

Stimulating fiber intake by personalized dietary advice

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To investigate if a personalized dietary advice is more effective in increasing dietary fiber intake in the Dutch population than the general advice that is currently provided by the Netherlands Nutrition center and the Dutch Digestive Foundation (...)

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

Summary

ID

NL-OMON45882

Source

ToetsingOnline

Brief title

Vezel_UP

Condition

- Other condition
- Gastrointestinal conditions NEC

Synonym

nvt

Health condition

In ogenschijnlijk gezonde mensen (met een lage vezelinname) wordt gekeken of gepersonaliseerd voedingsadvies daadwerkelijk leidt tot een verhoogde vezelinname. Daaraan gekoppeld wordt gekeken of stoelgang en welbevinden verbetert, maar dit zijn niet de primaire uitkomstmaten.

Research involving

Human

Sponsors and support

Primary sponsor: Wageningen Universiteit

Source(s) of monetary or material Support: Bolletje, Kellogg, Maag Lever Darm Stichting, MLDS subsidie en Topsector voor Kennis & Innovatie (TKI), Sensus, Sonneveld

Intervention

Keyword: fiber intake, perceived wellbeing, personalized dietary advice, stool pattern

Outcome measures

Primary outcome

Primary endpoint is dietary fiber intake, which will be assessed using an Food Frequency Questionnaire and 24hr recalls. Fecal microbiota composition and metabolite levels will be used as an objective marker for fiber intake.

Secondary outcome

Secondary parameters include stool pattern, well-being, hunger, satiety and body weight. Furthermore, psychological measurements will give insight into why the PDA was (not) effective.

Study description

Background summary

Dietary fibers are linked to improved health and prevention of diseases such as obesity, stroke, hypertension, diabetes and colorectal cancer. Moreover, fibers play a crucial role in improving and maintaining gut health, by increasing stool weight, stool frequency and improvement of stool consistency. Currently, very few adults meet the recommendation of 30 (females) or 40 (males) grams per day. Personalized dietary advice may be the solution to increase dietary fiber intake in large populations.

Study objective

To investigate if a personalized dietary advice is more effective in increasing dietary fiber intake in the Dutch population than the general advice that is currently provided by the Netherlands Nutrition center and the Dutch Digestive Foundation (MLDS). Second, to assess the effect of increased fiber intake on stool pattern, perceived well-being and consumer behavior parameters and the role of psychological factors in the effectiveness of personalized dietary advice on dietary fiber intake.

Study design

A 4.5-month (6 weeks intervention + follow-up after 3 months) single-blind randomized controlled trial with two groups: the intervention group, which receives personalized dietary advice (PDA), and the control group, which only receives the general dietary advice.

Intervention

The intervention group receives personalized dietary advice (PDA) based on their current food pattern, preferences and self-regulation capacity. The PDA aims to compute high-fiber alternatives for products that subjects currently use and that are close to their current eating behavior, to help increase dietary fiber intake. This PDA will be provided using an online web-portal. The control group only receives a general dietary advice, e.g. (a) flyer(s) containing information on fibers from the Netherlands Nutrition Center and the MLDS. The intervention group will also receive this general advice next to the PDA.

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 aims to follow the national dietary guidelines from the Netherlands Nutrition Center and is based on personal preferences. Moreover, all foods and drinks that are advised as fiber-rich alternatives are commercially available, and therefore safe for consumption.

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.
- Apparently healthy: no gastrointestinal complaints, no food allergies and no medication that can influence the outcome of the study (see exclusion criteria).
- Relatively low fiber intake: which is assessed by a short fiber intake screening questionnaire (score ranging from 1 to 22). Females with a score ≥13 and males with a score ≥15 will be included in the study.
- Living in the surroundings of Wageningen (max. 50 km).
- In possession of a mobile phone with android ≥4.4 or iOS system ≥9 to use apps.
- Signed informed consent.

Exclusion criteria

- Any digestive tract disorder that is expected to interfere with the study outcomes, such as chronic constipation or diarrhea, Crohn's Disease, Ulcerative Colitis, Irritable Bowel Syndrome, Coeliac disease.
- Diagnosis of Diabetes Mellitus, since the change in carbohydrate intake may interfere with medication usage.
- Currently following a 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 laxatives, diuretics,

antidepressants, codeine, antibiotics or fiber supplements

- Female subjects: currently pregnant or breastfeeding, or intending to become pregnant during the study, as this can affect stool patterns and well-being.
- Simultaneously participating in another study.
- Unwilling or unable to fulfill the study criteria.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2019
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO	
Date:	18-01-2019
Application type:	First submission
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	NL67998.028.18