The impact of a dried vegetable fiber on glucose metabolism and microbiota composition

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To study the effect of WF Fiber on insulin resistance and (continuous) glucose metabolism and potential underlying mechanisms, body weight and waist circumference, microbiota composition and fasting GLP1/PYY/SCFA, in subjects with pre-diabetes.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON46810

Source
ToetsingOnline

Brief title
VEZEL study

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Glucose metabolism

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Ministerie van OC&W,WholeFiber INC, levert het product gratis maar draagt verder niet financieel bij

Intervention

Keyword: fiber, glucose, inulin, microbiome

Outcome measures

Primary outcome

Changes in fasting insulin and HOMA-ir (a markers of insulin resistance) are

the primary outcomes of the study.

Secondary outcome

Changes in mean glucose and glycemic variability (CGM), body weight, waist

circumference, microbiota composition, breath hydrogen and GLP-1/PYY and SCFA

are the secondary outcomes.

Study description

Background summary

Dietary fiber is usually lower than recommended and dried vegetable can be a useful additional source. This may improve glucose metabolism by changes in microbiota composition.

Study objective

To study the effect of WF Fiber on insulin resistance and (continuous) glucose metabolism and potential underlying mechanisms, body weight and waist circumference, microbiota composition and fasting GLP1/PYY/SCFA, in subjects with pre-diabetes.

Study design

Single-blind randomized controlled parallel study.

Intervention

One group receives daily a dose of 30g of WholeFiber (WF fiber) and the other group 16g maltodextrin (placebo) for 21 days. Before that time a 2 week run-in

on half the dose wil take place.

Study burden and risks

The intervention is therapeutic to the participant of the intervention group, and non-therpaeutic to the control group. The risk associated with the participation is negligible and the burden can be considered as minimal. At screening the following measurements and questionnaires will be taken: inclusion and diabetes risk score questionnaire (1x), food frequency questionnaire for dietary fiber (1x), height (1x), weight (1x), fasting blood glucose (finger prick) and a breath sample for H2 (1x). During the intervention period over 3 weeks, with an additional 2 week run-in period and a 2 week wash-out period, subjects will take dietary supplements on the morning of each day of the intervention period, and come to the university on 3 occasions. During this 7 week period the following measurements will be taken: body weight (3x), fasting blood sample (2x), fasting breath sample (2x), continuous glucose monitoring (28 days), faecal samples (4x), well-being diary (49 days).

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/Female
* Age 40-75 yr
* Fasting blood glucose between 5.6 and 6.9 mmol/L (pre-diabetes according to American Diabetes Association 2016)
* Or fasting blood glucose between 5.0 and 5.6 mmol/L and diabetes risk score (DRS) * 9.

Exclusion criteria

* Having a history of medical or surgical events that may significantly affect the study outcome (IBS or IBD)
* Having Diabetes
* Medical drug use: for diabetes
* Medical drug use: antibiotic use within 3 months of the study start or chronic use of antacids
* Mental status that is incompatible with the proper conduct of the study
* Reported unexplained weight loss or weight gain of > 5 kg in the month prior to pre-study screening
* Reported slimming or medically prescribed diet
* Reported vegetarian, vegan or macrobiotic life-style
* Consumption of pre-probiotics or fibre supplements
* Sensitive to medical skin adhesives;* Recent blood donation (<1 month prior to Day 01 of the study)
* Not willing or afraid to give up blood donation during the study
* Personnel of Wageningen University, department of Human Nutrition, their partner and their first and second degree relatives
* Current participation in other research from the Division of Human Nutrition
* Not having a general practitioner

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-05-2018
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	27-03-2018
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	28-08-2018
Application type:	Amendment
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	NL63551.081.17