Participant Information Sheet

STER study 3

WAGENINGEN
UNIVERSITY & RESEARCH

Contact people:

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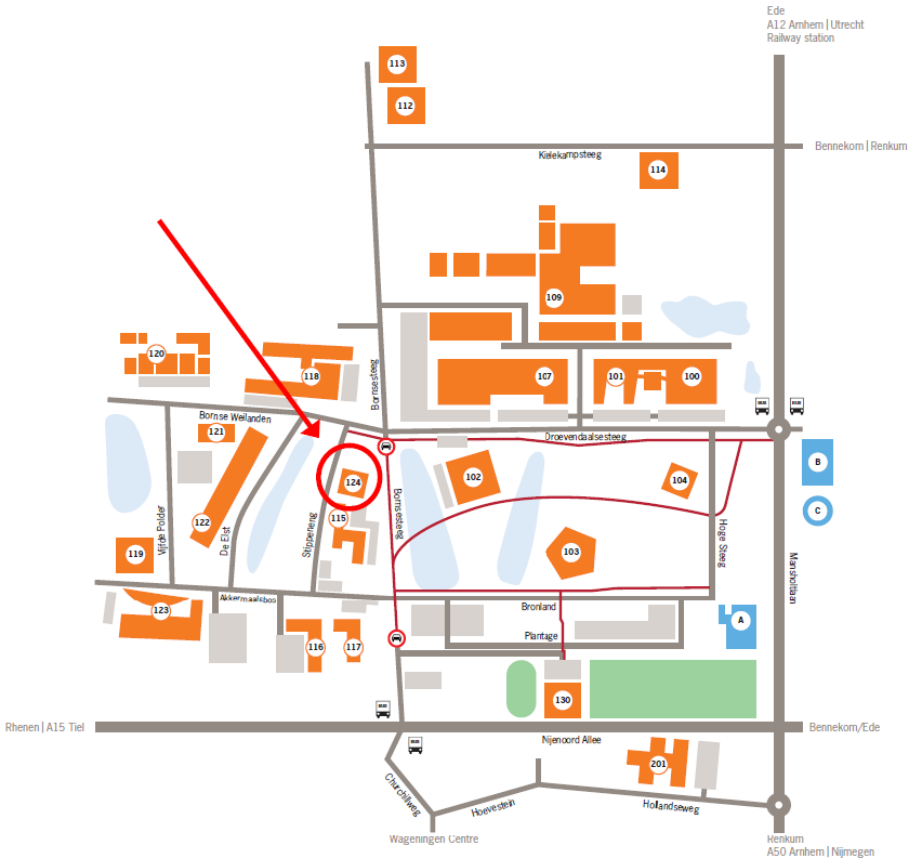

Subject information for participation in a medical-scientific study

STER study 3

Official title: The influence of hunger and satiety on the performance of memory tasks.

Introduction

Dear Sir/Madam,

You are being asked to take part in a scientific study.
Participation is voluntary. In order to participate your written consent is required.
Before you decide whether you want to take part in this study, you will be given an explanation about what the study involves. Please take your time to read this information and ask the investigator if you have any questions. You can also ask the independent expert mentioned at the end of this letter for additional information. You can also discuss it with your partner, friends or family.
Further information about participating in such a study is found on the government website www.rijksoverheid.nl/mensenonderzoek.

1. General information

This study is being conducted by Wageningen University. For this study, 60 participants are required.
The Medical Ethics Review Committee METC-WU has approved this study.

2. Purpose of the study

The aim of this research is to investigate the influence of hunger and satiety on the performance of memory tasks using eye-tracking technology.

3. Background of the study

Nowadays, our visual attention is continuously influenced by all sorts of information. Visual attention can also being steer by internal signals such as hunger state. Hunger or satiety can affect our mood, behaviour, and attention. Hunger state could also affect our memory, and thereby influencing our performance on a memory game. Hunger or satiety can affect our mood, behaviour, attention and memory. In this study we want to investigate the role of hunger and satiety on the performance of memory tasks such as a matching card memory game.

4. What participation involves

If you participate, your contribution will consist of one online questionnaire (screening questionnaire) and two visits to our test location for the test sessions. The online questionnaire will take about 20 minutes to complete. The two test sessions will last ~40 minutes. In the two

visits, you will be asked to consume a snack. The total study will take about one to three weeks, depending on your own availability. Test sessions take place on working days between 2:00 and 5:00 pm. Your two visits will be approximately at the same time, with a minimum of two days in between. We will schedule your test sessions by email.

Screening through an online questionnaire

First, we determine whether you can participate.

You can participate if you:

- Are between 18 and 35 years old.
- Are fluent in English.
- Are healthy and have a normal body weight (BMI: 18.5 –30 kg/m^2; $BMI = \frac{weight(kg)}{height(m)^2}$).
- Have a normal sense of taste, smell, and normal vision (the use of contact lenses is allowed).

You cannot participate if you:

- Are colour blind.
- Have had any eye surgery such as corneal surgery.
- Use (bifocal) glasses.
- Are a habitual smoker.
- Have any allergy, intolerance or oversensitivity to certain food products.
- Use medication other than occasional use of pain medication such as paracetamol and NSAID's (aspirin, diclofenac, ibuprofen, ketorolac, etc.) or hormonal contraceptives.
- Are pregnant or intend to become pregnant during the study, or are breastfeeding.
- Have gained or lost 5 kg or more in the past two months.
- Are an employee of the Department of Human Nutrition and Health at Wageningen UR or are currently writing an MSc thesis at the Department of Human Nutrition and Health.
- Are participating in other medical studies or if you have previously participated in the STER 1 and 2 study.

You can contact us, via email or phone call, if you have any questions. If you want to participate, you can send back this information sheet with the informed consent (last page) signed. You will then receive the informed consent signed by the research team, and a link to complete the screening questionnaire. This questionnaire will consist of questions regarding your general health, and your lifestyle. The screening is completed by a colour blindness test. The researchers will inform you if you are eligible to participate no later than one week after the completion of the screening questionnaire.

Visits and tests

For the study, you have to visit Helix (Building 124) two times in one to three weeks (depending on your own availability).

In each test session, we will measure your performance on memory tasks using different measures, in a hungry and satiated stage. The following will then take place (**Figure 1**):

- You will perform a questionnaire about your appetite, stress level and difficulty of the memory task – twice per visit.
- You will perform several memory games, where we will measure the highest score achieved at a hunger and satiated stage – twice per visit.
- We will measure your strategy to perform the memory tasks via your eye movements with an eye-tracker. Eye tracking is a non-invasive measure to assess eye movements. The eye-tracker used in this experiment is like normal glasses which allows you to move freely – each visit
- We will provide you with a snack before performing the memory tasks to put you in a satiated stage – once per visit. The snack will consist of common products, as available in the supermarket or in a vending machine.

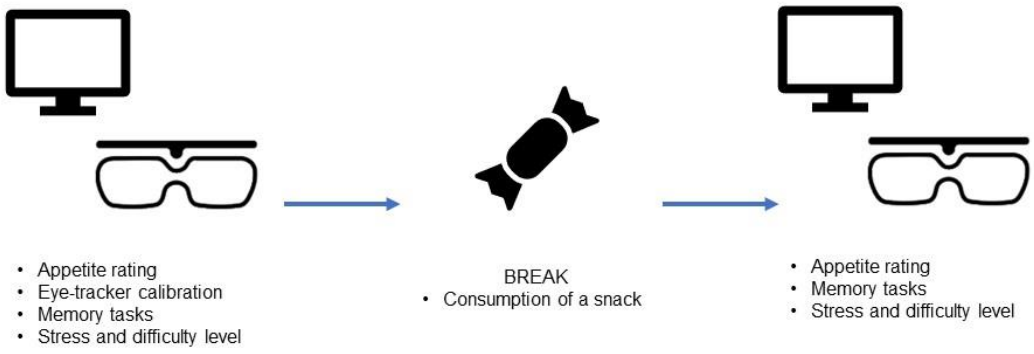

Figure 1. Procedure from a test session.

5. What will be expected of you

For the study to run smoothly, it is important that you follow the following agreements.

The agreements are that you:

- eat your habitual meal no later than two hours and no sooner than 45 min before the test sessions, and only drink water in the hour before the test session to standardize hunger state.
- refrain from using any heavy make-up around your eyes (e.g. mascara, eyeliner and eyeshadow) and strong perfume which could affect eye movement measures and visual attention.
- contact us if you have a cold, fever or a stuffed nose. This may affect the experiment, and we will then reschedule your appointment.
- adhere to the agreements made.

It is important that you contact the investigator:

- before you start taking (other) medicines. Even if these are homeopathic medicines, natural medicines, vitamins and/or over the counter medicines.
- if you are hospitalised or treated in a hospital.
- if you suddenly experience health symptoms.
- if you no longer wish to participate in the study.
- if your contact details change.

6. Possible side effects/inconveniences

The level of the tasks to measure your memory ability is moderate to difficult. We do not expect any (adverse) side effects or inconveniences from participating in the study. The snacks provided are safe and commercially available in the supermarket or in a vending machine.

7. Possible advantages and disadvantages

It is important that you consider the possible advantages and disadvantages before you decide to participate. You will not receive any personal advantage from taking part in this study. Your participation may contribute to more knowledge about the effects of hunger and satiety on memory. The only burden is time (less than 2 hours spread over 1-3 weeks).

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

You decide for yourself whether you want to participate in the study. Participation is voluntary. If you do participate, you can always change your mind and stop, even during the study. You do not have to state why you are terminating your participation. However, you should immediately inform the investigator. The data obtained thus far will be used for the study.

9. End of the study

Your participation in the study ends when

- all visits such as described under point 4 have been completed
- you personally choose to stop
- you become pregnant
- the investigator finds that it is better for you to stop
- the government or the assessing Medical Ethics Review Committee, decide to stop the study.

The entire study ends when all participants have finished the two test sessions.

10. Use and storage of your data

For this study, your personal data will be collected and used. It involves information such as your name, address, date of birth and data about your health. The collection, use, and storage

of your data is required in order to answer the questions asked in this study and to be able to publish the results. We ask your consent for the use of your data.

Confidentiality of your data

To protect your privacy, your data will receive a code. Your name and other information that could directly identify you are therefore omitted. This information can only identify you via a key. The key to the code will be stored securely in the local research facility. In reports or publications about the study, the data will also not be identifiable.

Access to your data for review

Some individuals may have full access to your data at the study site, also to the data without key. This is needed in order to check whether the study is performed properly and reliably. Individuals who have access to your data for review are the Medical Ethical Committee from Wageningen University and national and international regulatory authorities, for example, the Health Care Inspectorate and Youth. They will keep your data confidential. We ask your consent for this access.

Retention period of data

By signing the declaration of consent, you consent to the collection, storage and access of your personal data. Your data must be stored for up to 15 years at the study site after the end of the research.

Withdrawal of consent

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

More information about your rights concerning the processing of data

For general information about your rights concerning the processing of your personal data, please consult the website of the Dutch Data Protection Authority (https://autoriteitpersoonsgegevens.nl/en).

If you have any questions about your rights, please contact the person responsible for the processing of your personal data. For contact details, refer to Appendix A.

If you have any questions or complaints regarding the processing of your personal information, we recommend that you contact the study site. You can also contact the Data Protection Officer for the institution (see Appendix A) or the Dutch Data Protection Authority.

11. Insurance for subjects

If you take part in the study, you will not incur any additional risks. Wageningen University, therefore, is not required by the Medical Ethics Review Committee to take out additional insurance

12. Compensation for participation

You will receive €20 via bank transfer for participating in this study after completing your final test session. If the screening shows that you do not meet the inclusion criteria, you cannot participate in the study and you will not receive any reimbursement for filling the screening questionnaire. If you stop before the investigation ends, you will be paid a lower reimbursement. You should keep in mind that the money will be in your account approximately 2 to 4 months after the end of the entire investigation. This is reported to the tax authorities as income. The end of the entire study is expected to be October 2020.

13. Do you have any questions?

If you have any questions, please contact the research team through their email (ster.studie@wur.nl). If you would like independent advice about participation in this study, please get in touch with the independent doctor Dr. N.Muhsen (nmuhsen@hotmail.com). He knows a lot about the study, but has nothing to do with this study.
If you have any complaints about the study, you can contact the complaints' officer, Eveline Waterham (Eveline.Waterham@wur.nl). All information can be found in **Appendix A**: Contact information.

14. Signing of informed consent form

When you have had a sufficient time to consider your participation in this study (maximum one week) you will be asked for your decision. If you consent, you will be asked to confirm this on the corresponding consent form, in writing. With your written consent, you indicate that you have understood the information and agree to participate in the study.
Both you and the researcher will receive a signed version of this consent form.

Thank you for your attention.

16. Appendices with this information

A. Contact details

B. Consent form

Appendix A: contact details for Wageningen University

Researchers:

Elske Zwart, Ina Hellmich, and Paulina Morquecho
Department of Human Nutrition and Health, Wageningen University
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Principal investigator:

Sanne Boesveldt, PhD
Afdeling Humane Voeding en Gezondheid, Wageningen Universiteit
Stippeneng 4 (gebouw 124, Helix), 6708 WE, Wageningen
Email: sanne.boesveldt@wur.nl

Study doctor:

Dr. Ineke Klopping-Ketelaars, M.D., PhD
Stippeneng 4 (gebouw 124, Helix), kamer 0071, 6708 WE, Wageningen Universiteit
Telephone: +31 6 53558232.
Availability: Tuesday and Thursday

Independent expert:

Dr. N.Muhsen, M.D., MFPM
Willem Baerdesenstraat 4, 1067 XX Amsterdam.
Telephone: +31 6-1696 3517
Email: nmuhsen@hotmail.com

Complaints:

Eveline Waterham
Afdeling Humane Voeding en Gezondheid, Wageningen Universiteit
Stippeneng 4 (gebouw 124, Helix), 6708 WE Wageningen
Email: eveline.waterham@wur.nl

Data Protection Office of the institution:

Frans Pingen
Email: Privacy@wur.nl

Personal Data Authority:

www.autoriteitpersoonsgegevens.nl/

General e-mail adress:

ster.studie@wur.nl

Appendix B: consent form subject

- I have read the information letter. I was also able to ask questions. My questions have been answered sufficiently. I have had enough time to decide whether or not to participate.
- I understand that participation is voluntary. I also know that I may decide at any time to not participate or to stop participating in the study. Without having to provide any reason.
- I give consent to collect and use my data for answering the research question in this study.
- I know that for study monitoring purposes some individuals could have access to all my data. Those people are listed in this information letter. I consent to that access by these persons.
- I give consent to keep my research data for answering the research question for 15 years after publication of the research.
- I want to participate in this study.

Name of subject: ……..
Signature: Date : __ / __ / __

I certify that I have fully informed this subject about the said study.

If information becomes known during the study that could influence the consent of the subject, I will inform him/her of this on time.

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

The subject will receive a complete information letter, together with a signed version of the informed consent form.