WAGENINGEN
UNIVERSITY & RESEARCH

WUR – REC Non-Medical Research Informed Consent

Study Background

The Division of Human Nutrition and Health at Wageningen University has set up this study. Investigators conduct the study on the campus of Wageningen University and at Gelderse Vallei Hospital (ZGV) in Ede. China Scholarship Council (CSC) and Symrise provide financial support for this study. The study has been approved by the WUR-Research Ethics Committee for non-medical research as meeting the Netherlands Code of ethics for research in the social and behavioral sciences involving human participants.
Purpose of the study: To investigate how the brain is activated under visual and olfactory food exposure.

What is being asked of you as a participant?

Step 1: are you eligible to take part?

First, we want to know if you are eligible to take part.

To be able to participate, you must meet all of the following inclusion criteria:

- Aged 18 - 55 at the time of inclusion
- Healthy BMI (18.5 - 25 kg/m^2)
- Self-reported healthy
- Having normal or corrected-to-normal vision
- Having a normally functioning sense of smell (scoring at least 12/16 on the Sniffin' Sticks test)
- Being right-handed
- Willing to comply with study procedures
- Agreeing to know about chance findings that might suggest you have a disease and agreeing to let your general physician know about it

Moreover, to participate, you should not meet any of the following exclusion criteria:

- Dislike the odors under investigation
- Having any allergy, intolerance, or oversensitivity to certain food products or having dietary restrictions such as vegetarian, halal etc. (self-reported)
- Being a regular smoker (smoking one or more cigarettes per day)
- Being pregnant, lactating, or planning on becoming pregnant during the study period.
- Using prescribed or non-prescribed medication in the month prior to the time of inclusion other than occasional use of pain medication (such as paracetamol and NSAIDs) or oral contraceptives
- Having a history of drug or alcohol dependence
- Having a psychiatric, neurological, or eating disorder
- Being employed by the Division of Human Nutrition and Health of Wageningen University or doing an MSc internship/writing a thesis at the Sensory Science and Eating Behavior chair group within the Division of Human Nutrition and Health of Wageningen University
- Participating in another medical-scientific study

MRI-related Exclusion Criteria:

- Having a fear of tight spaces (claustrophobia)
- Having a contra-indication to MRI scanning (including, but not limited to):

    - Pacemakers and defibrillators
    - Epilepsy or family history of epilepsy
    - Metal pieces stuck anywhere on/in the head
    - Implants that respond to magnets
    - Having piercings on the head that can not be removed
- Having eyesight issues, that cannot be corrected with contact lenses or MRI-safe glasses (maximum strength is +6 and -6)

Step 2:you need to sign up to participate in the study

If, after reading the informed consent, you still have remaining questions, you have the option of attending an online information meeting with the researchers (20 minutes). During this meeting, any remaining questions will be answered. To participate in the study, you first need to provide us with written consent. After sending us a signed copy of the consent form, you will be asked to fill out an online screening questionnaire to assess your eligibility. If you are eligible, you will be invited to schedule the first session (screening/training).

Step 3: study and measurements
The study will consist of two sessions.

Session 1: screening/training, 40min, Helix building (Wageningen University)

For the first session, you will come to Helix, where we will measure your body weight and height (used to assess BMI), and then continue with testing of your sense of smell. During this test, you will be given 16 pens, each having a different smell. You will have to smell each of the pens and decide what they smell like. If you can correctly identify at least 12 of the presented smells, your sense of smell is considered to be normal, and you can participate in the study. If not, your participation ends. Next, you will smell five scented semi-transparent brown glass vials, and then rate their liking, familiarity, and healthiness on a 100-unit Visual Analogue Scale (VAS). If there is any odor you dislike or are unfamiliar with, your participation ends. Then you will lie down in a fake MRI scanner. This scanner does not have a magnetic field like the real scanner, but is made of wood and does have the same shape as the real scanner. Here you will be given odors through a tube in your nose that will be used during the test session. Afterward, you will be asked to complete a series of questionnaires. The goal of this is for you to get used to lying in an MRI scanner and practice the procedures.

Session 2: test session, 1 hour and 10 minutes, Hospital Gelderse Vallei (Ede)

Brain scanning will take place in the radiology department of the Gelderse Vallei Hospital (Ziekenhuis Gelderse Vallei), in Ede. The 2nd test session will last around 1 hour and 10 minutes. You will be asked to not use strong-smelling creams, perfumes, deodorant, and hair products on the day of the test session. You will also be instructed not to eat or drink anything but water, use chewing gum, or brush your teeth for two hours before the test session.
After arriving at the hospital, you will fill out a checklist to make sure that you follow the instructions described above. You will also be asked about having a cold or a blocked nose. If you did not follow the instructions, or have a cold or blocked nose, the test session will be rescheduled. At this point, you will also

fill out a standard MRI safety form, to make sure you do not have any metal in or on your body (such as piercings). In case you are wearing clothes not appropriate for MRI scanning (i.e., clothes containing metal parts that cannot be removed), you will be asked to change into MRI-suitable clothes (given by us). Then you will enter the MRI machine and will be given earplugs to protect you from noise (the noise does not last the whole time but happens every once in a while). We will also make sure your head does not move by putting a plastic piece around it (like a motorcycle helmet) and placing a pillow under your knees, to make you feel more comfortable. Two small tubes will be inserted into your nose (one per nostril; about 1 centimeter deep), so that smells can be delivered to you. While in the MRI machine, you will be able to talk with the researchers, using a built-in voice communication system. You will also be able to use an alarm system if you start feeling uncomfortable. During scanning, you will see instructions on a screen inside the MRI machine. A mirror on the head coil (a helmet-like piece of equipment) will make sure you see this screen from within the machine. If you need to wear glasses, we will give you ones that can be used in the MRI machine.

You will spend around 40 minutes in the MRI machine. While in there, you will be instructed to smell different odors and view different food pictures. Researchers will be supervising the scanning from a few meters away (behind glass) and will regularly check up on you using the voice communication system.

Then you will leave the scanner to complete a food evaluation task. You will be asked to rate the degree of liking, familiarity, and healthiness of the food pictures that appear during the MRI scanning ("How much do you like this food product?", "How familiar are you with this food product?", "How healthy do you think the product is?").

Are there any benefits for participating?

You will receive a compensation of 40€ and a snack after completing all study sessions (screening/training and test session). If you are not able to participate after the screening/training session or decide to stop participating in the study after screening/training, will receive a €5 voucher. Moreover, if you take part you will help the investigators to get more insight into brain activation during visual and olfactory exposure.

Are there any risks in participating?

Participating in MRI research is safe but can be uncomfortable because you have to lie without moving in the MRI machine for around 40 minutes. You can feel a bit uncomfortable because you are in a relatively tight space and have the head coil placed around your head and/or the olfactometer nose pieces in your nostrils. Also, the MRI machine makes a lot of noise during scanning, however, we will reduce the noise by giving you earplugs.

During an MRI scan, it is possible that we discover something that is not directly relevant to the study but is important to your health. The investigator will contact your general practitioner. You will then discuss what needs to be done with your GP. The cost of this will fall under your own insurance policy. With this form, you give consent to inform your GP.

The MRI scan is performed by non-medical researchers. This scan is not usually viewed by radiologists and therefore cannot be considered a medical examination. However, there is a small chance of unexpected discoveries during the study. In the event of an unexpected discovery, the investigators will consult with a radiologist for a further review of the scan. If the radiologist thinks the findings are of significance to your health, you and your GP will be informed. If you do not wish to be informed of such unexpected discoveries,

you may not participate in this study. Remember that the scans are made as part of a scientific study, not to make a medical diagnosis.

How will your information be handled?

What data do we store?

We store these data:

- your name
- your gender
- your address
- your date of birth
- information about your health

How do we protect your privacy?

To protect your privacy, we give a code to your data. We only put this code on your data. The code does not consist of person-identifying elements, such as birth date or initials. We keep the key to the code in a safe place at Wageningen University. When we process your data, we always use only that code. Even in reports and publications about the study, nobody will be able to see that it was about you. Your data will be possibly be made available for re-use in future research in other research areas and/or by other scientists. When we share the data / make the data available for this purpose, we will do this in a way that no information can be traced back to you.

For how long do we store your data and body material?

We will store your data in Wageningen University for 15 years.

Can you withdraw your consent to the use of your data?

You can withdraw from participation in the study at any time without giving any reason. Additionally, you can withdraw your consent to the use of your personal data at any time. Please inform the investigator if you wish to do so. However, please note that if your data has already been used in analyses or reported in study results prior to your withdrawal, that data will continue to be part of the study's findings, and it may not be possible to remove it from the analyses.

Do you want to know more about your privacy?

Do you want to know more about your rights when processing personal data? Visit www.autoriteitpersoonsgegevens.nl.
Do you have questions about your rights? Or do you have a complaint about the processing of your personal data? Please contact the person who is responsible for processing your personal data. For the present, this is: Mr. WFEM (Frans) Pingen (WUR's Data Protection Officer). E-mail: privacy@wur.nl (See Appendix A for contact details).
If you have any complaints about the processing of your personal data, we recommend that you first discuss them with the research team. You can also go to Wageningen University's Data Protection Officer. Or you can file a complaint with the Dutch Data Protection Authority (See Appendix A for contact details).

What if I have questions about the study, or change my mind?

You can ask questions about the study to the investigator team. Would you like to get advice from someone who is independent from the study? Then contact REC (WUR Research Ethics Committee for non-medical studies involving human subjects), for contact details go to Appendix A.

If you have a complaint? Discuss it with the investigator. If you prefer not to do so, you can also talk to the complaints officer (Eveline Waterham). All contact details can be found in Appendix A: Contact information.

If you want to stop participating in the study yourself. You can stop at any time. Report this to the investigator immediately. You do not have to explain why you want to stop.

I consent in participating in this research and to the use of my personal data as described.

- I have read the informed consent. I was also able to ask questions. My questions were answered to my satisfaction. I had enough time to decide whether to participate.
- I know that participation is voluntary. I know that I can 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 the investigator permission to let my general practitioner know that I am participating in this study.
- I give the investigator permission to inform myself and/or my general practitioner about unexpected findings based on the MRI scans that are (or maybe) relevant to my health.
- I know that MRI images collected in this study are not intended to be used for diagnosis
- I give the researchers permission to collect and use my data to answer the research question of this study.
- I know that data about me that is significant to this study will be used for scientific purposes and possibly published. This includes the possibility that the MRI images may be shared in an online database for further scientific analysis. I agree to this, provided that my privacy is guaranteed.
- For women: I know I can no longer participate in this study if I become pregnant.
- I give permission for my data to be kept for 15 years after this study.
- I want to participate in this study.

Name of study participant: Date:

Signature:

- I hereby declare that I have fully informed this study subject about this study.
- If information comes to light during the study that could affect the study subject's consent, I will inform him/her of this in a timely fashion.

Name of investigator: Xinmeng Yang Date:

Signature:

Appendix A: Contact information

Coordinating investigator:

Xinmeng Yang
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Complaints:

Eveline Waterham
Wageningen University - Division of Human Nutrition and Health
Stippeneng 4, 6708 WE Wageningen
Helix (bulding 124)
E-mail: Eveline.waterham@wur.nl

Privacy:

Officer of personal data Wageningen University & Research
Mr. WFEM (Frans) Pingen
E-mail: privacy@wur.nl
Data Protection Office of the institution

Dutch Data Protection Authority
PO Box 93374, 2509 AJ The Hague
Phone: +31(0)881805250
Website: https://autoriteitpersoonsgegevens.nl/en

REC (WUR Research Ethics Committee for non-medical studies involving human subjects)

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