Subject information for participation to medical scientific research

The OrthoFAT study

Human ability to detect fat content through smell

WAGENINGEN UNIVERSITY
WAGENINGEN UR

Introduction

Dear Sir / Madam

We ask you to participate in a medical scientific study.
Participation is voluntary. Your written permission is required to participate.
Before you decide whether you want to participate in this study, you will be given an explanation of what the study entails. Please read this information carefully and ask the researcher for an explanation if you have any questions. You can also ask the independent expert named at the end of this letter for additional information. You can also talk about it with your partner, friends or family. Before you decide whether you want to participate in this study, you will be given an explanation of what the study entails.
General information about participating in such a study can be found on the website of the Dutch government: https://www.government.nl/topics/medical-research.

1. General information

This research is carried out by the Division of Human Nutrition and Health of Wageningen University. This study requires 33 subjects. The Medical Ethics Review Committee (METC-WU) has approved this study. General information about the assessment of research can be found on the website of the Dutch government: https://www.government.nl/topics/medical-research.

2. Purpose and background of the study

The aim of this research is to gain more insight into eating behavior and the processes involved in smell and taste perception. The purpose of this study is to gain more insight into the smell perception of fat.

3. What participation involves

If you participate, your participation will last a total of approximately 3 weeks.

Screening test

By means of a screening questionnaire and smell function test we will determine whether you can participate in the study.

You can participate the test if meet all requirements, which includes:

- between 18 to 55 years old
- BMI between 18.5 and 27.5
- not lactose intolerance
- not pregnant, do not intend to become pregnant and do not breast-feed

- have a normally functioning sense of smell (this will be assessed)
- are not currently on a calorie-restricted diet or have been in the past 2 months
- do not smoke

Furthermore, you have to pass a smell function test: During the test, you are asked to smell 16 different odorous pens and identify the odours they emit. You can participate if the test indicates that you have a normally functioning sense of smell (a score of at least 12/16).

Visits and measurements

For the study you have come to the test location Helix - Wageningen Campus (Stippeneng 4, 6708 WE Wageningen) for 3 sessions in the period 9-11-2020 to 27-11-2020). Each visit lasts 40-50 minutes.

The following will then happen:

Smell test: You will receive a number of odor samples and evaluate them on various aspects such as pleasantness, or intensity, or identity. You will also receive serval sets of samples to distinguish which one is different (odd) in each set. All odors that used are commonly used in everyday life and are safe.

In addition, you will have to fill out a questionnaire about your (eating) behaviour.

4. What will be expected of you

- do no participate in another medical-scientific study.
- follow appointments for visits.

It is important that you contact the investigator:

- before you use another medicine. 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.

5. Possible adverse effects

Since orthoFAT study is a study where the smells are considered safe to smell, there is no reason to believe that smelling these fragrances entails a risk. The other procedures of the investigation (tasks, measuring instruments) do not entail any risk.

6. Possible advantages and disadvantage

It is important that you carefully consider the possible advantages and disadvantages before deciding to participate.
You will not personally receive any advantage from taking part in this study. Your participation may contribute to more knowledge about smell perception of people.

The disadvantages of participating in the study can be
- possible adverse effects of the measurements in the study.

Participation in the study also means:
- that you lose additional time;
- (additional) testing;
- that you have appointments that you have to attend;

All of these things are described below under point 3, 4 and 5.

7. 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 stopping. However, you should immediately inform the investigator.
The data obtained thus far will be used for the study.
If there is any new information about the study that is important for you, the investigator will inform you of this. You will then be asked if you wish to continue your participation.

8. End of the investigation

Your participation in the study ends when

- all visits such as described under point 3 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 study is concluded once all the participants have completed it.

9. Use and storage of your data

For this study, your personal data will be collected, used and stored. 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. Your personal data will be sent to other parties who need it for certain parts of the study, 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 with the key. The key to the code will be stored securely in the local research facility. The data that is sent to the sponsor only contain a code, but not your name or other data that can identify you. In reports or publications about the study, the data will also not be identifiable.

Access to your data for verification

Some individuals may have full access to your data at the study site. Also to the data without a code. 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 committee monitoring the safety of the study, national and international regulatory authorities, for example, the Health Care Inspectorate. They will keep your data confidential. We ask your consent for this access.

Retention period of your data

Your data must be stored for 15 years at the study site.

Withdraw 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 when processing your personal data, you can consult the website of the Dutch Data Protection Authority.

If you have questions about your rights, please contact the person responsible for the processing of your personal data. See **Appendix A** for contact details

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 (see **Appendix A**) or the Authority Personal data.

10. Insurance for test subjects

If you participate in the study, you will not run any additional risks. Wageningen University is therefore not required to take out additional insurance from the METC-WU.
If you take part in the study, you will not incur any additional risks. The Wageningen University, therefore, is not required by the METC-WU to take out additional insurance.

11. Compensation for participation

For participating in this study you will receive an expense allowance (including travel expenses) of 25€. This is indicated to the Dutch tax administration as income, If you stop before the study ends, you will receive a lower reimbursement.

12. Do you have any questions?

If you have any questions, please contact the research team. For independent advice on getting involved in this investigation please contact the independent expert. He knows a lot about the research, but has nothing to do with this research.
If you have complaints about the research, you can discuss this with the researcher. Would you rather not, then you can turn to the complaints officer of the Division of Human Nutrition and Health, Wageningen University. All details can be found in **Appendix A**: Contact details.

13. Signing the consent form

When you have had a sufficient reflection period, you will be asked to decide about participation in this study. If you consent, you will be asked to confirm this on the corresponding consent form, in writing (see **Appendix B**). With your written consent, you indicate that you have understood the information and agree to participate in the study.
Both you and the investigator will receive a signed version of this consent form.
Thank you for your attention.

14. Appendices to this information

A. Contact details
B. Informed Consent Form
C. Screening Questionnaire

Appendix A: contact details

Research team

MSc. Shuo Mu.

Dr. Sanne Boesveldt, Dr. Markus Stieger,

Contact:

Shuo Mu

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6708 WE Wageningen

Independent expert:

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Complaints:

Eveline Waterham

Division of Human Nutrition and Health, Wageningen University

Stippeneng 4 (building 124, Helix), 6708 WE Wageningen

Email: eveline.waterham@wur.nl

Data Protection Officer of the institution:

Frans Pingen Email: Privacy@wur.nl

Dutch Data Protection Authority:

www.autoriteitpersoonsgegevens.nl/

Appendix B: Subject Consent Form

Subject Consent Form

OrthoFAT study

- I have read the information letter. I could also ask questions. My questions are sufficient answered. I had enough time to decide whether to participate.
- - I know that participation is voluntary. I also know that at any time I can decide not to
- to participate or to discontinue the study. I don't have to give a reason for that.
- - I consent to the collection and use of my data <if applicable
- application> and human tissue to answer the research question in this study
- - I know that some people will have access to all of my data for audit purposes
- can get. Those people are listed in this information letter. I consent to that
- inspection by these persons.
- I do ☐ give
  ☐ none
- permission to approach me again after this investigation for a follow-up investigation.
- - I want to participate in this investigation.

Name of subject:

Signature: Date : __ / __ / __

I declare that I have sufficiently informed this subject about the said study.
If information becomes known during the study that would give the subject's consent influence, I will inform him / her of this in good time.
Researcher name:

Signature: Date: __ / __ / __

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