Gut health Enhancement by Eating Favourable Food

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

Summary

ID

NL-OMON56340

Source
ToetsingOnline

Brief title
Care about your gastrointestinal tract

Condition

- Other condition

Synonym
gut health, Microbiota

Health condition

Darmgezondheid, microbiota

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: MLDS;Cidrani;WholeFiber;KeepFoodSimple

Intervention

Keyword: Fermented food, Fiber, Gut Health, Microbiome

Outcome measures

Primary outcome

The main study parameter is the microbiota diversity index

Secondary outcome

Secondary parameters are fecal microbiota composition, 92 immune markers,

gastrointestinal complaints (bloating, flatulence and abdominal pain), stool

frequency, stool consistency, transit time, quality of life, well-being, sleep

quality, fiber intake, fermented food intake, behavioural change and awareness.

Study description

Background summary

Gut microbiome homeostasis is important for maintaining overall human health. Disturbances in the gut microbiota are associated with a number of medical conditions and chronic diseases. Many chronic diseases are driven by chronic inflammation, an immunological state that can be modulated by the gut microbiome. Diet has emerged as a driving factor in microbiota composition and function. The question remains whether there are dietary recommendations, that can leverage extant host-microbiota interactions for improved health, across broader populations.

Study objective

The primary objective is to investigate the effect of either a high fiber or fermented food intervention on the microbiota diversity indexcompared to control. Secondary objectives are the effect of either a high fiber or fermented food intervention on fecal microbiota composition, immune markers,

gastrointestinal complaints, stool pattern, transit time, Quality of Life, well-being and sleep quality. Additionally, the effect of a dietary advice using recipe booklets and daily reminders will be investigated on dietary fiber and fermented food intake and long-term behavioural change and awareness. Tertiary, we will look into the effect of a diet high in fiber and fermented food on body weight.

Study design

The study applies a randomized, parallel design of 8 weeks intervention and a follow-up after 3 months.

Intervention

The study consist of three arms: 1) an intervention high in fiber, 2) an intervention high in fermented foods, 3) a control group. All 3 arms receive a link towards the website of MLDS and Voedingscentrum, with information about diets and microbiota. The fiber arm receives 8 weeks dietary advice, based on recipe booklet. Additionally, this group receives three times a day 3.3 gram of WholeFiber product for 6 weeks (after 2 weeks ramp-up with use of the recipe booklets). The fermented food arm receives 8 weeks dietary advice, based on a recipe booklet, in which they are recommended to use 3 servings of fermented food a day. Additionally, after 2 weeks ramp-up using this recipe booklet, study participants receive three times a day 19 ml Kombucha. The control arm receives the link towards the website of MLDS and Voedingscentrum. Additionally, after 2 weeks ramp-up, they receive three times a day 3.3 gram of maltodextrin for 6 weeks.

Study burden and risks

Study participants have to invest about 30 hours of their time in this study, mainly to complete questionnaires (daily, weekly and 4 times a more extensive questionnaire). On three timepoints they need to record their food intake for 3 days and they need to collect a fecal sample and a dried blood sample via a fingerprick. Additionally, on these three timepoints study participants have to make a picture of their fecal smear and to consume two blue muffins to measure transit time. Furthermore, study participants have to consume an intervention product 3 times a day for 6 weeks and are asked to follow dietary recommendations for 8 weeks. The dietary recommendations include the consumption of recipes from a recipe booklet (fiber group), consumption of 3 serveings of fermented food a day (fermented group), visit a website of MLDS and Voedingscentrum and follow the recommendations on website (control group). There are minor risk for the participants of this study.

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

- Men and women, aged >=18 - <=70 years;
- Being able to read and speak Dutch
- Willing to keep a stable dietary pattern throughout the study;
- Having a smartphone to fill out the daily questionnaires.

Exclusion criteria

- Having a disease or medical condition which can influence the study results such as diabetes, cancer, diagnosed irritable bowel syndrome, renal disease, liver enzyme abnormality, malignant neoplasm, or a history of inflammatory diseases (such as multiple sclerosis and rheumatoid arthritis inflammatory

bowel disease);
- Having a history of intestinal surgery that might interfere with study outcomes (this does not include an appendectomy or cholecystectomy);
- Average dietary fiber intake of >=18 gram (women) or >=22 gram (men) per day, according to the fiber screen questionnaire (see F1 questionnaires);
- More than 3 servings of fermented foods per day as assessed with the fermented food frequency questionnaire (see F1 questionnaires);
- Having a BMI >= 30 (self-reported);
- Currently following a strict diet and unwilling or unable to change; for example, a gluten free diet or a *crash diet* using meal substitutes;
- Specific food allergies that interfere with dietary intervention (for example, gluten, lactose, etc);
- Use of prebiotics, probiotics and/or synbiotics (this should be stopped 4 week before the start of the study) and use of fiber supplements;
- Use of antibiotic treatment less than 3 months before start of the study and/or use of antibiotics during the study;
- Use of medication that can interfere with the study outcomes, as judged by the medical supervisor;
- Alcoholic use of >=14 (women) or >=28 (men) glasses of alcoholic beverages per week;
- Use of drugs (should be stopped at least 4 weeks before start of the study);
- Being pregnant or lactating;
- Participation in another clinical trial at the same time;
- Student or employee working at either Food, Health and Consumer Research from Wageningen Food and Biobased Research, Microbiology at VU, the MLDS, at Whole Fibre, Keep Food Simple or at Cidrani;
- Unable to follow or comply to study rules

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-05-2023
Enrollment:	147
Type:	Actual

Ethics review

Approved WMO Date:	14-03-2023
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	25-05-2023
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	24-11-2023
Application type:	Amendment
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	NL83652.028.23