# The effects of mastication and sweetness on cephalic phase responses

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Primary aim: To determine the effects of oro-sensory exposure stimulation through mastication duration and sweetness intensity on the endocrine and metabolic cephalic phase responses.Secundary aim: To determine whether the magnitude of cephalic...

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

## Summary

### ID

NL-OMON43316

**Source**
ToetsingOnline

**Brief title**
JellyHead study

### Condition

- Other condition

**Synonym**
Obesity, Overweight

**Health condition**

Overgewicht of Obesitas

**Research involving**
Human

## Sponsors and support

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

## Intervention

**Keyword:** Cephalic phase, Mastication, Oro-sensory exposure, Sweetness

## Outcome measures

### Primary outcome

The main parameters of interest are glucose levels, Insulin, PP, Ghrelin, FFA

and Leptin hormonal responses.

### Secondary outcome

The secondary study parameter is intake in gram during an ad libitum lunch

meal.

# 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. Quick eating and binge eating have an enormous effect on body weight as it often leads to overconsumption.
The ability of the human body to regulate food intake plays a key role in the prevention of overconsumption. Although feeding is necessary for survival it is also a great challenge for the body to maintain homeostasis through metabolic adaptations, which has been referred to as the paradox of feeding.
Intake regulation starts with the oral processing of food. During the chewing process nutrients, odour and taste molecules are released from the food matrix in the mouth, increasing oro-sensory exposure which stimulates the cephalic phase response (CPR). The cephalic phase response is the first phase of digestion, including all physiological, endocrine and autonomic responses stimulated by sensory cues such as taste, smell and the sight of food before swallowing food.

The function of CPR is to prepare the body for incoming food and subsequently digestion. The cephalic signals consequently help to induce satiation. A Lack of, or diminished cephalic phase as a result of quick food consumption has been shown to disrupt the digestive system. Processes affected are metabolism systems such as the insulin and blood glucose regulation and lipolysis together with the reward and satiety systems. In both animal and human studies it has been shown that this disruption of the digestive system is related to decreased appetite responses and weight gain.
Mastication and oro-sensory exposure help to regulate food intake by inducing the cephalic phase response consequently inducing satiation. Mastication induces satiation through several mechanisms; a direct effect (shown in rodents) through histaminergic activation of the hypothalamus and paraventricular nucleus, by stimulating the cephalic phase responses through increased effort and increased oral processing time duration and the consequently slower ingestion rate and mere contribution to sensory specific satiety. Besides the duration of the oro-sensory exposure as determined through the mastication process the cephalic phase response could also be enhanced through the intensity of the stimuli (i.e. taste) by for example changing the sweetness of a food product.
Taken together; quick food consumption seems to play an important role in weight balance. However, it is not known whether the chewing movements or the sensation of (sweet) taste is most important in inducing the cephalic responses. Therefore the main objective of this study is to determine the effects of mastication duration and oro-sensory stimulation intensity (sweetness) on the endocrine and metabolic cephalic phase hormonal responses. This knowledge may be used to develop products or strategies that enhance healthy choices and eating behaviour.

## Study objective

Primary aim: To determine the effects of oro-sensory exposure stimulation through mastication duration and sweetness intensity on the endocrine and metabolic cephalic phase responses.
Secundary aim: To determine whether the magnitude of cephalic phase responses affects subsequent satiation.

## Study design

The study has a randomized cross-over (2x2) study design with a control condition; all participants (n=22) receive each treatment and are their own control (within subject effects). Participants join an information meeting during which they sign conformed consent if willing to participate, after that participants fill in a questionnaire about the in- and exclusion criteria of the study and taste the model foods. If eligible, participants come to the modified sham feed training, after the training participants should be able to have a recovery rate of at least 85% in order to pass the second screening. If

the participants is found to be eligible according to all study criteria he/she participates in 5 test sessions during which the participant sham feeds either a sweet or non-sweet chewy or non-chewy strawberry *gel like* model food. During the control condition participants do not sham feed. Immediately after the sham feed session participants are offered an ad libitum lunch.

**Intervention**

At the day of the test sessions, a canulla is inserted after which the participant has to feel " good" (this will be asked to the participant) for at least 30 minutes. After that the sham feed experiment will start. Participants will be asked to sham feed on one type of model food and will be instructed when to eat a new gel and when to spit out. Participants will chew approximately 30 gels of 5 gram in +/- 15 minutes. During the sham feed period 9 blood drawings will be taken and participants are asked to fill in appetite questionnaires.
During the ad libitum intake video recordings will be made. Markers (stickers) will be placed on the chin and nose of the participant to measure chin movement. Based on the movements of the chin chewing behaviour will be determined (22).
All subjects will eat all four types of model foods in a randomized order, one type per session.
After the sham feeding experiment participants will be invited to the lunch room where they will receive a glass of water and buns with cheese, ham, hazelnut pasta, or strawberry jam from which they can eat until pleasantly full. After the ad libitum breakfast/lunch participants will again be asked to fill in an appetite questionnaire.

**Study burden and risks**

The intervention is non-therapeutic to the subjects. The risk associated with participation is negligible and the burden can be considered as moderate. During five morning sessions participants will sham feed on model foods which is a common technique used in sensory research to study the cephalic phase response. Ingredients used to make the model foods in this study are commercial available or are present in commercially sold food products and are approved by the FAO. Blood samples are taken by a qualified research nurse.Sometimes a hematoma, feelings of dizziness, nausea or fainting due to fasting can occur, but the risks of these events are minimal. If during the screening glucose concentrations outside of 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 mastication and oro-sensory exposure are contributing to the regulation of food intake as they are closely related. 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 small 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 18.5-25 kg/m2
* Good general health and appetite (F1 questionnaire and judge by the subject)
* Eating three meals a day around the same time (self-report, see F1 questionnaire)

## Exclusion criteria

* Dental pathologies such as known caries, full dentures or planning to undergo dental treatment
during the study
* Difficulties with swallowing, chewing and or eating
* Suffering from an endocrine or eating disorder, gastrointestinal illness or illness of the thyroid
gland 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
* Facial hair not willing to shave (due to facial markers video)
* Use of medication that may influence study outcomes ( see, F1 questionnaire)
* Allergies or intolerance to any ingredient of the model food or ad libitum lunch.
* Not willing to eat the model foods or ad libitum lunch because of eating habits, (religious) believes or vegetarianism.
* 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). ;Exclusion after information meeting:
* Low score (< -1) for liking on a nine point likert scale or score with more than 2 points difference between the four different types of gel;Exclusion after training:
* After repeatedly practising the participant is not able to have a recovery rate of 85% of the dry weight of the gel.
* Hb value is not between 8.1-11.0 mmol/L at training
* Veins not suitable for placement of the indwelling cannula (judged by the research nurse).

# Study design

## Design

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| Study type: | Interventional |
| Intervention model: | Crossover |
| Allocation: | Randomized controlled trial |

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| Masking: | Single blinded (masking used) |
| Control: | Active |
| Primary purpose: | Other |

### Recruitment

NL

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| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 18-10-2016 |
| Enrollment: | 22 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 26-05-2016 |
| Application type: | First submission |
| Review commission: | METC Wageningen Universiteit (Wageningen) |
| Approved WMO Date: | 20-12-2016 |
| Application type: | Amendment |
| 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: 26344
Source: NTR
Title:

## In other registers

| Register | ID |
| --- | --- |
| CCMO | NL56824.081.16 |
| OMON | NL-OMON26344 |