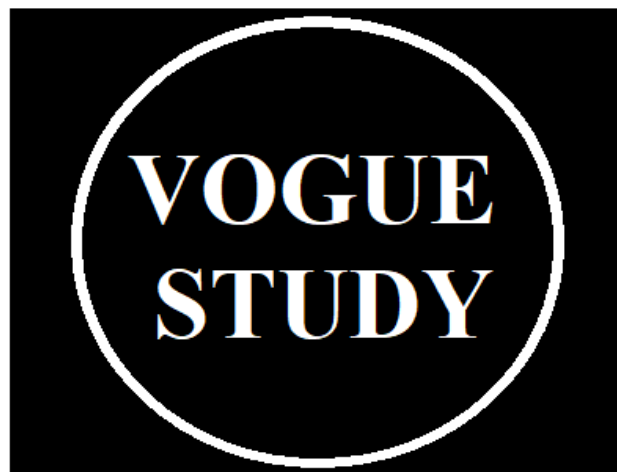


Information Folder



Subject information for participation in scientific research

Vogue study

Research to study eating behaviour

Introduction

Dear Sir/Madam,

You are kindly requested to take part in a 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 may also discuss it with your partner, friends or family.

This study is performed by the Division of Human Nutrition and Health of Wageningen University. The Social Ethics Committee of Wageningen University has approved this study.

1. Purpose of the study

The purpose of this study is to investigate eating behaviour. Depending on the culture you grow up in, you eat different types of foods. This determines eating behaviour. Within this study we are interested in cultural differences in eating behaviour. In order to do so we will video record you with a camera while eating. With this study we hope to better understand how eating behaviour differs between cultures.

2. What participation involves

During the information meeting you can indicate whether you would like to participate in this study. After the information meeting we will let you know whether you are eligible for participating in this study. When eligible we will ask you to join 4 test days during which you eat a breakfast, lunch and dinner meal that we provide you with, in a diner room at the university (Helix building 124 Wageningen university). The meals will consist of commercially available food items.

- 1x you will join an online information meeting which is also a screening (in case you immediately decide to participate). After the information meeting we will determine whether you can participate in the test days.
- 1x you will join a short 15 minute visit such that we can measure your weight and height

When you participate you will visit the university:

- For 4 days; for breakfast, lunch and dinner, to eat a meal (+/- 1 hour) while we record you on video and you will have an ear sensor (comparable to a hearing device that will be placed on the outside of your ear only). Before and after the meal we will ask you some questions about your appetite.

This study will take 13 hours of your time which includes the information meeting and test days.

Information meeting (first part)

The information meetings will be held a month till a week (depending on when you subscribe) before the first test days start. If you decide to participate after joining the information meeting we will ask you to sign an informed consent. If you need time to think about your participation after having received all the information you can schedule a new appointment with the researcher, in case you later decided to participate in this study. After you have given your consent by signing the form (and send it to us using the [surffilesender](#) website) we will give you a short questionnaire to fill in. This questionnaire contains questions about your health, and questions about your age, and gender. After you have filled in this questionnaire we will give another questionnaire with questions about your eating behaviour.

When you have finished filling in the questionnaires we will be asked to rate food items on how much you like these foods and how familiar you are with them. The information meeting will take 1 hour. After the information meeting we will contact you by email or phone to let you know whether you are eligible and we will ask you to come to the Helix building such that we can measure your weight and height. After that you can join the 4x test days if your BMI falls within the 18.5-20 kg/m² range and if your schedule allows for 4x a test day.

Test sessions

You will join a test day once a week for 4 consecutive weeks, you will always need to come on the same week-day. Test days will be held on Tuesdays, Wednesdays and Thursdays. Breakfast lunch and dinner will be on fixed times.

The evening before the session you will always eat the same meal (of your own choice). At the morning of the session you are not allowed to eat or drink anything besides one glass of water.

During a test day:

- We will check your diary that you have kept for 24 hours prior to the test session. In your diary you write down what you have eaten and drank and your exercise.
- We will provide you with a meal of which you can eat as much or as little as you want.
- While you are eating you are video recorded and it is therefore important to look forward and not put your hand in front of your mouth.
- Before and after the meal you will answer questions about your appetite.
- After 1 hour you can go home, when you finish a meal before this hour is finished we still ask you to remain seated. You can however read a book or be on your phone.
- Before you go home we will provide you with snacks of which you can eat as much or as little as you want, we ask you to bring back the bag (to the next meal) with the empty packages and remaining snacks even when the bag is empty. Please do not provide others with snacks. You are the only person allowed to eat from it. Furthermore, during the entire day you are only allowed to drink water, tea and coffee without sugar and milk or creamer.

3. What is expected of you

For this study we are looking for men who fulfil the following criteria:

- Generally healthy
- Good appetite
- Between 18 and 55 years old
- Speak and understand English without difficulty
- BMI between 18.5-30 kg/m².
- Non-smoker
- Commonly (5 out of 7 week days) eat three meals a day every day around the same times.

You are unable to participate in this study if you:

- Have difficulties with swallowing, chewing and or eating in general
- Are suffering from an endocrine or eating disorder, gastrointestinal illness or illness of the thyroid gland, respiratory disease or diabetes.
- Have a taste or smell disorder
- Have braces (excluding a dental wire) or oral piercing
- Are a smoker, smoking on average more than 1 cigarette a day.
- Consume on average more than 21 glasses of alcohol per week
- Are not willing to stop using drugs during the study period (from inclusion till last test day)

- Use medication that may influence study outcomes (self-report)
- Have allergies or intolerance to any ingredient of the test meals or snacks.
- Are not willing to eat the test food because of eating habits or believes.
- Are following a vegetarian or vegan diet
- Products used in the study contain animal products (including pork), gluten, eggs, peanut, soy, milk(lactose) and nuts.
- (As a Men) have facial hair such as a beard, because eating behaviour cannot be analysed.
- Have followed an energy restricted diet during the last 2 months
- Have gained or lost 5 kg of body weight over the last half year
- Signed up for participating in another research study
- Are an employee of Human Nutrition department of Wageningen university
- Are a thesis student or intern at the chair group of Sensory Science and Eating Behaviour Human Nutrition (WUR).
- Do intensive exercising more than 8 hours per week

You are able to participate in the test sessions if you fulfil these criteria

In order to perform the study it is important that you agree to do the following.

The agreements are that you:

- Do not exercise intensively or drink alcoholic drinks 24 hours before each test session.
- Do not use drugs throughout the entire study (starting after the screening)
- Will eat the same evening meal (of your own choice), the evening proceeding the test sessions between 18.00-20:00 and you will not eat or drink anything after 22:00 hrs except for water.
- Will keep a diary the day before, and the day of the test session, in which you note down your exercise (walking, biking etc.) and everything you eat and drink.
- The morning of your test day you will not eat or drink anything besides one glass of water.
- On the test day you are only allowed to eat the food provided by the researchers. You can eat as much or as little as you want from this foods.
- On the test day you can only drink water, Tea and coffee without sugar and milk.
- Please bring back the remainders of the snacks that you got from us (also empty packaging).
- Do not participate in another study
- Show up for scheduled sessions or let us know by time you are not able to visit us (preferably one week before).

It is important you contact the researchers in case

- You are feeling ill or have a cold before a test day
- You no longer want to participate in the study
- Your contact information changes (i.e. phone number/ email)

4. Possible undesirable discomforts

We do not expect you to experience discomfort while eating the snacks, breakfast, lunch or dinner meals that we provide you with. These are all commercially available food items that will be prepared in line with the hygiene rules (HACCP).

5. Advantages and disadvantages

You will not personally benefit from participating in this study. Your participation will however contribute to knowledge about eating behaviour and overconsumption; in return you will receive a reimbursement and free meals and snacks.

Disadvantages of participating in this study are:

- The time it will cost you to participate in this study
- The agreements you are required to oblige

6. 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. You may stop participation 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.

7. End of study

Your participation in the study stops when

- You completed all the visits as described under point 2
- You choose to stop
- The, government or Wageningen University 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. This will happen about a year after your participation.

8. Usages and storage of your data

For this study it is necessary to collect video recordings and personal data. Each study subject will receive a code that will be marked on all the questionnaires you will fill in and the same code will be used on the video-recordings. Your name will be deleted. However, it is not possible to fully anonymize the videos. Video recordings will not be (digital) published or shared with persons who are not directly involved in this study. The video recordings will not be used for presentation purposes without your consent. Researchers will ask you whether or not they can use your video for presentations. Only when you have given permission in writing and verbally the researchers are allowed to use it.

Your data

All your data will remain confidential. The research coordinator and project leader are the only persons who will know which code belongs to you. Some people may access your medical and personal data. This is to check whether the study is good and reliable. People who may access your data are people from the study team (and people from health inspection. They will keep your data a secret. If you sign the consent form, you consent to your personal data and video recordings being collected, stored and accessed. If you are not eligible to participate in the study (based on the information meeting) we will destroy the personal data collected during the information meeting after we have informed you that you are not able to participate.

Researchers will keep the collected research data 15 years after the end of the study.

Use of video recordings

We would like to save your video recordings up to 5 years after the results of the study are published. On the informed consent form you can indicate whether or not you agree on this. You can withdraw this permission at any time. Your video recordings will then be destroyed however if your video has already been analysed the results will be used for publication/research purposes.

Use of ear sensor data

On the informed consent form we will ask you whether you agree that we share your anonymous ear sensor data (PPG-heart rate, and head movement) with a company called Fast focus. Based on this data we can estimate the number of bites and chews you took.

9. Study subject insurance

This nutrition research study will be performed with products or ingredients that can be used in daily life therefore we do not anticipate on negative side effects.

10. Compensation for participation

When you finish the entire study you will receive € 100, - on your bank account. If you stop before the study is over, you will receive a smaller amount. This reimbursement should be communicated to the Tax Authorities as income. It will take 2-4 months before you will receive the money on your bank account.

11. Any questions?

If you have any questions, please contact the study team (Vogue@wur.nl).

Tel. number: +316 3832 3237

Coordinating investigator: Marlou Lasschuijt

Wageningen University and Research

Helix (building 124)

Stippeneng 4

6708 WE Wageningen

12. 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. The signature sheet is kept by the investigator. You will get a copy or a second copy of this consent form.

Thank you for your attention.

13. Appendices to this information

A. Informed consent forms

Appendix A: Informed consent Vogue study

- 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 know that some people can access my data. These people are listed in this the information folder.
- I consent to my data being used in the way and for the purpose stated in the information sheet
- I consent to collect video recordings during the test meals and being used in the way and for the purpose stated in the information sheet
- I consent to my personal data being stored for another 15 years after this study.
- I want to participate in this study
- I give permission to save my video recordings up to 5 years after publication of the results:

yes

no

- I give permission to share my ear sensory data with the company FastFocus:

yes

no

Name of participant:

Signature:

Date: __ / __ / __

I hereby declare that I have adequately 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: __ / __ / __