Improving resilience with whole grain wheat

Published: 21-01-2015
Last updated: 21-04-2024

Primary objective: To investigate the health benefits of WGW on cardiovascular/ cardio-metabolic health by means of applying a mixed meal challenge. Secondary objective(s): To investigate the health benefits of WGW on liver- and adipose tissue...

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

Summary

ID

NL-OMON42136

Source
ToetsingOnline

Brief title
graandioos

Condition

- Other condition

Synonym
fatty liver, glucose metabolism, vascular health

Health condition

algehele en metabole gezondheid

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: cereal partners worldwide (CPW),kampffmeyer,nederlands bakkerij collectief (NBC),TNO,Topconsortia voor Kennis en Innovatie (TKI).

Intervention

Keyword: cardiometabolic health, metabolic flexibility, resilience, whole grain wheat

Outcome measures

Primary outcome

The main study parameter is cardiovascular/ cardio-metabolic health Blood

markers include cholesterol, triglycerides, glucose, insulin, lipid profiles,

glucagon, oxidized LDL, C-peptide, GIP, GLP-1, HbA1c, plasma adhesion molecules

and markers of inflammation. Flow-mediated dilatation (FMD), blood pressure,

Pulse Wave Analysis (PWA) and white blood cell count and activation.

Secondary outcome

Secondary study parameters include liverfat, abdominal fat distrubution, liver-

and adipose tissue health,mood questionnaires and do-it-yourself (DIY) devices

in quantifying health effects in a nutritional intervention study.

Study description

Background summary

Wheat is a dominating staple food source in the Netherlands and the number of whole grain wheat (WGW) products is growing rapidly. Intervention studies on WGW products mainly focused on cholesterol and a few other outcome parameters of either vascular health or glucose metabolism. However metabolic health is the result of a complex interplay of different organs. Investigating WGW effects on only a few parameters will therefore give a simplified picture about the health effects. In the current study we aim to investigate the effect of

12-week WGW intake on cardiovascular health, glucose metabolism and liver and adipose tissue health. We will do this by comprehensive phenotyping in the fasting state and by quantifying metabolic flexibility after a mixed meal challenge. This approach will provide us with more mechanistic insights on how WG may affect health and how different organs are affected and work together. Furthermore there is an increasing number of possibilities for individuals to map their health status at home. These measures can contribute to health assessment in the future, but the usability of such devices for scientific purposes has not been investigated.

Study objective

Primary objective: To investigate the health benefits of WGW on cardiovascular/ cardio-metabolic health by means of applying a mixed meal challenge. Secondary objective(s): To investigate the health benefits of WGW on liver- and adipose tissue health and to evaluate the potential of do-it-yourself (DIY) devices in quantifying health effects in a nutritional intervention study.

Study design

The study is a double blind, parallel trial. Two different treatments will be evaluated e.g. a 12-week intervention with WGW products (98g of WGW per day) and a 12-week control intervention with refined wheat (RW) products. A 4-week run-in period with RW products will be included prior to the intervention. Two experimental visits will be planned before and two experimental visits will be planned after the 12-week intervention period. In the first experimental visit we will determine liver fat and abdominal fat distribution. In the second experimental visit we will comprehensively phenotype the participants which will include a response to a mixed meal challenge test.

Intervention

A twelve week intervention of either 98g whole grain wheat (WGW) or a control intervention of refined wheat (RW) in the form of 4 slices of bread and 2 servings of ready to eat cereals (RTEC).

Study burden and risks

The subjects that will participate in this study will invest approximately 26 hours. There are minor risks for the participants. There is no evidence that the intervention products are unsafe. It is not likely that the intervention products will induce weight gain or loss, but in order to minimize this effect we will weigh all subjects each week and will intervene if necessary so that weight variation is kept at a minimum. Subjects in the RW group will have a reduced intake of fibre. In our opinion this reduction is minimal, however this can be more substantial in persons who have a high intake of dietary fibre.

Therefore, we will monitor gastrointestinal discomfort every week. In case of structural complains we will council our medical supervisor. MRI is a non-invasive and safe procedure as long as no contraindication is met. The vascular measures are non-invasive. After the FMD measurement we will determine endothelium independent dilation by sublingual nitroglycerin administration. Side-effects of nitroglycerin administration may include headaches and dizziness. The adipose tissue biopsy can occasionally cause a local hematoma or bruise and some participants may report pain or discomfort. During the study we will collect 2x200ml of blood with 12 weeks in between. The Hb value of each participants will be checked before blood collection and blood collection will therefore not lead to anaemia. Participants will receive ¤400,- after completion of the study and will receive a repayment of travel expenses, receive a warm evening meal the day before a study day and a lunch/breakfast on each study day.

Contacts

Public
Wageningen Universiteit

Bomenweg 2
Wageningen 6703HD
NL
Scientific
Wageningen Universiteit

Bomenweg 2
Wageningen 6703HD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet the following inclusion criteria:
Males or postmenopausal females (target 50: 50 for both genders)
For females: menstrual cycle absent for more than 1 year
Age 45-70yrs
BMI between 25 and 35 kg/m2
Signed informed consent
Normal food habit of bread and cereal consumption

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
• Not having a general practitioner
• Having a history of medical or surgical events that may affect the study outcome
• Smoker
• Use of cholesterol lowering medication
• Mental status that is not compatible with proper conduct of the study
• Aversion, intolerance to gluten, whole wheat or other items in the intervention products
• Alcohol consumption of > 21 glasses a week
• Abuse of drugs
• Recent use of antibiotics (<1 month prior to day 01 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 vegan or macrobiotic life-style
• Not willing 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
• Contraindication for MRI
• Having blood vessels that make it difficult for inserting a cannula

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-03-2015
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	21-01-2015
Application type:	First submission
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	NL51389.081.14