Improving constipation by stimulating fiber intake using personalized dietary advice

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To investigate the effectiveness of personalized dietary advice (PDA) in reducing constipation-related complaints, by increasing dietary fiber intake in people with constipation.

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

Summary

ID

NL-OMON49152

Source
ToetsingOnline

Brief title
PAC-study

Condition

- Gastrointestinal conditions NEC

Synonym
obstipation

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Bolletje,Kelloggs,Maag Lever Darm Stichting,MLDS subsidie en Topsector voor Kennis en Innovatie (TKI),Roquette,Sonneveld

Intervention

Keyword: Constipation, Dietary fiber, Personalized Advice

Outcome measures

Primary outcome

primary outcomes are stool pattern, gastro-intestinal complaints and constipation quality of life and severity.

Secondary outcome

Secondary parameters include dietary fiber intake, physical activity, body weight, psychological questionnaires, and fecal microbiota composition and metabolite levels. Furthermore, the PDA will be evaluated.

Study description

Background summary

constipation is prevalent in 5-20% of the population. Dietary fibers play a crucial role in improving and maintaining gut health, increasing stool weight, stool frequency and improvement of stool consistency. Currently, very few adults meet the recommendation of 30 (females) or 40 (males) grams of fiber per day. Personalized dietary advice may be the solution to increase dietary fiber intake and reduce constipation-related complaints in large populations.

Study objective

To investigate the effectiveness of personalized dietary advice (PDA) in reducing constipation-related complaints, by increasing dietary fiber intake in people with constipation.

Study design

This study has a one-group pre-test post-test design with a run-in period. The duration of the study is 8 weeks, which includes a 4-week run-in phase and a 4-week intervention period. All subjects receive the PDA.

Intervention

personalized advice based on their habitual food pattern (as assessed using a food frequency questionnaire) and preferences. Based on a special algorithm, the PDA provides high fiber alternatives for low-fiber products that subjects currently use, close to their current eating behavior, to help increase dietary fiber intake. This PDA will be provided using an online web-portal.

Study burden and risks

This study has a negligible risk for subjects, and the burden of the study is in line with possible gains for the subjects. The PDA follows the national dietary guidelines from the Netherlands Nutrition Center and is based on personal preferences and habitual dietary intake. Moreover, all foods and drinks that are advised as fiber-rich alternatives are commercially available, and therefore safe for consumption. Subjects will be guided to increase dietary fiber intake gradually, and are advised to drink plenty of water and exercise regularly, which is in accordance to the guideline for treating constipation.

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

- Age *18 years and <55 years.
- BMI < 30 kg/m2
- Has constipation-related complaints. For our study, subjects has to fulfill the following criterion: response <6 to the question *how satisfied are you with your stool pattern*, which is rated on a visual analog scale (VAS) from 1-10, together with at least one of the following criteria:
1. Habitual stool form of Bristol stool type 1-4 or
2. *4 defecations per week
Note: these criteria are less stringent than the official *constipation* definition [35], because we preferably want to include participants that do not use laxatives (yet), and we assume that in this *mild constipation* group increasing fiber intake can have the most beneficial effects. Moreover, we chose not to use the Rome IV criteria as definition of constipation-related complaints, due to the proven inability to distinguish functional constipation from Irritable Bowel Syndrome [2]. If there are sufficient eligible participants, the participants with the lowest stool frequency will be selected.
- Relatively low fiber intake, for females <26 grams and males <33 grams, as assessed by a fiber screening questionnaire which was validated in the previous study. When enough eligible participants are available, we will choose the participants with the lowest dietary fiber intake.
- Living in the surroundings of Wageningen (max. 50 km). Subjects have to visit the research facilities of Human Nutrition a few times for weighing and to drop-off of fecal samples, therefore it is logistically not feasible if subjects life far away. If recruitment is unsuccessful, subjects who live further away will be included and samples will then be collected by researchers or by a parcel service.
- In possession of computer (with Chrome browser available) for the PDA, and a mobile phone with android *4.4 or iOS system *9 to use apps. In general, phones which are bought *2013 are compatible with the apps. And independently able to install applications on a phone and log-in on to a website, with the use of a manual and video provided by the researchers.
- Signed informed consent.

Exclusion criteria

- Subjects with a disease that may interfere with the personal dietary advice

or outcomes, such as a known autonomic disorder, inflammatory bowel disease, coeliac disease, cancer, dialysis patients, chronic kidney failure, depression or hypothyroidism.
- Currently following strict diet and unwilling or unable to change; for example a gluten free diet or a *crash diet* using meal substitutes.
- Use of medication that can interfere with the study outcomes, including diuretics, antidepressants, codeine, antibiotics or fiber supplements. Preferably laxative use is excluded, but if recruitment is hurdled by this, we at least exclude specific laxatives like resolor, relistor and constella. These are laxatives who have a significant impact on bowel movements, and are only available on prescription. Osmotic (over the counter available) laxatives will be included if recruitment is difficult. Subjects will then be asked to keep their laxative use stable or reduce, but not to increase usage from their habitual pattern (unless necessary, but then report it to the researchers). Moreover, additional questions regarding laxative usage will be included to estimate the effect of laxatives on stool pattern.
- Female subjects: currently pregnant or breastfeeding, or intending to become pregnant during the study, as this can affect stool patterns and wellbeing.
- Are simultaneously participating in another study.
- Unwilling or unable to fulfil the study criteria.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-08-2020
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO Date:	13-05-2020
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	18-05-2020
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	02-07-2020
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	NL73256.028.20