Extended umbrella protocol: sensory and behavioural studies of eating behaviour

Published: 06-02-2015
Last updated: 21-04-2024

This protocol involves studies that aim at:1. A better understanding of sensory perception and eating behaviour2. Validation of newly developed sensory and behavioural methods3. To determine the effect of fat, sugar and/or salt reduction on sensory…

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

Summary

ID

NL-OMON50541

Source
ToetsingOnline

Brief title
sensory and behavioural studies of eating behaviour

Condition

- Other condition
- Appetite and general nutritional disorders

Synonym
sensory science and eating behavior; hunger and satiety

Health condition

sensoriek en eetgedrag

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Ministerie van OC&W,afhankelijk van de studie,afhankelijk van de studie

Intervention

Keyword: behavioural experiments, food, odour, questionnaire, taste

Outcome measures

Primary outcome

The main study parameters will depend upon the primary aim(s). For example,

sensory evaluations may be correlated to product characteristics (e.g.

instrumental analysis) and/or behavioural measures (questionnaires).

Secondary outcome

n/a

Study description

Background summary

Many studies in the field of sensory science and eating behaviour can be considered non- or minimally invasive and of minimal risk and burden to the participant. However, ethical approval is becoming increasingly important for publication in peer-reviewed journals.

Study objective

This protocol involves studies that aim at:
1. A better understanding of sensory perception and eating behaviour
2. Validation of newly developed sensory and behavioural methods
3. To determine the effect of fat, sugar and/or salt reduction on sensory perception and/or preference.

Study design

Dependent upon the primary aim(s), different tasks will be used, including

questionnaires (e.g. appetite and thirst, personality characteristics, eating behaviour), sensory tests and/or computerized behavioural or neuropsychological tests. Sensory tests may involve taste, odour and/or visual stimuli, or other commercially available food products or ingredients, and may include measures of food choice or intake. Neuropsychological tests may include questionnaires on paper, or on computer, e.g. measuring reaction times. Computerized behavioural experiments may involve software programs such as E-prime, CANTAB, and other software programs (e.g. using food pictures, animation characters that represent emotions), or saliva may be collected. Heart rate or skin conductance can be measured. Participants may be video recorded, to assess their facial expressions or chewing behaviour; or their eye (pupil) movements may be tracked.

Intervention

Exposure to commercially available food products and ingredients, at concentration levels that are approved by the Food and Consumer Product Safety Authority (Voedsel en Waren Autoriteit), and/or odours in concentrations that can be found in consumer products, that are non-toxic and/or can be considered safe.
Saliva may be collected and weighed, and in a subgroup of max 50 subjects collected saliva composition will be analysed.
Video recordings may be taken to monitor facial expressions or chewing behavior.
Pupil movements may be recorded via eye-tracking software.
Heart rate and/or skin conductance can be measured via sensors.
Hunger condition, refrain from eating/drinking food products that contain calories and/or caffeine for a maximum of 3 hours, or to fast overnight;
Satiety condition: subjects can be given food products to consume

Study burden and risks

Each subject will spend a maximum of 60 minutes per session, with a maximum of 6 sessions. The risk associated with participation is negligible and the burden can be considered as 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

Aged between 18 and 55 years on the first study day
Being healthy (as judged by the subject)

Exclusion criteria

- Being an employee of the Division of Human Nutrition and Health (WU), or of other departments involved in the study.
- Being hypersensitive (allergy or intolerance) for the odours or tastes under study
- Having a history of any medical event that could interfere with the study outcome (e.g. diabetes, gastrointestinal disease, thyroid disease or any other endocrine disorder)
- Having a mental or physical status that could hinder the study procedures
- Being pregnant, having the intention to become pregnant or currently breastfeeding, Depending on the study objective, additional exclusion criteria may include
- Having a taste or smell disorder
- Having difficulties with swallowing/chewing
- Use of medication, except for paracetamol and contraceptive medication
- Lacking appetite
- Using an energy restricted diet during the last 2 months

- Having weight loss or weight gain of more than 5 kg during the last 2 months
- Smoking , Depending on the study objective, a screening session may be used to determine additional exclusion criteria using scores on any of the above described questionnaires, sensory and/or behavioural tasks.
For studies including video recordings, participants can only take part in the study if they agree to being filmed during the experiment.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-03-2015
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO Date:	06-02-2015
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	04-02-2016
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)

Approved WMO Date:	16-05-2017
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	20-03-2018
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	20-03-2019
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	23-03-2020
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	19-08-2020
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)
Not approved Date:	01-10-2020
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

No registrations found.

In other registers

Register	ID
CCMO	NL51747.081.14