

Prebiotic fibre study

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Dietary fibre intake provides many health benefits. A sufficient or generous intake of dietary fibre reduces the risk for developing coronary heart disease, stroke, hypertension, diabetes, obesity and certain gastro-intestinal disorders. Increased...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23115

Bron

Nationaal Trial Register

Aandoening

Obesity, Gastrointestinal Health, Metabolic Health

Ondersteuning

Primaire sponsor: Maastricht University

Overige ondersteuning: na

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Whole gut transit time

Toelichting onderzoek

Doel van het onderzoek

Dietary fibre intake provides many health benefits. A sufficient or generous intake of dietary fibre reduces the risk for developing coronary heart disease, stroke, hypertension, diabetes, obesity and certain gastro-intestinal disorders. Increased consumption of dietary fibre has been shown to improve serum lipid concentrations, reduced blood pressure, improve blood glucose control in diabetes, promotes regularity, helps in losing weight and improves immune function [1]. The most pronounced effect of dietary fibers is on gastrointestinal transit (GI) time and fecal bulking, attributed mostly to insoluble, non-fermentable dietary fibers such as wheat bran. GI transit is an important parameter of gut health relevant for many physiological and metabolic processes. Other dietary fibers such as soluble and fermentable fibers function as prebiotics, which are fermented in the colon and thus positively affect microbiota composition and activity. However, little is known about effect of prebiotic fibers on gastrointestinal transit and the metabolic consequences. Additionally, potential shifts in the microbiome have not been evaluated at a large scale with 'state-of the art' metagenomic profiling techniques. In this study, we investigate the effect of prebiotic fiber arabinoxylan-oligosaccharides (AXOS) on gastrointestinal transit time and markers of gut health and relate them to the metabolic parameters. Integrating gut physiology and microbiome with host parameters of systemic inflammation, glucose, lipid and energy metabolism would yield unique new insights that may hold great relevance in the prevention of chronic metabolic diseases. This is of particular relevance for the wheat bran derived arabinoxylans, which have been reported to have a distinct effect on short chain fatty acid (SCFA) production by the microbiota, and affect satiety and glycemic and insulinemic profiles in the human host.

Onderzoeksopzet

Markers of metabolic health

Onderzoeksproduct en/of interventie

1. Wheat-derived, Arabinoxylan-oligosaccharides (AXOS)

15g/day ingested with the meals (5 g in beverage, to be consumed three times a day)

2. Placebo: maltodextrin

15g/day ingested with the meals (5 g in beverage, to be consumed three times a day)

Contactpersonen

Publiek

Muller

Wetenschappelijk

Muller
Maastricht
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Overweight to obese men and women (BMI $\geq$ 25 kg/m² <35 kg/m²)

- Aged 20-50 years
- Caucasian
- Normal fasting glucose (<6.1 mmol/L.)
- Normal blood pressure (systolic blood pressure 100-140 mmHg, diastolic blood pressure 60-90 mmHg)
- Weight stable in last 3 months ($\pm$ 2 kg)
- A low defecation frequency, <3 times/week and no constipation or underlying pathology, as determined by gastro-intestinal questionnaires).
- A low whole gut transit

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

4.3 Exclusion criteria

- Woman lactating, pregnant (where pregnancy is defined as the state of a female after conception and until the termination of gestation, confirmed by a positive hCG laboratory test) or (post)-menopausal
- Regular smokers

- People with intensive fitness training, eg. athletes (≥ 3 per week ≥ 1 hour training)
- Diabetes Mellitus (defined as FPG ≥ 7.0 mmol/l and or 2h PG ≥ 11.1 mmol/l)
- Gastro-intestinal diseases or abdominal surgery, cardiovascular diseases, cancer, liver or kidney malfunctioning (determined based on ALAT and creatinine levels, respectively) disease with a life expectation shorter than 5 years
- Following a hypocaloric diet
- Gluten intolerance
- Regular use of laxation products, or use of antibiotics, probiotics or prebiotics 3 months prior to the start of the study
- More than 2 symptoms occurring over a period of 12 weeks in the preceding 12 months such as
 - (1) Straining in $>1/4$ defecations;
 - (2) Lumpy or hard stools in $>1/4$ defecations;
 - (3) Sensation of incomplete evacuation in $>1/4$ defecations;
 - (4) Sensation of anorectal obstruction/blockade in $>1/4$ defecations
 - (5) Manual maneuvers to facilitate $>1/4$ defecations (e.g., digital evacuation, support of the pelvic floor); and/or
 - (6) <3 defecations/week
- Current use of medication interfering with study intervention or interfering with study endpoints/hypotheses
- Not to be able to understand the study information
- Blood donation 2 months prior to the study and during the study
- Participation in other studies

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2015
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing	
Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 42114
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4847
NTR-old	NTR5102

Register

CCMO

OMON

ID

NL52300.068.15

NL-OMON42114

Resultaten