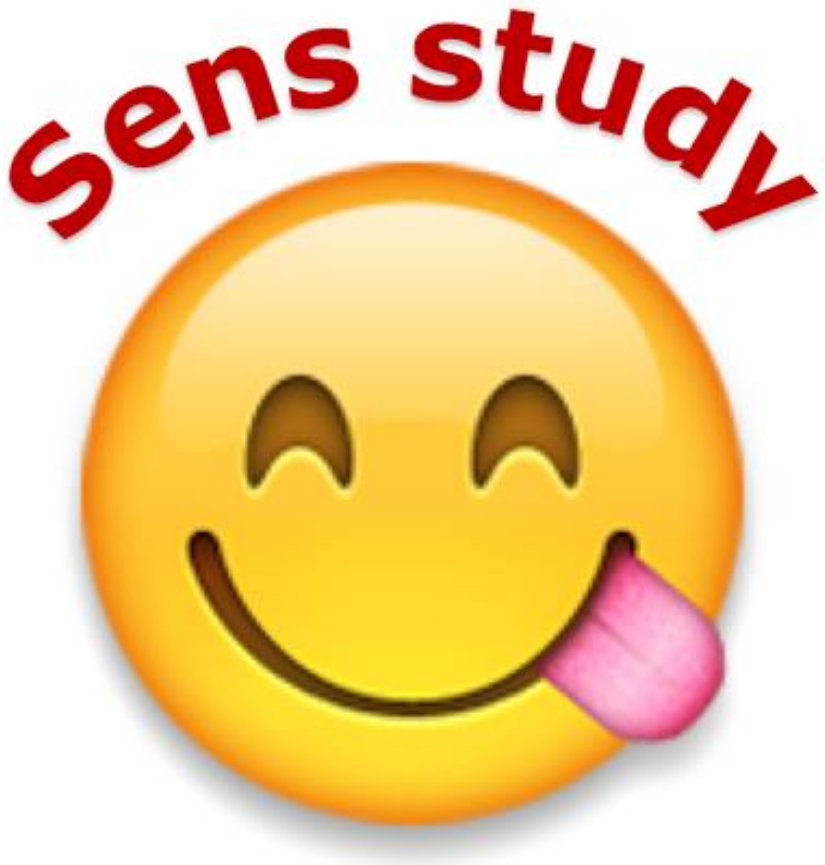
2018

Information leaflet – Sens study



Research to study the oral sensitivity and sensory functionality of consumers varying in gender and ethnicity

Subject information for participation in medical scientific research

Sens study

Official title: Sens study – Understanding the oral sensitivity and sensory functionality of consumers varying in gender and ethnicity

Introduction

Dear Sir/Madam,

You are asked to take part in a medical-scientific study. Participation is voluntary. Participation requires your written consent. Before you decide whether you want to participate in this study, you will be given an explanation about what the study involves. Please read this information carefully and ask the investigator for an explanation if you have any questions. You can also ask the independent expert, who is mentioned at the end of this document, for additional information. You may also discuss it with your partner, friends or family.
Additional information about participating in a study can be found in the enclosed general brochure on medical research.

1. General information

This study is being carried out by the Division of Human Nutrition of Wageningen University. The Medical Research Ethics Committee of Wageningen University has approved this study. This research is funded by Wageningen University.

2. Purpose of the study

The purpose of this study is to understand the oral sensitivity and oral physiology of consumers with a different age and ethnicity (Caucasian and Asian ethnicities).

3. Background of the study

When eating, food is chewed and mixed with saliva so it can be easily swallowed. During this process, consumers perceive different tastes, aroma's and textures, which will affect the experience of the food product.

A previous study found that different consumer groups have a different eating behaviour of food products. To understand why these consumers eat food products differently it is interesting how these consumer differ with respect to the oral sensitivity and sensory functionality.

4. What participation involves

Your participation will include 4 visits.

- The first session is an information meeting which will be followed by a screening. After the meeting it will be determined whether or not you are eligible to participate in the following part of this study. This session will take approximately 30 minutes.
- The test sessions consist of 4 sessions. Test session one, two and three will take 30 minutes each and test session four will take approximately 60 minutes.

Overall, participating in this study will take you a total of 3 hours, including the information meeting, screening and the 4 test sessions.

Information meeting and screening session

First of all, you will join an information meeting where the researchers will explain the entire research setup and you can ask questions. After that, if you decide to participate we will ask you to sign an informed consent form (see appendix B). Then, in order to decide whether you are eligible to participate in this study you will fill in an inclusion questionnaire. Finally, we will measure you height and weight.

A few days after the screening we will contact you by email to let you know whether you are eligible to participate in the study.

Test session

For the test sessions you will visit the University four times. Test session one, two and three will take about 30 minutes and will be scheduled with you on working days between 13:00 to 18:00 hours. The fourth test session will take approximately 60 minutes and will take place between 9:00 to 18:00 hours.

During test session 1, 2 and 3 the oral sensitivity of the participant will be measured. This will be conducted as following:

- The participant will receive two samples at the same time and will be asked to select the sample which is different from the other sample. This measurement will be repeated for several sets of two samples. One break of 5 minutes is included to divide all samples into two blocks.
    - The samples are texture and taste solutions and will differ in thickness or sweetness. The texture solutions are made of water samples with added Maltodextrin. The taste solutions are made of water samples with added sucrose.

During test session 4 the sensory functionality of the participant will be measured. This will be conducted as following:

- Papillae density: The papillae are small structures on the tongue. To calculate the number of papillae, the tongue will be stained with blue food colouring and a picture will be taken of the tongue. The picture will be analysed and the papillae will be counted.
- Oral tactile threshold: The oral sensitivity will be determined with the Semmes Weinstein Monofilaments. During the test the filaments will be pressed against the tongue of the participants. The participants will indicate the absence or presence of pressure.

5. What is expected of you

In order to carry out the study properly, it is important that you follow the study instructions.

The study instructions require that you:

- do not participate in another medical study.
- keep appointments for visits.
- Do not eat, drink (with the exception of water) or chew chewing gum in the 2 hours preceding the test session.

You are eligible to participate in this study if you:

- Have good general health.
- Have a BMI of 18.5-25 kg/m2.
- Do not have food allergies or intolerances for any of the food ingredients used in this study: maltodextrin, sucrose.
- Fit in one of the following groups:
    - Men and women with Chinese nationality and Asian ethnicity, born in China, aged 18 – 30 years, living outside China for less than one year and no missing teeth (except wisdom teeth).

- Men and women with Dutch nationality and Caucasian ethnicity, born in the Netherlands, aged 18 – 30 years and no missing teeth (except wisdom teeth).

You are not eligible to participate in this study if you:

- Have followed an energy restricted diet during the last 2 months.
- Are pregnant, have the intention to become pregnant or are currently breastfeeding
- Are an employee of the Division of Human Nutrition.
- Are a thesis student or intern at the chair group of Sensory Science and Eating Behaviour.
- Are participating in another medical study, with the exception of the EetMeetWeet study.

It is important that you contact the investigator:

- if you are admitted to hospital or are going for treatment there.
- if you suddenly develop any health problems.
- if you no longer want to participate in the study.
- if your contact details change.

6. Possible undesirable effects

All food products are suitable for consumption; therefore, we do not expect any risks or discomfort from your participation in the research.

7. Possible advantages and disadvantages

It is important that you properly weigh up the possible benefits and disadvantages before you decide to join.

You will not personally benefit from participation in this study. Your participation may contribute to increased knowledge about the oral sensitivity and sensory functionality of consumers varying in gender and ethnicity. In return you will receive a reimbursement for your participation.

8. If you do not want to participate or you want to stop participating in the study

It is up to you to decide whether or not to participate in the study. Participation is voluntary. If you do participate in the study, you can always change your mind and decide to stop, at any time during the study. You do not have to say why you are stopping, but you do need to tell the investigator immediately. The data collected until that time will still be used for the study.

If there is any new information about the study that is important for you, the investigator will let you know. You will then be asked whether you still want to continue your participation.

9. End of the study

Your participation in the study stops when

- you have completed all the visits as described under point 4
- you choose to stop
- you become pregnant
- the end of the entire study has been reached
- the investigator considers it best for you to stop
- Wageningen University, the government or Medical Research Ethics Committee, decides to stop the study.

The study is concluded once all the participants have completed the study. After processing the data, the investigator will inform you about the most important results of the study.

10. Usage and storage of your data

Your personal data will be collected, used and stored for this study. This concerns data such as your name, address, date of birth and data about your health. The collection, use and storage of your data is required to answer the questions asked in this study and to publish the results. We ask your permission for the use of your data.

Confidentiality of your data

To protect your privacy, your data will be given a code. Your name and other information that can directly identify you, will be omitted. Data can only be traced back to you with the encryption key. The encryption key remains safely stored in the local research institute. The data that is sent to the sponsor and any other interested parties will only contain the code, not your name or other data with which you can be identified. The data cannot be traced back to you in reports and publications about the study.

Access to your data for verification

Some people can access all your data at the research location. Including the data without a code. This is necessary to check whether the study is being conducted in a good and reliable manner. Persons who have access to your data for review are are the research team listed in appendix A; the committee that monitors the safety of the study They will keep your data confidential. We ask you to consent to this access.

Retention period of your data

Your data must be kept for 15 years at the research location.

Storage and use of data

Your data may also be of importance for other scientific research in the field of oral sensitivity and sensory functionality. To this end, your data will be stored for 15 years. You can indicate on the consent form whether or not you agree with this. If you do not agree with this, you can still participate in the current study.

Withdrawing consent

You can withdraw your consent to the use of your personal data at any time. This applies to this study and also to storage and use for future research. The study data collected until the moment you withdraw your consent will still be used in the study.

More information about your rights when processing data

For general information about your rights when processing your personal data, you can consult the website of the Dutch Data Protection Authority.

If you have questions or complaints about the processing of your personal data, we advise you to first contact the research location. You can also contact the Data Protection Officer of the institution or the Dutch Data Protection Authority.

11. Study subject insurance

This study is not associated with any risks for you. The reviewing committee has therefore decided that the Wageningen University does not need to take out additional insurance.

12. Compensation for participation

When participating in the entire study you will receive a financial compensation of €40 in VVV-vouchers. If you stop before the study is over, you will receive a smaller amount equivalent just to parts (test sessions) completed.
This reimbursement should be communicated to the Tax Authorities as income. You will receive the reimbursement after completion of the third test session.

13. Any questions?

If you have any questions, please contact the investigator. If you would like any independent advice about participation in this study, you may contact an independent doctor. He knows about the study but is not involved in it.
If you have any complaints about the study, you can discuss this with the investigator. If you prefer not to do this, you may contact the complaints' committee. All the relevant details can be found in **Appendix A**: Contact details.

14. Signing the consent form

When you have had sufficient time for reflection, you will be asked to decide on participation in this study. If you give permission, we will ask you to confirm this in writing on the appended consent form. By your written permission you indicate that you have understood the information and consent to participation in the study. Both yourself and the investigator will receive a signed copy of the consent form.

Thank you for your attention.

16. Appendices to this information

A. Contact details

B. Informed Consent Form

Appendix A: Contact details

Research team

Eva Ketel, MSc

Dr. Markus Stieger

Dr. Rene de Wijk

Contact person

Eva Ketel: sensstudy@wur.nl

Division of Human Nutrition & Health, Wageningen University

Independent physician

The independent physician can be contacted for any questions related to this study which you do not prefer to ask to the research team.

For the Division of Human Nutrition this is dr. J.J. van Binsbergen (physician in Brielle). You can ask your questions by email: j.vanbinsbergen@outlook.com

Please, clearly indicate to the assistant which study you (intend to) participate in.

Complaints

Eveline Waterham

E-mail: Eveline.Waterham@wur.nl

Appendix B: Subject Consent form Sens study

Sens study – Understanding the oral sensitivity and sensory functionality of consumers varying in gender and ethnicity

- I have read the subject information form. I was also able to ask questions. My questions have been answered to my satisfaction. I had enough time to decide whether to participate.
- I know that participation is voluntary. I know that I may decide at any time not to participate after all or to withdraw from the study. I do not need to give a reason for this.
- I give permission for the collection and use of my data to answer the research question in this study.
- I know that some people may have access to all my data to verify the study. These people are listed in this information sheet. I consent to the inspection by them.
- I agree that my GP will be informed of coincidental findings that (may) be of interest for my health.
- I know that I should not become pregnant during the study.
- I □ **do**
  □ **do not**
  consent to keeping my personal data longer and to use it for future research.
- I want to participate in this study.

Name of study subject:
Signature: Date: __ / __ / __

I hereby declare that I have fully informed this study subject about this study.

If information comes to light during the course of the study that could affect the study subject's consent, I will inform him/her of this in a timely fashion.

Name of investigator (or his/her representative):
Signature: Date:__ / __ / __
