The effect of wheat fiber on increase of fecal bulk

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Investigate if an increased consumption of VITACEL Wheat Fiber can enhance fecal bulk. Furthermore, we want to demonstrate that the increased consumption of wheat fiber can increase stool frequency and consistency.

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

Summary

ID

NL-OMON44243

Source
ToetsingOnline

Brief title
FIBER study: Fiber Intake & fecal Bulk Enhanced Response

Condition

- Other condition
- Gastrointestinal motility and defaecation conditions

Synonym
improvement bowel function and defecation

Health condition

het gaat hier niet zozeer om aandoeningen aan het maag-/darmstelsel, maar de interventie is gericht op het verbeteren van de stoelgang

Research involving
Human

Sponsors and support

Primary sponsor: J.Rettenmaier & Sohne GmbH & Co.KG
Source(s) of monetary or material Support: J. Rettenmaier & Sohne GmbH & Co KG

Intervention

Keyword: fecal bulk, gastrointestinal functioning, wheat fiber

Outcome measures

Primary outcome

The primairy study parameter is change in fecal bulk between a *low fiber*

intervention (with control products) and the wheat fiber enriched product

intervention.

Secondary outcome

Secondary parameters are stool consistency, gut-related complaints (e.g. stool

frequency, bloating, flatulence), appetite/satiety and food liking.

Study description

Background summary

Dietary fibre intake of the general population is much lower than recommended, while consumption of fibres has many health benefits. Some dietary fibres, including wheat fibres, have shown to increase fecal bulk and improve stool. In previous studies, this effect on fecal bulk was especially studied for intact wheat fibers. Moreover, in most studies, the wheat fiber was offered daily as a single dose in cereals. In this study, we investigate whether an increased intake of extracted wheat fiber (VITACEL Wheat Fiber, supplied by J. Rettenmaier & Sohne GmbH & Co. KG), implemented at several time points in a normal daily dietary pattern, can also increase fecal bulk and improve stool frequency and consistency. VITACEL Wheat Fiber can be easily incorporated in many food products, which might make it easier for the general population to increase their dietary fibre intake, and subsequently improve their intestinal health.

Study objective

Investigate if an increased consumption of VITACEL Wheat Fiber can enhance fecal bulk. Furthermore, we want to demonstrate that the increased consumption of wheat fiber can increase stool frequency and consistency.

Study design

The study is a double-blind crossover design in which participants receive products enriched with VITACEL Wheat Fiber and control products. The intervention products have almost identical taste, appearance and caloric values. Both intervention periods are10 days with a wash-out period of at least 4 days.

Intervention

Subjects will be randomly assigned to the intervention groups; (*control * *fiber-enriched OR *fiber-enriched * *control). In one of the intervention periods participants receive *control boxes* with products low in wheat fiber and in the other period they will receive boxes with products enriched with VITACEL Wheat Fiber. During an intervention period of 10 days participants will receive 10 boxes, one for each day, and they can choose themselves which box they want on which day, except for day 1 and 2 (due to step-wise increase of fiber intake). In the last 5 days of the intervention + 1 additional day after the intervention (so in total 6 days), participants will collect their fecal samples to analyse fecal bulk. Subjects will also keep a daily diary and fill in questionnaires to check compliance to the intervention, to assess stool consistency, gut-related complaints (e.g. stool frequency, bloating, flatulence), appetite/satiety and food liking.

Study burden and risks

Participants only have to visit the research facility to collect the food products, hand in collected fecal samples and have a final meeting with the study MD. Most fecal samples will be collected at their houses to limit the number of visits to the research facility. Consumption of the foods and fecal collection will take place at home. Participants need keep a diary and fill in questionnaires to report compliance and assess stool consistency, gut-related complaints (e.g. stool frequency, bloating, flatulence), appetite/satiety and food liking. Fiber intake will be gradually increase in the high fibre intervention in order to addapt. No significant adverse effects from the fiber-enriched diet are expected. Altogether, it is concluded that the risks for the participants is negligible and the burdens are minimal. The increase intake of fibre may even improve bowel function of some subjects. The FIBER study is not group related.

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

- Male
- Apparently healthy
- Age range between 18-70 years old
- BMI between 20 and 30 kg/m2
- Average fiber intake of 12-18 grams per day
- Living in the surrounding area of Wageningen (radius ~20 km)

Exclusion criteria

- Any digestive tract disorder that is expected to interfere with this study (e.g. (partial) gastric resection, (hemi)colectomy, Crohn*s disease, ulcerative colitis, irritable bowel

disease, Coeliac disease)
- Known food allergy (e.g. lactose, gluten, nuts, egg, etc)
- Vegetarians
- Use of pro- or prebiotics
- Use of medication that can interfere with study outcomes (including laxatives, diuretics, antidepressants, codeine or antibiotics)
- Alcohol intake * 40g/day (* 3 glasses of beer/wine per day)
- Drug abuse
- Current smokers
- Participation in other clinical trials in the past month

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-10-2017
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO

Date:	07-09-2017
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

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	NL62342.081.17