The impact of a dried vegetable on bowel function and gut microbiota in subjects with bowel function issues

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON53536

Source
ToetsingOnline

Brief title
Impact of a dried vegetable on bowel function and gut microbiota

Condition

- Other condition

Synonym
bowel function issues, defecation problems, difficulty to have bowel movements

Health condition

niet medische problemen met darmfunctie (stoelgang)

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Bowel function, Dietary fiber, Gut microbiota

Outcome measures

Primary outcome

To compare four-week differences in bowel function assessed by stool frequency, stool consistency, ease of defecation, feeling of incomplete bowel emptying and bowel habit satisfaction between subjects with bowel function issues consuming either 15 g/day dried chicory root particles or placebo (rice puff crisp particles).

Secondary outcome

To compare four-week differences in bowel function assessed by stool frequency, stool consistency, ease of defecation, feeling of incomplete bowel emptying and bowel habit satisfaction and gut microbiota and its activity, quality of life, constipation symptom assessment between subjects with bowel function issues consuming three different dosages dried chicory root particles or placebo (rice puff particles). Furthermore, to compare four-week evolution of bowel function, gut microbiota and its activity over time in subjects with bowel function issues consuming dried chicory root particles or placebo.

Study description

Background summary

Bowel function issues can have a substantial effect on quality of life. Additional fibre intake might modulate bowel function and gut microbiota, thereby increasing stool frequency and consistency. This could improve defecation ease, feeling of incomplete bowel emptying and bowel function satisfaction. We hypothesize that a dried vegetable, that is naturally high in fibre within plant cells could improve bowel function in subjects with bowel function issues.

Study objective

The main objective of the study is to assess whether a dried multifibre vegetable improves bowel function assessed by stool frequency, consistency, defecation ease, feeling of incomplete bowel emptying and satisfaction. Secondary objectives are to assess whether these effects are dose-dependent and associated with the modulation of the gut microbiota and activity. Furthermore, the adaption of bowel function and adaptation of the gut microbiota and activity over time will be analysed.

Study design

A parallel, randomized, double-blind, placebo-controlled trial of four weeks with one placebo control and three intervention arms that differ in intervention product dose.

Intervention

A vegetable product consisting of dried chicory root cubes containing 85% dietary fibre is added to the daily diet. The intervention product is consumed twice daily for four weeks with a maximum dose of 15 g/day. The control (placebo) consists of easily digestible rice puff pieces and is consumed in the same manner as the intervention.

Study burden and risks

The intervention is therapeutic for three-quarters of the subjects and non-therapeutic for the remaining quarter (placebo). Subjects will consume the product split into two daily portions and monitor their bowel functions daily by means of a short questionnaire while maintaining their habitual diet and lifestyle. Subjects will collect a weekly faecal sample (5x), fill in twice two retrospective questionnaires on quality of life and constipation symptom assessment, fill in once a short questionnaire about their fiber intake and twice a three-day food recall (begin and end of study). In case the current COVID-19 circumstances allow it, subjects may be offered to come to the research facility to explain all study procedures and for product pick-up - alternatively, information will be given online and the product will be sent by mail. Possible risks relate to eventual changes in side-effects generally

associated with changes in fibre intake (e.g., bloating, flatulence etc). Yet, these risks are expected to be minimal due to the consumption of the vegetable product split into two daily portions and, if symptoms occur, cessation of these symptoms is expected over the course of the study due to the adaptation of the gut to the increased fibre intake. Hence, the risk associated with participation and the burden is minimal.

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

• 20 - 80 years old
• Unsatisfied with bowel habits (self-reported), rated on a visual analogue scale (VAS, 0-10) as <6 AND
• Four or less bowel movements per week AND/OR

• Hard, lumpy or solid stools (Bristol stool form 1-4) during at least 90% of the bowel movements
• Able to speak and understand Dutch or English

Exclusion criteria

• Having a history of medical or surgical events that may significantly affect the study outcome: IBS or IBD patients and subjects with medically diagnosed constipation (i.e. constipation related to anatomic, medication-related, or readily identifiable physiological causes.)
• Less than one bowel movement per week during the screening period.
• Medical drug use:
o Antibiotic use within 3 months of the screening
o Chronic use of antacids and PPI*s
o Use of laxatives 1 month during the screening
o Chronic use of blood glucose lowering medication
• Consumption of supplements containing fibres (other than laxatives), pro-/ post-/ synbiotics 1 month before the screening
• Unable to comply with proper study procedures
• Not willing to provide faecal samples
• For women of childbearing age: current or planned pregnancy, lactation
• Known allergic reactions to plants from the Asteraceae (Compositae) family (e.g. lettuce, daisies, sunflowers, artichokes, sage, tarragon, chamomile, chicory etc.)
• Reported unexplained weight loss or weight gain of > 5 kg in the month prior to screening
• Reported slimming or medically prescribed diet or macrobiotic life-style
• Personnel the Division of Human Nutrition & Health or the Laboratory of Microbiology
• Current participation in other medical scientific research
• Not having a general practitioner
• Not willing to be informed about accidental discoveries in relation to the subjects health

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:	Recruiting
Start date (anticipated):	22-08-2022
Enrollment:	160
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	16-05-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-12-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-05-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-02-2024
Application type:	Amendment
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	NL80274.091.22
Other	registratie in clinicaltrial.gov NCT05473793