Oral, gastric and cognitive contributions to satiation

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Ethical review	Not approved
Status	Will not start
Health condition type	Appetite and general nutritional disorders
Study type	Interventional

Summary

ID

NL-OMON45566

Source
ToetsingOnline

Brief title
Satisfaction study

Condition

- Appetite and general nutritional disorders

Synonym
obesity, overweight

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: NWO

Intervention

Keyword: Cognitive factors, Gastric load, Oro-sensory exposure, Satiation

Outcome measures

Primary outcome

The main study outcome is intake in kcal of the ad libitum load in all 4

conditions.

Secondary outcome

The Secundairy outcome measures of this study are:

Insulin, ghrelin, PP, CCK-8, PYY and GLP-1 responses over time.

Cognitive outcome measures: Mouth feel, expected satiety, hedonic evaluation

and appetite feelings.

Study description

Background summary

Obesity is one of the world*s major health problems and the number of obese people in the western society continues to increase. One of the major contributors to obesity is the obesogenic food environment that is characterised by large portion sizes of palatable, high energy dense foods that can be consumed at a fast rate.
The ability of the human body to regulate food intake plays a key role in the prevention of overconsumption. When food is consumed at a quick rate the in mouth perception to food (oro-sensory exposure) is limited. Because of that, some people are not able to regulate food intake causing overconsumption and ultimately an increase in body weight.
Food intake is controlled by the hypothalamus which is continuously informed about the metabolic state of the body. The hypothalamus is among which informed by peripheral signals triggered by oro-sensory exposure, stomach content or distention conveyed by gastrointestinal peptides. However we do not know which of these signals plays the most important role in meal termination or feeling satiated. For example studies have shown that slower eating and longer chewing lead to higher postprandial satiety hormone responses indicating that oro-sensory exposure to food plays an important role in meal termination.

However, gastrointestinal *kinetics* function, upon eating, may also play a key role in the regulation of satiation. For example stomach distention activates stretch and mechanoreceptors that send satiety signals to the brain. Although often the meal is terminated before the stretch sensors are activated. Also the gastric emptying rate especially in high caloric foods sends satiety signals to the brain . The gastrointestinal peptides involved in appetite regulation are Ghrelin, CCK, PYY and GLP1. Besides the oro-gastric signals cognitive factors play an important role in terminating a meal led by the perceived sensory qualities of a food. Sweet and harder foods are thought to be more filling and palatability of a food may result in eating beyond metabolic needs.
The separate roles of oral and gastric signals and the cognitive role in intake regulation are not completely understood. Therefore the primary objective of this study is to determine whether, oral, or gastric feedback is most important for meal termination (satiation). As a secondary objective we aim to understand how cognitive factors modulate the oral and gastric signals and which gastrointestinal appetite hormones are triggered, and to what extend by the oral and gastric signals.
We hypothesis that oral feedback together with cognitive factors are most important for meal termination. In addition, we expect Insulin, Ghrelin, PP, CCK-8, PYY and GLP-1 endocrine responses to be increased (higher peak and AUC) when oral signals are limited. However these endocrine responses do not relate to food intake as this is overruled by cognitive factors (Lack of mouth feel and hedonic evaluation of food).
Buy understanding the pathways through which food intake is regulated we could also understand possible roles of alterations of this mechanism in the pathophysiology of obesity. In addition overweight obese people could specifically be trained to focus on the products* taste, texture or stomach feelings to become more aware of the amount eaten within a meal.

Study objective

The primary objective of this study is to determine whether, oral, or gastric feedback is most important for meal termination (satiation). As a secondary objective we aim to understand how cognitive factors modulate the oral and gastric signals and which gastrointestinal appetite hormones are triggered, and to what extend by the oral and gastric signals.

Study design

The study has a randomized cross-over study design with 4 conditions; all participants (n=34) receive each treatment and are their own control (within subject effects). Participants join an information meeting during which they sign informed consent when willing to participate, after that participants fill in a questionnaire about the in- and exclusion criteria of the study. If eligible, participants come to a screening session for anthropometric measures (height and weight) and to check Hb-value, fasting glucose levels and blood

pressure and suitability of the veins to insert a cannula. If the participant fulfills the screening criteria he/she joins a training session during which the study protocol is practiced and a nasogastric tube is inserted to determine whether the participants feels comfortable with the insertion of the cannula. When both the participant and researcher agree that insertion of the tube is comfortable enough to participate in the four test sessions these sessions are scheduled. The participant participates in 4 test sessions during which the participants receives one of the four study conditions in a randomized order.

Intervention

Participants perform 4 test sessions during which the participant receives one of the following 4 treatments/conditions. During one session participants eat the test food in a normal fashion (A. 100% oral ingestion load), in another session participants receive a gastric load of the test food through a naso-gastric tube (B. 100% gastric load) but are aware of the amount inserted in the stomach. During the third condition (C. 50% oral, 100% gastric) participants receive half of the amount to eat normally while the other half is loaded in the stomach. During the fourth condition participants can eat normally (same as condition A) however half of the amount ingested is siphoned/drained from the stomach (D. 100% oral, 50% gastric condition). In each condition each participant receives a fixed pre-load after the fixed preload participants indicate by clicking on a go or no go button on a pc screening whether or not they would like to receive another piece or load until they are comfortably satiated. Satiation is thus measured through ad libitum intake.

Study burden and risks

The intervention is non-therapeutic to the subjects. The risk associated with participation is small and the burden can be considered as moderate. During four sessions participants will be incubated with a naso-gastric tube with subsequent infusion of a gastric load (two conditions) or stomach content will be drained (one condition) in one condition a naso-gastric tube will be inserted but no gastric load will be administered. This procedure may cause complications although these risks are low when done by a nurse. A likely complication is irritation of the mucous membrane of the nose or irritation of the throat for some hours after removal of the tube. To prevent the nose and throat of becoming too irritated at least one rest week between sessions will be scheduled. Another likely complication is that participants may feel sick/ nauseous because of insertion of the tube. In some cases the nose or throat may become to irritate which could lead to a nose bleed or mucosa may become inflammatory. Wrong placement of the tube may happen whereby the tube is places in the trachea and food enters the trachea which could have severe consequences such as pneumonia. However to prevent this from happening the nurse will work according to a protocol. A pH test will be done to determine if the tube lies

within the stomach (pH *5.5). If the outcome of the test is uncertain and the location of the tube cannot be determined feeding will not start. A study nurse will insert and remove the nasogastric tube.The nurse will keep a log to report about the tube placement/removal of each participant.
The risks of inserting a naso-gastric tube and the procedure will be thoroughly explained to the participants both verbally and in written.
If during the study endocrine concentrations outside the normal range are detected, subjects will be notified by the research nurse and redirected to a general practitioner. Permission for this will also be asked in the IC.
Subjects who do not agree with this requisite are excluded from participation in this study. With this study we would like to determine how cognitive, oral and gastric factors contribute to satiation. In other words; why do we stop eating and when. This knowledge may be used to develop products or strategies that enhance healthy choices and eating behaviour and consequently help prevent overweight and obesity. In conclusion, we consider the knowledge obtained and possible implications of this study to outweigh the individual burden.

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
* Between 18-35 years old at the day of inclusion
* Able to understand and speak Dutch or English fluently or without difficulty
* BMI 18.5-26 kg/m2
* Good general health and appetite (F1 questionnaire and judge by the subject)
* Eating three meals a day, every day around the same times. (Self-report see F1 questionnaire).

Exclusion criteria

* Difficulties with swallowing, chewing and or eating
* Suffering from an endocrine or eating disorder, gastrointestinal illness or illness of the thyroid gland, respiratory disease or diabetes.
* Having taste or smell disorders (self-report)
* Braces (not including a dental wire) or oral piercing
* Smoking
* Consuming on average more than 28 glasses of alcohol per week
* Use of medication that may influence study outcomes (see, F1 questionnaire)
* Allergies or intolerance to any ingredient of the test food.
* Not willing to eat the test food because of eating habits or believes.
* Followed an energy restricted diet during the last 2 months
* Gained or lost 5 kg of body weight over the last half year
* High restrained eater according to the Dutch Eating Behaviour Questionnaire (men: score>2.9).
* Signed up for participating in another research study (with the exception of the EetMeetWeet study).
* Employee of Human Nutrition (WUR)
* Thesis student or intern at the chair group of Sensory Science and Eating Behaviour Human Nutrition (WUR).
* Intensive exercising 5 days per week for at least one hour or more, or more than 8 hrs per week in total.
* Low score (< -1) for liking on a nine point likert scale of the test food;Exclusion after screening:
* Hb value is not between 8.1-11.0 mmol/L
* Veins not suitable for placement of the intravenous cannula (judged by the research nurse)
* Fasted glucose level is below <3.5 mmol/l
* Blood pressure is below 90/60 mm hg (below 90 and/or below 60 mm hg) and/ or if the participant has a history of low blood pressure.;Exclusion after training:

* Participant is not comfortable with insertion of a cannula; this can either be determined by the participant or the researcher/nurse.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	40
Type:	Anticipated

Ethics review

Not approved

Date:	06-04-2017
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	NL60862.081.17