The effect of breakfast test products on acute satiety scores in different test conditions.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Appetite and general nutritional disorders
Study type	Observational invasive

Summary

ID

NL-OMON42491

Source
ToetsingOnline

Brief title
Breakfast test products and acute satiety scores (PPS Satiety)

Condition

- Appetite and general nutritional disorders

Synonym
not applicable

Research involving
Human

Sponsors and support

Primary sponsor: TNO
Source(s) of monetary or material Support: TKI-AF-12230; publiek private samenwerking met Nederlandse Bakkerij Centrum (NBC);PepsiCo en het ministerie van

Economische Zaken.

Intervention

Keyword: satiety, test conditions, weight concerned women, whole grain breakfast products

Outcome measures

Primary outcome

1. Satiety scores rated with visual analogue (rating) scales

Secondary outcome

2. Test condition (controlled at TNO versus less controlled at home)

3. Blood glucose (in controlled condition only)

Study description

Background summary

The worldwide prevalence of obesity increases rapidly, and at the moment there are more overweight than underweight people in the world. Prevalence of overweight (BMI 25-30 kg/m2) and obesity (BMI > 30 kg/m2) in adults in the industrialized world is in the order of 30-40% and 5-20%, respectively. Obesity is a major determinant of many chronic diseases and induces Diabetes Mellitus, coronary heart disease and stroke. In addition it increases the risk of several types of cancer, gallbladder disease, musculoskeletal disorders and respiratory problems (WHO, 2014).
The principal causes of the accelerating obesity problem worldwide are sedentary lifestyles and an abundance of food available everywhere, resulting in a high volume of high-fat, energy-dense diets. The cause is thus a combination of decreased energy expenditure and increased energy or food intake. The positive energy balance results in weight gain.

The food intake process can be divided into three different phases: (1) the pre-prandial or cephalic phase, (2) the prandial phase during food intake and (3) the postprandial phase after food intake. In the pre-prandial phase mainly sensory and cognitive processes like smell and sight mediate (stimulation of) the sensation of hunger. During the prandial phase the central nervous system receives information on the amount of food eaten and initial estimation of its energy content by post ingestive processes. Mechanoreceptors and chemoreceptors in the gastrointestinal tract initiate the release of peripheral satiety

factors. In the postprandial phase post-absorptive processes mediate the perception of food after nutrient absorption.

One of the physiological factors regulating the food intake pattern is satiety. Satiety is defined as the absence of ingestive motivation, which ends when the next meal is initiated known as the satiety cascade (Blundell et al., 2010). Food intake affects a number of physiological objective parameters in blood known to be involved in signaling satiety, such as glucose (Melanson et al, 1999; Chapman et al, 1999; Campfield et al, 1996), insulin (Speechly et al, 2000) and cholecystokinin (CCK) along with other numerous hormones such as NPY and PYY (Gutzwiller et al., 2000, Beglinger et al., 2001, French et al., 2000, Degen et al., 2001). The gastric hormone ghrelin was identified as a marker for hunger and meal initiation (De Graaf et al, 2004). Ghrelin concentrations in blood were highly correlated with subjective measures of appetite.
Humans do not only eat in response to a metabolic or physiological need. Humans also respond to a significant extend to other internal subjective and emotional signals (cues). The exact relations between the physiological internal signals and subjective and emotional internal signals are not known. Besides also external and social factors modulate physiological-derived hunger and satiety signals.

Though the regulation of food intake has been studied quite extensively, the underlying mechanisms are not elucidated and new factors involved in this regulation are still being found. It is known that the macronutrients such as lipids, proteins and carbohydrates affect satiety differently, but the mechanisms are still being determined.

The present clinical study is part of a public-private strategic project Wholegrain satiety (PPS Satiety, TKI-AF-12230). Aim of this project is to develop an in vitro screening tool combined with an in silico model for measurement of satiety, for cost- and time - effective screening of satiating properties of new and existing complex food products and (functional) ingredients. Identification of the relation between specific product characteristics and physiological parameters affecting satiety will allow quicker evaluation and targeted selection of ingredients for testing in human interventions. The tool will thus speed up knowledge on physiological mechanisms and development of new product concepts, candidate ingredients, or complex food products aimed at reducing caloric intake. The base of the integrated screening tool will be 1) the dynamic gastrointestinal (GI) digestion model Tiny-TIM, 2) intestinal tissue segments to study the secretion of satiety hormones and 3) an in silico model in which the obtained in vitro data are used to predict satiety. The Tiny-TIM model is developed by TNO, and described in detail by Schaafsma (2005). The principle of using intestinal segments to study the release of satiety hormones is described by Voortman et al (2012).
A second aim of the Wholegrain Satiety project is to evaluate satiating properties of different types of wholegrain breads (eg. whole wheat,

multi-whole grain including nuts and seeds, fiber and oat enriched bread) and oat based breakfast cereals and oats based bars/cookies with both the new technology and *golden standard* methodology. This is done for validation purposes and to strengthen the scientific evidence of health benefits of wholegrain products. Wholegrain bread has a high nutrient density. Besides supplying energy and essential nutrients, wholegrain bread is assumed to sustain satiety for a longer period of time and therewith reduce food intake. A longer satiating effect is relevant in the battle against ever increasing prevalence of overweight. With the integrated approach we aim to develop an accepted screening methodology to optimize the human intervention study design needed for a health claim dossier for submission to EFSA.

In the present study we will conduct a clinical trial in which a standard protocol will be used to examine study substances (breakfast cereals and bread) with satiating ingredients which will reveal actual human satiety scores. The visual analogue scales used for determination of satiety feelings is an accepted method by EFSA and studied extensively (Raben et al., 1995). It is used by TNO in an earlier carbohydrate containing breakfast experiment (Pasman et al., 2003).

Subjects may feel and eat differently at home. Especially since supervision by a researcher is known to influence behaviour of participants. Self-measuring has the potential of giving more reliable estimates of intervention effects (Marschollek et al., 2012). Therefore, it is interesting to repeat the tests that are performed in the clinical unit, in an *at home* condition, because that is the place consumers eat their breakfast habitually.

Study objective

The primary objective is to investigate the acute effect of five different breakfast test products (breakfast cereals or bread or traditional) on satiety scores (feelings of hunger, fullness, satiety, desire to eat, prospective food consumption).
- The two oat meal products of PepsiCo, Inc. will be compared against each other;
- The two bread meals of NBC will be compared against each other;
- The traditional breakfast of TNO (bread with fried egg) will be compared against literature and previous findings.

The secondary objective is to compare the VAS satiety scores of all test products measured under *controlled conditions* versus satiety scores of the same test products measured *at home*.

The glucose responses after the five different breakfasts will be compared for the controlled condition only.

Study design

The study will be a randomized, controlled trial (RCT) with an open and cross-over design. The study will not be blinded, because of the acquaintance of the subjects with the breakfast test products. Subjects will either start in the controlled condition in the metabolic ward with five test days or start with the five test days in the *at home* test conditions (cross-over). After the first period of five test days the second period of five days will be performed at the other location. The test days will be separated by a two days-out period at least.

Study burden and risks

Subjects will consume prescribed, standardized breakfast products; five times at a clinical unit and five times at home. No risk is associated with intake of the test products. The VAS questionnaire will be filled in on the laptop multiple times on all test days (at home and at the clinic). No risk or real burden is of concern in this study. Subjects will perform finger pricks five times in each controlled session at TNO, what is known as a minimally invasive technique to obtain drops of blood.

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

1. Female subjects aged 18-50 years;
2. BMI: 22-32 kg/m2;
3. Written consent regarding participation after full information regarding all details of the study;
4. Normal Dutch eating habits (consuming mostly three main meals per day; used to eat bread for lunch; used to consume dietary fibres; like the test products (P9619 F02));
5. Normal dietary eating behaviour (non-restrained eaters, estimated with the Dutch Eating Behaviour Questionnaire; P9619 F06);
6. Healthy as assessed by the Health and Lifestyle questionnaire (P9619 F02);
7. Subjects with a normal dietary fibre intake (between 10-30 grams/day) (P9619 F07);
8. Voluntary participation;
9. Willing to comply with study procedures;
10. Willing to accept use of all nameless data, including publication, and the confidential use and storage of all data by TNO;
11. Have a laptop with adequate internet access at home and experience how to use it. You are also willing to bring the laptop to TNO and use it at TNO.

Exclusion criteria

1. On-going or recent treatment for diabetes, hypertension, coronary heart disease, psychiatric conditions, inflammatory chronic disease - rheumatoid arthritis, Crohn Disease, ulcerous colitis, chronic constipation, eating disorders;
2. Reported postmenopausal;
3. Having menstruation problems, e.g. PCOS;
4. Reported to be on a slimming diet or other dietary treatment (currently or during last two months, like vegetarian diet, lactose restricted diet etc.);
5. On-going use of any slimming preparations;
6. Any kind of dysfunction of digestive tract, food allergies/intolerances related to the supplied test products (like gluten intolerance), chronic constipation, recent/actual gastroenteritis;
7. Reported unexplained weight loss or gain of > 2 kg in the three months prior to the pre-study screening
8. Smoking;
9. Subjects with a high level of physical activity (> 5h intense sporting activity/week);
10. Heavy alcohol consumers, no more than 14 units per week (1 unit represents 1 standard

glass/portion of alcohol, independent of the type of alcoholic drink);
11. Physical, mental or practical limitations in using computerized systems;
12. Partner or first or second-degree relative from TNO personnel stationed at TNO Zeist.

Study design

Design

Study type:	Observational invasive
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-10-2015
Enrollment:	32
Type:	Actual

Ethics review

Approved WMO Date:	29-07-2015
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	21-10-2015
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL53772.028.15