The effects of 'HealthBread4Kids' vs. brown bread in overweight adults

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON40564

Source
ToetsingOnline

Brief title
Health bread overweight adults

Condition

- Other condition

Synonym
Overweight

Health condition

Volwassenen met overgewicht

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Adults, Bread, Metabolism, Overweight

Outcome measures

Primary outcome

Post prandial:*

- substrate oxidation

*- energy expenditure

*- hunger and satiety feelings

*- vascular function

- levels of blood glucose, insulin, triacylglycerol (TAG) and free fatty acids

(FFA).

Secondary outcome

N/A

Study description

Background summary

Consuming a healthy diet is essential to prevent chronic diseases. There is a large body of evidence that consuming whole-grain bread reduces the risk of developing cardiovascular disease (CVD), type 2 diabetes and certain types of cancer. In addition, it seems to have beneficial effects on body weight management and may therefore prevent the development of overweight. Despite many recommendations it seems very difficult to change eating behavior, reflected in an ever-increasing prevalence of obesity, diabetes and CVD. Also, there is a global concern about the impact of high sodium intakes and the development of high blood pressure, a major risk factor for coronary heart

disease and stroke. In the Netherlands, the highest contribution of food to salt intake is by bread consumption. However, reducing bread salt content is a real challenge. On the one hand because of the required role of sodium in the dough preparation, on the other hand because of very poor sensory perception leading to clear disliking and non-consumption of low salt bread.*Apart from developing healthier food compositions, tackling overweight should above all happen at a family- and school behavioral level, where the role of parents, teachers and *childhood food and drink environment* are expected to be crucial factors. In the present study, the metabolic effects of a whole grain bread for children (HB) will be investigated. More specific, the oxidative, satiety- and quantitative food intake responses of consuming HB will be compared to the effects of white bread (WB; control).

Study objective

To this end, two study protocols have been developed, one concerning the *target group* of overweight children (aged 12-16), only including non-invasive measurements, and one targeting adult overweight participants (aged 18-45), allowing for invasive metabolic measurements.*Although we expect that metabolic responses differ between children and adults, it is for ethical reasons not feasible to collect blood samples in children to study metabolic responses in more detail. In another part of the work, executed by the faculty of FPNS, children of similar age will be tested for perceptions related to taste, flavor and mouth feel. This will yield relevant information, representative of this age group. Nevertheless, the other leg of this work (separate METC protocol), which will address study in adults, will give us important additional information about the potential beneficial metabolic effects of HB vs. WB, in particular related to the obese body physique. *The present METC protocol, related to study in overweight adults, will investigate the metabolic effects of HB vs. WB using both non-invasive and invasive measures.

Although we expect that metabolic responses differ between children and adults, it is for ethical reasons not feasible to collect blood samples in children to study metabolic responses in more detail. Accordingly, this study in adults will give us important additional information about the potential beneficial metabolic effects of HB vs. WB, in particular related to the overweight body physique.

Study design

Randomized cross over intervention n=18. Comparing the effects of a white bread based meal to the effects of a wholegrain based bread meal*.

Intervention

Participants will be provided with different bread meals on 2 separate test

days (in random order). Bread meals will consist of healthbread4kids (HB) or brown bread (BB) with strawberry jelly or chocolate paste (each participant will get the same spread on both test days). Pre- and postprandial metabolism (in response to the different bread meals) will be measured (see primary study parameters/outcome of the study).

Study burden and risks

The burden of the proposed research is minimal. An intraveneus catheter will be placed on both test days and on each test day, 8 samples of blood will be obtained via this catheter (a maximum of 10 mL blood / sample will be obtained). The only risks associated with participation are the risks related to blood samples, which are minimal.

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

• Blood pressure: diastolic blood pressure between 60 and 90 mmHg and a systolic bloodpressure between 100 and 150 mmHg
• Body Mass Index > 28 (overweight) (BMI: bodyweight/length2)
• Protein and glucose are not allowed to be present in urine that will be collected during the screening.
• Subjects have to be healthy (self reported) and are not allowed to use any medication Which can interfere with the current study.
• Normal Dutch dietary eating habits (no vegan, vegetarian or macrobiotic lifestyle)

Exclusion criteria

• Having a history of medical events that may significantly affect the study outcome (gastro-intestinal diseases)
• Having regularly gastro-intestinal complaints (stomach upsets, diarrhea, constipation, wind, abdominal colic) without clear medical cause
• Any current metabolic or endocrine disease
• Diabetes Mellitus (type I and II)
• Reported intolerance for gluten and lactose
• Recent weight loss or gain of >2kg without clear reason
• Reported slimming or medically prescribed diet
• Reported vegan, vegetarian or macrobiotic lifestyle
• Use of antibiotics during the last three months
• Pregnancy
• More than 28 consumptions of alcohol a week (for men) and more than 21 consumptions of alcohol a week (for women)

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2013
Enrollment:	18
Type:	Anticipated

Ethics review

Approved WMO Date:	21-06-2013
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	20-06-2014
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL43613.068.13