OrCa study: oral cavity & food intake differences in consumers varying in age, gender and ethnicity

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON44509

Source
ToetsingOnline

Brief title
OrCa study

Condition

- Other condition

Synonym
Oral cavity, oral physiology

Health condition

alleen gezonde deelnemers

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Top Institute for Food and Nutrition

Intervention

Keyword: Food intake, Inter-individual variation, Oral cavity

Outcome measures

Primary outcome

6 study parameters will be assessed with measurements of the oral cavity:

o Mastication efficiency: The mastication efficiency will be determined by masticating an artificial model food (Optosil) for 20 times. Particle size and particle number will be calculated from the spit out samples. Mastication efficiency will be determined for 1 extra commercially food product.

o Dental status: The dental status will be determined by the number of teeth, number of molars and number of wisdom teeth.

o Salivation: The flow rate (mL/min) will be assessed by weighing the amount of saliva every 30 seconds for 5 minutes, both unstimulated and stimulated. For the stimulated measurements, participants will masticate a 5x5cm piece of Parafilm to simulate mechanical stimulation.

o Volume of oral cavity: The volume of the oral cavity (mL) will be determined using the water-retaining method. Participants receive a cup of water and will keep as much water in their mouth as possible. When the maximum is reached, participants spit out the water in another empty cup.

o Swallowing threshold: The swallowing threshold will be determined by the

particle size immediately before swallowing. Participants will masticate an artificial model food (Optosil) as long as they want. Immediately before swallowing participants have to spit out the sample and particle size & number of particles before the threshold will be calculated. Swallowing threshold will be determined for 1 extra commercially food product.

o EAT-10 score: A questionnaire on self-reported swallowing problems consisting of 10 statements.

5 online questionnaires will be filled in to understand the food intake aspects between different consumers:

o Food diary: to quantify the foods which are consumed during 2 days.

o Food Choice Questionnaire: to quantify the importance of nine factors underlying food choice.

o Health and Taste attitude scale: to measure the importance of health and taste aspects of foods in the food choice process

o Jeltema/Beckley Mouth Behaviour (JBMB) tool: to understand the texture preferences of the consumers

o Food context questionnaire: to understand the important context factors during food consumption

Secondary outcome

The secundary study parameter will be:

o BMI

Study description

Background summary

Food oral processing is the first stage of human digestion, where food is transformed into a bolus that can be safely swallowed. A previous study showed that age, gender and ethnicity have an effect on the natural eating behaviour of different food products. These differences in oral behaviour may be related to specific physiological differences between different consumers groups. Also the relation between the oral physiological parameters and the natural oral behaviour is not clearly studied yet.

Study objective

This study explores the oral physiological differences of different consumer groups and the systematic associations with natural eating behaviour. Secondly, the food intake strategies during food consumption will be explored for the different consumer groups.

Study design

Recruitment of participants will be done through advertising on the website: https://voedingonderzoek.wur.nl/orca, email to subjects registered in the database of the Division of Human Nutrition and of the SenTo panel ("Senioren van de Toekomst'', elderly of the future), social media and printed posters at the University Campus Boards and at elderly homes. Potential participants that react to the advertisement will receive the information leaflet by email and will be invited to come once for an information session at the study location. During this session, the entire research setup will be explained and any questions from the participants will be answered. Those who decide to continue and participate in the study, will sign the informed consent and a screening will take place. During the screening, participants will be selected based on the inclusion and exclusion criteria.

During the test session several measurements will be conducted to understand the oral cavity differences. During the test session 5 physiological measurements will be done. These include: salivary flow (unstimulated and stimulated), mastication efficiency (for artificial model food and carrots), swallowing threshold (for artificial model food and carrots), volume of oral cavity, dental status. Next the participants will consume 3 food products, while being video recorded to quantify the eating styles for the different consumers. After the test session 5 questionnaires on the food intake

strategies during food consumption will be send to the participants.

Study burden and risks

The burden for the participants can be considered low to moderate since they will come twice, once for an information session and once for a test session. The information session will take 20 minutes and the test session 70 minutes. Additional, 5 online questionnaires will send to the participants. This will take approximately 30 minutes. The test session is considered to be non-invasive and will have no risks for the participant.

The study will give insight in the oral cavity differences between consumers varying in age, gender and ethnicity. This will lead to a better understanding of differences in eating behaviour.

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

The study consists of two participant groups, group A participating in the oral physiology measurements and the online questionnaires. Group B will only participate in the online questionnaires.;Inclusioncriteria group A:
Have good general health.
Have a healthy weight (BMI 18.5-25 kg/m2).
Do not have food allergies or intolerances for any of the food products used in the study: carrots, cheese and sausage.
No beard or willing to shave (due to facial markers that need to be attached to the skin for the video recordings).
Do not have braces or non-removable piercing in or around the mouth (with the exception of a metal wire behind the teeth).
Do not use medication that affects your chewing behaviour or saliva production. This will be checked by the researchers in the first questionnaire during the information meeting. ;Fit in one of the following three groups:
-Men and women with Chinese nationality and Asian ethnicity, born in China, aged 18 to 30 years, living outside China for less than one year and no missing teeth (wisdom teeth and non-removable implants, crowns and bridges are allowed).
-Men and women with Dutch nationality and Caucasian ethnicity, born in The Netherlands, aged 18 to 30 years and no missing teeth (wisdom teeth and non-removable implants, corwns and bridges are allowed).
-Men and women with Dutch nationality and Caucasian ethnicity, born in The Netherlands, aged 65 to 85 years and a maximum of 2 missing teeth (wisdom teeth and non-removable implants, corwns and bridges are allowed).;Inclusioncriteria group B:
Have good general health.
Have a healthy self-reported weight (BMI 18.5-25 kg/m2).
Do not have braces or non-removable piercing in or around the mouth (with the exception of a metal wire behind the teeth).
Do not use medication that affects your chewing behaviour or saliva production. This will be checked by the researchers in the first questionnaire during the information meeting. ;Fit in one of the following three groups:
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-Men and women with Dutch nationality and Caucasian ethnicity, born in The Netherlands, aged 18 to 30 years and no missing teeth (wisdom teeth and non-removable implants, crowns and bridges are allowed).
-Men and women with Dutch nationality and Caucasian ethnicity, born in The Netherlands, aged 65 to 85 years and a maximum of 2 missing teeth (wisdom teeth and non-removable implants, corwns and bridges are allowed).

Exclusion criteria

Exclusioncriteria group A:
Mastication and/or swallowing problems caused by neurological problems, i.e. stroke, Parkinson, Alzheimer, Huntington.
Have followed an energy restricted diet during the last 2 months.
Is pregnant, has the intention of becoming pregnant or is currently breastfeeding
Employee of the Division of Human Nutrition.
Thesis student or intern at the chair group of Sensory Science and Eating Behaviour.
Participate in another intervention study, with the exception of the EetMeetWeet study.
Have a non-removable denture;Exclusioncriteria group B:
Mastication and/or swallowing problems caused by neurological problems, i.e. stroke, Parkinson, Alzheimer, Huntington.
Have followed an energy restricted diet during the last 2 months.
Is pregnant, has the intention of becoming pregnant or is currently breastfeeding
Have a denture.
Employee of the Division of Human Nutrition.
Thesis student or intern at the chair group of Sensory Science and Eating Behaviour.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-01-2018
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO

Date:	15-12-2017
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	NL62694.081.17