Effect of low dose galacto-oligosaccharides (GOS) on faecal gut microbiota in adult women

Published: 02-03-2023
Last updated: 07-04-2024

The primary objective is to investigate the effect of a 3 week intervention with either 1.,3 gram or 2 gram of GOS on the abundance of the genus Bifidobacterium in faecal samples in healthy women of 40 - 70 years old. The secondary objective is to...

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

Summary

ID

NL-OMON53648

Source
ToetsingOnline

Brief title
Denali study

Condition

- Other condition

Synonym
gut bacteria, microbiota

Health condition

n.v.t.

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: FrieslandCampina (FC C.V.)

Intervention

Keyword: GOS, microbiota

Outcome measures

Primary outcome

The main study parameter is the absolute abundance of faecal Bifidobacterium.

Secondary outcome

The secondary study parameters are faecal microbiota composition. Tertiary

Objectives are gastrointestinal (GI) comfort, sleep quality (Athens Insomnia

scale), well-being and stress (DASS-21).

Study description

Background summary

Gut microbiota homeostasis is important for maintaining overall human health. The ageing process is associated with a loss of microbiota diversity, with a reducing proportion of beneficial bacteria, including bifidobacteria. Disturbances in gut microbiota are associated with several medical conditions. Acting as substrates, prebiotics as part of a dietary habit can support the gut microbiota composition. However most of the clinical proof comes from studies done with higher dosages of prebiotics and data on the effect of low dosages are limited. Low dosages have the benefit that they can be incorporated in a tablet or capsule. Even though supplements are not a substitute for a balanced healthy diet, they might support people to fulfil the daily nutrient requirements and contribute to (gastrointestinal) health and wellbeing. Therefore, there is a need for scientifically substantiated insights into the effect of low dosages of prebiotics on the gut microbiota composition

Study objective

The primary objective is to investigate the effect of a 3 week intervention

with either 1.,3 gram or 2 gram of GOS on the abundance of the genus Bifidobacterium in faecal samples in healthy women of 40 - 70 years old. The secondary objective is to determine the effect of both interventions (dose of 2 -gram and 1.,3 -gram) on faecal microbiota composition in healthy women of 40 - 70 years old. Tertiary objective is to investigate the effect both interventions (dose of 2- gram and 1.,3 gram) on subjective measures of GI comfort, sleep quality, well-being and stress. Interest is in the within-group effects only; the two different groups will not be compared with each other.

Study design

The study has a randomized, double-blind design of 6 weeks (3 weeks control + 3 weeks intervention).

Intervention

Subjects receive 1 sachet of GOS (1.3 or 2 grams) per day. They have to dissolve this in a product of their choice (water, yogurt, milk, tea, coffee, custard) at breakfast. Subjects are instructed to dissolve the sachets in a product the are used to consume during breakfast, to avoid unintended changes in diet during the study.

Study burden and risks

Study participants have to invest about 12 hours of their time in this study mainly to complete several questionnaires (weekly online questionnaire), which is conveniently all possible from home. On three occasions they have to record their food intake in an app and to collect a faecal sample. They have to comply to consume an intervention product once a day for three weeks. Furthermore, they have to visit the Research unit twice. There are minor risks for the participants of this study (bloating and flatulence). There are no direct benefits for the participants.

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

- Apparently healthy women (based on screening questionnaire), living in the surrounding of Wageningen (+50 km)
- Aged between 40 - 70 year
- Body Mass Index (BMI) between 18,5 - 30 kg/m2

Exclusion criteria

- Having a gastro-intestinal disease, such as celiac disease, Crohn*s disease, Ulcerative colitis, or diagnosed irritable bowel disease;
- Having a history of intestinal surgery that might interfere with study outcomes. This does not include an appendectomy or cholecystectomy;
- Diagnosed with diabetes mellitus; Use of medication that may influence the study results, such as laxatives, lactase preparations, metformin, antibiotics, proton pomp inhibitors, antipsychotics, NSAID*s (judged by our research physician);
- Self-perceived or diagnosed constipation;
- Having a food allergy to cow*s milk or being lactose intolerant;
- Reported slimming, medically prescribed or other diets
- Reported weight loss or weight gain of >5kg in the month prior to screening
- Use of pre-, pro- , syn- and/or postbiotics (should be stopped at least 4 weeks before the start of the study), or other supplements that can influence the study results (to be determined by the medical investigator);
- History of side effects with the use of prebiotic supplements

- Use of antibiotic treatment less than 3 months before start of the study
- Pregnant or lactating (or having the wish to become pregnant during the study period, self-reported);
- Not able to comply with study procedures;
- Abuse of drugs (should be stopped at least 4 weeks before the study);
- Alcohol intake >=7 glasses of alcoholic beverages per week, on average
- Participation in another clinical trial at the same time;
- Being an employee of the Food, Health & Consumer Research group of Wageningen Food & Biobased Research or employee of FrieslandCampina R&D.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-03-2023
Enrollment:	88
Type:	Actual

Ethics review

Approved WMO

Date:	02-03-2023
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL81854.091.22