considered relevant as determined during screening.
- Use of antibiotics, opiates, anti-inflammatory drugs (NSAIDs) and/or metformin, and/or other medication that are known to affect the composition of the gut microbiota during the 14 days before inclusion.
- Pregnant or lactating.
- Self-reported lactose intolerance
- Self-reported cow*s milk protein allergy.

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):	09-01-2021
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	04-11-2020
Application type:	First submission
Review commission:	METC NedMec

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
Other	Bij akkoord registreren we het bij NTR

Register	ID
CCMO	NL73755.041.20

Study results