Oro-sensory exposure, eating rate and satiation

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

Summary

ID

NL-OMON44445

Source
ToetsingOnline

Brief title
Fudge study

Condition

- Other condition

Synonym
overeating, overweight

Health condition

overgewicht en obesitas

Research involving
Human

Sponsors and support

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

Intervention

Keyword: cephalic phase, eating rate, oro-sensory exposure, satiation

Outcome measures

Primary outcome

The main study outcomes are intake in gram and insulin, glucose, PP and ghrelin responses over time.

Secondary outcome

The secondary outcomes of this study are appetite ratings before and after the meal, eating behaviour parameters (number of bites, number of chews, chewing duration, eating duration, eating duration per bite), and expected satiation.

Study description

Background summary

Foods that can be eaten at a fast rate - with low mastication effort - lead to shorter orosensory exposure (OSE) per unit of food consumed. This results in a decreased satiation response and consequently higher subsequent food intake. Oro-sensory exposure and ingestion rate play an important role in controlling intake and are closely related. Based on the findings of our previous study we concluded that increasing mastication duration decreases intake.
However, it remains unclear whether an increase in mastication duration leads to a decrease in food intake because of enhanced oro-sensory exposure or because of decreased ingestion rate. Therefore the mechanisms by which both factors act on food intake and the underlying physiological mechanisms remains unclear.

Study objective

The primary objective of this study is to determine the independent and

additive effects of oro-sensory exposure (mastication effort) and ingestion rate (bite interval) on satiation in relation to the cephalic endocrine and metabolic hormonal responses.

Study design

The study has a 2x2 randomized crossover design with a control condition; all participants receive each treatment and are their own control (within subject effects). Although all participants receive each treatment not all (outcome) measures are performed in each participant. For this study we decided on a design in which the measures of the study are divided in two parts. We decided on this design to have enough power to find the expected effect size of each of the outcome measures of the study but not to be overpowered for the endocrine outcomes of this study and where participants would be unnecessarily subjected to measurements (see power calculation paragraph 4.5 of the C1 protocol).

Depending on the part in which the participant is included either:
Part A. Intake is measured (4 treatment sessions).
Part B. Intake and blood hormone levels are measured (4 treatment, and 1 control session).

The conditions of this study are:
Part A+B 1. Treatment: Low oro-sensory exposure, fast ingestion rate
Part A+B 2. Treatment: High oro-sensory exposure, fast ingestion rate
Part A+B 3. Treatment: Low oro-sensory exposure, slow ingestion rate
Part A+B 4. Treatment: High oro-sensory exposure, slow ingestion rate
Part B 5. Control condition for the hormone measures: No OSE, no intake

Intervention

Participants will eat chocolate custard with fudge pieces or fudge/caramel sauce (long vs. short orosensory exposure (OSE) in a slow or fast rate until they are satisfied. The 4 conditions of this study are: 1) short OSE, fast ingestion 2) short OSE, slow ingestion, 3) Long OSE, fast ingestion, 4) Long OSE slow ingestion and 5) control condition for the hormone measures: no treatment.

Study burden and risks

The risk associated with participation is small and the burden can be considered as moderate. With this study we would like to determine how oro-sensory exposure (mastication) and eating rate affect food intake. In other words; when we chew more on each bite do we eat less because of enhanced oro-sensory exposure or because we are forced to eat slower? The knowledge obtained may be used to develop products or strategies that enhance healthy choices and eating behaviour and consequently help prevent overweight and

obesity. 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 English fluently or without difficulty (self-report)
* BMI 18.5-27 kg/m2
* Good general health and appetite (F1 questionnaire and judged by the subject)
* Commonly (5 out of 7 week days) eating three meals a day every day around approximately the same times. (This is a Self-report question; see F1 questionnaire).

Exclusion criteria

Participants participating in part A and B of this study:;* Difficulties with swallowing, chewing and or eating in general
* 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 21 glasses of alcohol per week (25)
* Not willing to stop using drugs during the study period (from inclusion till last test session)
* Use of medication that may influence study outcomes (self-report see F1 questionnaire)
* Allergies or intolerance to any ingredient of the test food.
* Having facial hair not willing to shave (because of stickers put on chin and nose for the video recordings)
* 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 department of Wageningen university
* Thesis student or intern at the chair group of Sensory Science and Eating Behaviour Human Nutrition (WUR).
* Intensive exercising more than 8 hours per week (excluding walking and biking)
* Low score (< -1) for liking the test food or more than a 2 point score difference between test foods (strong preference) on a nine point likert scale;Participants participating in part B of this study:
* Recent blood donation (<1 month prior to the first study day)
* Planning to donate blood as a blood donor during the study;Screening:
Participants participating in part A and B of this study:
* Measured weight and height at the screening results in a BMI below 18.5 or above 27 kg/m2 ;Participants participating in part B of this study:
* Hb value is not between 8.1-11.0 mmol/L
* Veins not suitable for placement of the intravenous cannula (judged by a 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.

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:	Completed
Start date (anticipated):	05-10-2017
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	24-08-2017
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

ID: 21159
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL62157.081.17
OMON	NL-OMON21159