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# Impact of dried vegetable fibre on sugar metabolism and gut bacteria

**Submission date**
14/05/2019

**Recruitment status**
No longer recruiting

**Registration date**
22/07/2019

**Overall study status**
Completed

**Last Edited**
12/08/2022

**Condition category**
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Obesity and type 2 diabetes mellitus (T2DM) are worldwide expected to rise exponentially, with increasing health care costs and reduction in life expectancy and quality of life. Several observational studies have shown that people with a higher fibre intake have a reduced risk of developing obesity, and T2DM. The bacteria in the gut may play an important role. Gut bacteria use dietary fibre as food source. They ferment fibre and thereby produce a variety of components that can positively influence sugar metabolism e.g. by secreting gut hormones or insulin from the pancreas. Despite national recommendations to increase vegetable and fruit intake and intake of wholegrain foods, the habitual intake of dietary fibre is still low in the Netherlands (20-25 g/d compared to 35 g/d or more recommended) as well as in many other Western countries. The aim of this study is to show whether WholeFiber™, a product with very high fermentable fibre levels, can affect insulin resistance, continuous glucose metabolism and /or the microbiome during a three-week period in people with an increased risk of developing T2DM.

Who can participate?
People aged 40-75 with an increased risk of developing T2DM

What does the study involve?
Participants are randomly allocated to consume either 30 g of dried vegetable fibre (WholeFiber™) daily or 16 g of control carbohydrate (maltodextrin) daily. To reduce potential side effects, the study starts with a 2 week run-in period during which half of the dose is taken. Afterwards the participants take the full dose for 3 weeks (21 days). There are three study visits at the start, the end of the run-in period (2 weeks later) and the end of the intervention (5 weeks after baseline). At the start and end of the intervention a venous blood sample of 15 mL is taken. During the run-in and the intervention a Continuous Glucose Measuring System is worn. At the start and the end of each period (run-in, intervention, wash-out) a faecal sample of 1mL is taken. Moreover participants are asked to fill in a well-being diary to note possible gastrointestinal side-effects during the whole period (7 weeks). Participants are also asked to fill in a Food Frequency Questionnaire at the start of the study.

What are the possible benefits and risks of participating?
There are no known and potential risks.

Where is the study run from?
Wageningen University (Netherlands)

When is the study starting and how long is it expected to run for?
May 2018 to November 2018

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
1. Marie-Luise Puhlmann
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2. Edith J. M. Feskens
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# Contact information

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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
NL63551.081.17

## Study information

### Scientific Title
The impact of a dried vegetable fibre on glucose metabolism and gut microbiota composition

### Acronym
VEZEL

### Study objectives
The objective of the VEZEL study is to study the effect of a dried vegetable fibre (WholeFiber™) on insulin resistance, (continuous) glucose metabolism, body weight, waist circumference, microbiota composition and breath hydrogen in subjects with pre-diabetes.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 27/03/2018, Medisch Ethische Toetsingscommissie van Wageningen University (METC-WU) (Wageningen Universiteit, Afdeling Humane Voeding, METC-WU secretariaat, t.a.v. Mevr. dr. C. Dullemeijer, Gebouw Helix - kamer 1.063, Stippeneng 4, 6708 WE Wageningen; Tel: +31 (0)317 485 603; Email: hne.metc@wur.nl), ref: NL63551.081.17 METC nr. 17/25

### Study design
Single-centre randomised placebo-controlled parallel trial

### Primary study design
Interventional

### Secondary study design
Randomised parallel trial

### Study setting(s)
Other

### Study type(s)
Prevention

### Participant information sheet

Not available in web format, please use contact details to request a participant infomration sheet.

## Health condition(s) or problem(s) studied
Prediabetes, increased risk to develop diabetes

## Interventions
Subjects were stratified to sex and fasting blood glucose group (between 5.6 and 6.9 mmol/L or between 5.0 and 5.6 mmol/L) and within these strata subjects were randomly assigned to arm A or B. Randomisation was performed using a random number generator by a researcher unrelated to the study. The treatment was 30 g of dried vegetable fibre (WholeFiber™) daily and the placebo was 16 g of control carbohydrate (maltodextrin, in iso-caloric amount) daily.

The study was carried out as if it was double-blinded. However, the products were not alike in particle size and taste and, hence, blinding from the participant side wasn't guaranteed. Therefore, even though participants and researcher were blinded to who received the intervention/control, it is more justifiable to call the study "single-blinded". To reduce potential gastrointestinal side effects of WF, the study started with a 2 week run-in period during which half of the dose of the treatment or the placebo was taken. Thereafter the participants took the full dose, treatment 30 g and placebo 16 g, for 3 weeks (21 days).

## Intervention Type
Supplement

## Primary outcome measure
Fasting insulin measured in EDTA plasma using ELISA, and HOMA-ir calculated using software from Matthews et al. (1985) (https://www.dtu.ox.ac.uk/homacalculator), at baseline and at end of intervention period, i.e. after 5 weeks (2 weeks run-in and 3 weeks intervention)

## Secondary outcome measures
1. Mean glucose and glycaemic variability measured using continuous glucose monitoring (FreeStyle Libre) for 14 days during baseline and run-in and again 14 days during the intervention (first two weeks of three weeks intervention)
2. Fasting GLP-1/PYY level in aprotinin plasma with DPP4-inhibitor measured using ELISA at baseline and at end of the intervention period, i.e. after 5 weeks (2 weeks run-in and 3 weeks intervention)
3. Fasting breath hydrogen measured using Quintron Microanalyzer at baseline and at end of the intervention period, i.e. after 5 weeks (2 weeks run-in and 3 weeks intervention)
4. Body weight measured using a digital weighing scale to the nearest 0.1 kg, and waist circumference measured using a measuring tape to the nearest 0.5 cm, at baseline, at the end of the run-in (after 2 weeks) and at the end of the intervention (after 5 weeks from baseline)
5. Microbiota composition measured using DNA extraction and 16s RNA gene sequencing at baseline, at the end of the run-in (after 2 weeks) and at the end of the intervention (after 5 weeks from baseline) and after a wash-out period (7 weeks after baseline)
6. SCFA measured in faeces using HPLC at baseline, at the end of the run-in (after 2 weeks) and at the end of the intervention (after 5 weeks from baseline) and after a wash-out period (7 weeks after baseline)

## Overall study start date
09/05/2018

### Completion date
26/11/2018

# Eligibility

### Key inclusion criteria
1. Age 40-75 years
2. 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

### Participant type(s)
Healthy volunteer

### Age group
Mixed

### Sex
Both

### Target number of participants
60 (30 per arm)

### Total final enrolment
55

### Key exclusion criteria
1. Having a history of medical or surgical events that may significantly affect the study outcome: IBS or IBD patients
2. Medical drug use: for diabetes
3. Medical drug use: antibiotic use within 3 months of the study screenings day or chronic use of antacids
4. Mental status that is incompatible with the proper conduct of the study
5. Reported unexplained weight loss or weight gain of > 5 kg in the month prior to pre-study screening
6. Reported slimming or medically prescribed diet
7. Reported vegan or macrobiotic lifestyle
8. Consumption of pre-probiotics or fibre supplements as of 1 month before the screening
9. Sensitive to medical skin adhesives
10. Not willing or afraid to give a blood donation during the study
11. Personnel of Wageningen University, Department of Human Nutrition, their partner and their first-degree relatives
12. Current participation in other research from the Division of Human Nutrition
13. Not having a general practitioner

### Date of first enrolment
23/05/2018

### Date of final enrolment
01/10/2018

# Locations

### Countries of recruitment
Netherlands

### Study participating centre
**Wageningen University**
Department of Human Nutrition
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# Sponsor information

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Wageningen University (WU) Division of Human Nutrition (Bode 62)

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### Sponsor type
University/education

### Website
https://www.wur.nl/en/Research-Results/Chair-groups/Agrotechnology-and-Food-Sciences/Human-Nutrition-and-Health.htm

### ROR
https://ror.org/04qw24q55

# Funder(s)

### Funder type
Other

### Funder Name

Investigator initiated and funded

# Results and Publications

## Publication and dissemination plan

A medical-ethical protocol including all required information has been written and was registered at the “Centrale Commissie Mensgebonden Onderzoek” in the Netherlands. Its registration can be found at: https://www.toetsingonline.nl/to/ccmo_search.nsf/fABRpop?readform&unids=83D8117FFA76CE1AC12582FA00152505
Analysis of results in 2019/2020. Publication in 2020.

## Intention to publish date

31/12/2020

## Individual participant data (IPD) sharing plan

Researchers interested in the data can contact the principal investigator (Prof dr Edith Feskens, edith.feskens@wur.nl, +31 (0) 317 482 567) as the data contains sensitive personal information.

## IPD sharing plan summary

Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 28/04/2022 | 01/08/2022 | Yes | No |
| Protocol file | version 6 | 16/07/2018 | 12/08/2022 | No | No |