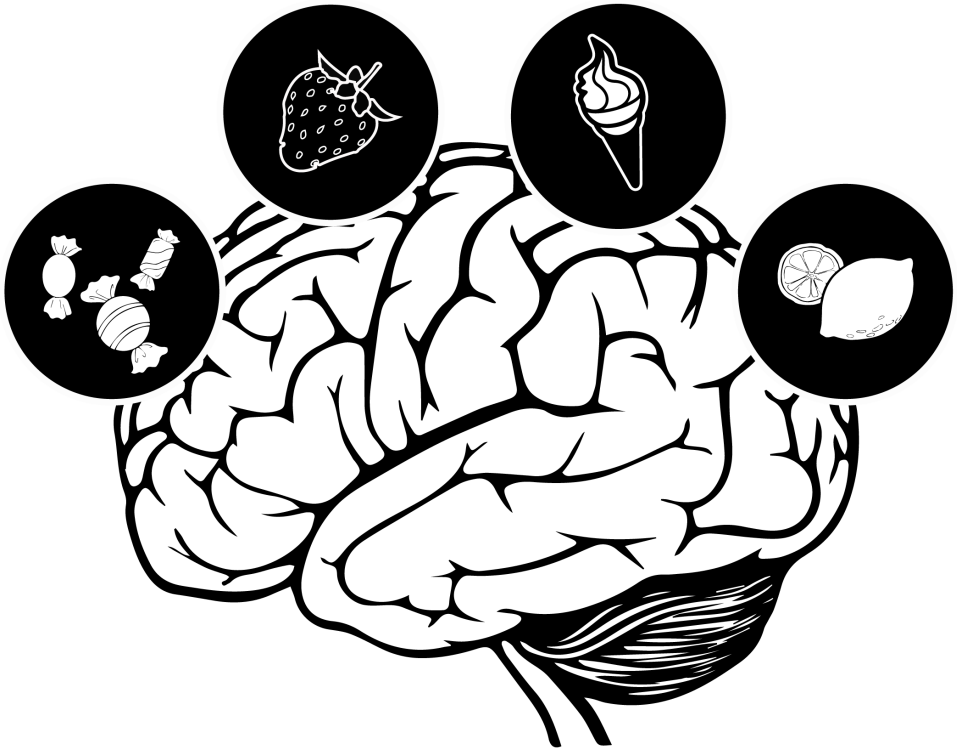
Information brochure

BrainAppeal study



Contact

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https://www.wur.nl/nl/Waardecreatie-Samenwerking/Voedingsonderzoek-WUR/Show-Voedingsonderzoek/BrainAppeal-studie.htm

Disclaimer: Wageningen University aims to discourage the use of tobacco products, to which this study contributes

Subject information for participation in medical-scientific research

BrainAppeal study

fMRI study on neural correlates of odor liking in a food and e-cigarette context

Introduction

Dear Sir/Madam,

We ask you to participate in a medical scientific study. Participation is voluntary. However, if you want to participate, your written permission is required. Before you decide whether you want to participate in this study, you will receive an explanation of what the study entails. Please read this information carefully, and ask the investigator for clarification in case you have any questions. You can also ask the independent expert, mentioned at the end of this letter, for additional information. You can also talk about it with your partner, friends, and family. Further information about participating in such a study can be found in the brochure ‘Medical scientific research’ (see appendices).

1. General information

This research is performed by the Department of Human Nutrition and Health of Wageningen University in cooperation with the National Institute for Public Health and the Environment (RIVM). The Ministry of Health, Welfare and Sport (VWS) is funding the study. For this study 25 smoking and 25 non-smoking subjects are needed.
The medical ethics review committee of Wageningen University has reviewed and approved this research.

2. Study aim

The purpose of this study is to investigate which brain regions are involved in the perception of different odors. These odors are representative of food products that you can eat or liquids from electronic cigarettes that you can smoke. This study is performed because it is unknown whether the role of odors in eating and e-cigarette smoking is similar.

To measure brain activity we use "magnetic resonance imaging", or "MRI".

MRI-scan
The abbreviation MRI stands for "Magnetic Resonance Imaging." With a strong magnetic field and radio waves, radio signals are generated in the body and processed into pictures of cross sections of the body. fMRI (f=functional) is a technique in which, in addition to brain structure, also brain activity can be made visible.
Before entering the MRI scanner, you must leave all metal objects and bank cards in a changing room. This is because of the strong magnetic field of the scanner.

3. Background of the study

Some years ago, the e-cigarette entered the market. Whereas smoking involves the burning of tobacco, using an e-cigarette (vaping) involves the heating of a liquid (e-liquid). E-liquids are available in thousands of different flavors, which contributes to the attractiveness of the product. The availability of e-liquids in different flavors is both positive and negative. On the one hand, scientific research has shown that e-liquid flavors can help people who are addicted to smoking switch to the e-cigarette, a potentially less harmful product. On the other hand, research shows that e-cigarette use is increasing among college students and that the flavor availability is one of the main reasons for this increase in use. Governments around the world are concerned about e-cigarette use among young people and therefore more knowledge about the attractivity of e-liquid flavors is needed.

By looking at brain activity, we can gain more insight into the role that different flavors play in e-cigarette use. Because much is already known about the role of flavor in eating behavior, we want to investigate whether this is similar to the role of flavor in the use of e-cigarettes.

4. What participation entails

To complete the study you have to come to the campus of Wageningen University (Helix building number 124) twice. Additionally you have to come to the hospital Gelderse Vallei in Ede once.

- You will come to the university once for an **information meeting**, where you will receive information about the study. During this meeting you will fill out a consent form and a number of questionnaires. This is the first part of the screening (in case you immediately decide to participate in the study). This visit takes about 30 minutes.
- You will come to the university another time for the second part of the **screening**. This visit lasts about 30 minutes and consists of a short smell test and training in a dummy MRI scanner to familiarize with the experimental setting and procedure.
- If, based on both parts of the screening, you are suitable to participate in the study, you will come to the hospital Gelderse Vallei once for a **test session** in the MRI scanner. This visit will take approximately 1 hour and 10 minutes.

In total this study will take about 2 hours and 10 minutes of your time. The visits to the university and hospital can be spread over several weeks. The dates will be scheduled in consultation with the participant.

Information meeting and first part of the screening

If during or after the information meeting you decide that you want to participate in the study, you will be asked to fill out a consent form indicating that you want to participate. After signing, you can immediately participate in the first part of the screening. You may also decide at a later timepoint whether you want to participate in this study. The signing of the consent form and the first part of the screening will then follow at a later point.

The first part of the screening consists of filling out a number of questionnaires about your health, smoking status, lifestyle and general information such as age and gender. Based on the results of these questionnaires, we will determine whether you are suitable to participate in the second part of the screening.

The second part of the screening

During the second part of the screening we assess your ability to smell. You will smell 16 odors and choose the correct description for each odor. Based on this test, we determine if you can participate in the study.

After that you will be trained to feel comfortable in an MRI scanner. You will lie in a dummy, or fake, MRI scanner for a short time. This scanner does not have a magnetic field like the real scanner, as it is made of wood. It does however have the same shape as the real scanner. During this training you will hear the sounds that a real MRI scanner makes. We will also give you a tube in the nose through which different odors are delivered. You will also be shown a presentation with instructions on what to do (such as "breathe in through your nose now") and questions to answer. This presentation contains the same information and questions that will be shown in the real MRI scanner.

Based on the results of the second part of the screening (smell test and whether you are comfortable with lying in the dummy MRI scanner), we will determine if you are suitable to participate in the actual test session of the study. Within a few days after the screening/training we will contact you about this via e-mail.

The test session

For the test session you will come to the hospital Gelderse Vallei in Ede once. Upon arrival at the test site, we will:

- Ask you to fill out the MRI screening and safety questionnaire, to make sure you don't have any metal in or on your body (such as a piercing).
- Explain the experimental procedure again.

If you wear clothing that is not suitable for the MRI scanner, you can change into hospital clothing (usually just the pants) that is suitable for the MRI scanner.

During the test session:

- We ask you to lie down on the scanner bed/table. You will be given a pillow under your head and knees so you lie comfortably and you will be given earplugs to protect your ears from the noise of the scanner.
- You can always communicate with the researchers via the intercom. You also get an alarm bell in your hand. You can press this bell and thus stop the scan immediately if you feel uncomfortable.
- You will get a helmet-like device on your head, which allows us to make scans of your brain.
- Through a mirror in the scanner you can see a screen with instructions. These instructions are similar to the ones you have seen during the screening/ training. If you wear glasses, we can give you glasses that are suitable for the MRI scanner.
- You will get to smell odors through a tube in your nose and answer questions about how much you like these odors.
- You will answer a few practice questions before we begin with the real test.

In total you will be in the scanner for about 50 minutes. There will be a 1 minute break after every 15 minutes.

5. What is expected of you

For research purposes and for your own safety, it is important that you stick to the following agreements. The agreements are that you:

- Do not use any scented creams, perfumes, deodorants, or hair products on the day of the test session.
- Maintain a normal eating pattern for the part of the day prior to the test session, which will prevent you from being hungry during the test session.
- Eating a small snack (yoghurt) 30 to 60 minutes before the test session, which you can pick up in Helix from 3 days to an hour and a half before the test session.
- For smokers only: smoke a cigarette 30 to 60 minutes prior to the test session.
- Two hours prior to the test session, do not eat or drink anything other than water and the snack mentioned above (including chewing gum), and do not brush your teeth.
- On the day of the test session wear clothes that allow you to enter the scanner, without metal, such as zippers, buttons, or bras with braces. This is not important for the screening/ training session.
- Keep appointments or cancel in time if you cannot come.

Pregnancy

Participants who are pregnant or breastfeeding cannot participate in this study. We do not know if MRI is safe for unborn children. Is there a chance you will be pregnant during the study? If so, please let the researcher know immediately.

6. When can you participate in this study?

For this study, we are looking for smoking and non-smoking subjects (both men and women) who meet the conditions below.

You are eligible to participate in this study if you:

- Are right-handed
- Are a light cigarette smoker or a non-smoker
    - As a light smoker, you have smoked *more* than 100 tobacco cigarettes or shags in your lifetime, smoke *more often* than 1 x a month, smoke *less* than 10 cigarettes or shags per day (on average), and do not smoke only on weekends. This does not include smoking cigars, pipe or marijuana.
    - As a nonsmoker, you have smoked *less* than 100 cigarettes and shags in your entire life. You also do not smoke cigars, pipe or marijuana.
- Are not generally opposed to e-cigarettes (previous use is allowed, but is not required)
- Are between 18 and 55 years old on the day of the information session
- Are in good general health
- Have a good command of the English language
- Have a normal sense of smell (this will be tested during the second part of the screening)
- Have a healthy BMI (18.5 - 25 kg/m2)
- Consent not to use drugs (other than tobacco and alcohol) in the week before the test session
- Are willing to obey to the study instructions
- Agree to be informed by your physician in the event of unexpected findings that may require medical treatment

You can **NOT** participate in the study if you:

- Are allergic or hypersensitive to yogurt
- Are claustrophobic (suffer from a fear of tight spaces)
- Wear glasses with a visual acuity of more than +6 or -6 (lenses of any acuity are no problem)
- Have irremovable metal in your body, such as a piercing, pacemaker, artificial heart valve, or metal implants/prosthetics
- Wear braces that are not removable (with the exception of a wire behind your teeth)
- Have a history of drug or alcohol addiction
- Have a psychiatric, neurological or chronic medical condition or an eating disorder
- Have used prescription or nonprescription drugs in the month prior to the test session, other than occasional painkillers (such as paracetamol, ibuprofen, and other NSAIDs), or oral contraception
- Are employed by the division of Human Nutrition and Health of Wageningen University
- Are a thesis student or intern at the chair group Sensory Science and Eating Behavior of Wageningen University

- Are simultaneously participating in another medical scientific study (with the exception of EetMeetWeet)

As a woman, you cannot participate in this study if you:

- Use an intra-uterine device (IUD) as contraception (with the exception of a hormonal IUD)
- Are pregnant or breastfeeding

During the screening, it may appear that are not suitable to participate in the study because:

- Your score for the smell test is insufficient
- You feel uncomfortable lying in the (dummy) MRI scanner

It is important that you contact the investigator if you

- Have taken any prescribed or non-prescribed medication other than pain medication (such as paracetamol, ibuprofen and other NSAIDs) and oral contraception in the time between the information meeting and test session
- Are ill or have a cold during the week of the screening or the test session
- Do not want to participate in the study anymore
- Change your contact details

7. Possible discomforts

Participating in MRI research is safe, but it may come with discomforts. You must lie still for a longer period of time (50 minutes) in the supine position in the tunnel (narrow space) of the MRI scanner. The MRI scanner makes a lot of noise while scanning. You will be given earplugs to reduce the noise. In addition, two tubes will be placed in your nose, through which a heated and humidified stream of air is constantly delivered. Occasionally the air stream will carry an odor. This procedure may take some getting used to. That is why you can practice with this during the screening session in the dummy MRI scanner.

8. Possible advantages and disadvantages of participation

It is important that you weigh the possible advantages and disadvantages carefully before deciding to participate. There is no direct benefit to you from participating in this study. Your participation may contribute to knowledge gain about brain areas involved in the use of e-cigarettes with different flavors. This research helps to understand the attractiveness of flavored e-cigarettes. Ultimately, feedback will be given to the Ministry of Health, Welfare and Sport on the role that different flavors play in the use of e-cigarettes and how this knowledge could be incorporated into tobacco control policy. Furthermore, you will receive a financial compensation for participating in this study.

Disadvantages of participating in the study may include:

- That you have to lie still in an MRI scanner for a longer period of time

- You will be informed by your general practitioner in the case of a chance finding that might suggest that you have a disease
- It will take up some of your time
- You have to comply with study procedures

9. If you don’t want to participate or you want to stop the study

You decide for yourself whether you want to participate in the study. Participation is voluntary. If you chose to participate, you can change your mind at any time and stop your participation, even if the study is taking place already. You do not have to give a reason why you are stopping. However, in case you are withdrawing from participation, you should report this to the researcher immediately. The data collected up to that point will be used for the study. If there is new information about the study that is important to you, the researcher will let you know. You will then be asked if you want to continue to participate.

10. The end of the study

Your participation in the study stops when

- all study steps as described under point 4 are completed
- you choose to stop
- you become pregnant
- the government or Wageningen University's medical ethics review committee (METC) decides to stop the study

The entire study ends when all subjects are finished.

After all the data have been processed, the researcher will inform you of the main results of the study. This happens about six months after your participation.

11. Use and storage of your data

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

Confidentiality of your data

To protect your privacy, your data will be coded. Your name and other data that can directly identify you are omitted. Only the key to the code can be used to trace the data back to you. The key to the code remains safely stored at the local research institution. The data sent to the sponsor will contain only the code, but not your name or other data that can identify you. Also in reports and publications about the research the data cannot be traced back to you.

Access to your data

Some people can access all your data at the research site. Also to the data without a code. This is necessary in order to check whether the research has been carried out properly and reliably. Persons who may inspect your data are: the medical ethics review committee (in Dutch: medisch-ethische toetsingscommissie (METC)) of Wageningen University and the Inspectorate of Healthcare and Youth (in Dutch: Inspectie Gezondheidszorg en Jeugd (IGJ)). They will keep your data confidential. We ask you to give us your permission to access these data.

Storage duration of your data

The researcher keeps the key for the code to your data for 3.5 years. After that, your data is anonymous. These anonymous research data are kept for 15 years after the end of the study. This is according to the Code of Conduct for Academic Practices by the Association of Universities in the Netherlands (VSNU), which instructs that raw research data should be stored for at least 10 years In addition, anonymous MRI data may be shared in an online database for further scientific research.

Information about chance findings

The MRI scan is performed by non-medically trained research staff. This scan is not routinely reviewed by radiologists and therefore cannot be considered a medical screening.
However, there is a small chance that chance findings may be made. Chance findings are abnormalities found during a medical check, without the doctor or patient looking for them based on complaints or concerns. An example would be a cyst (fluid-filled cavity) seen on a brain scan that requires further diagnosis. In the case of chance findings, the investigators will talk to a radiologist for a further assessment of the scan. If the radiologist thinks that the findings might be caused by a disease, you and your general practitioner will be informed about it. Keep in mind that the chances of finding something abnormal are relatively small. If you do not wish to be informed about such chance findings, you cannot take part in this study. Please note that the scans are made for research purposes, not to make a medical diagnosis.

Withdrawal of consent

You can always withdraw your permission for the use of your personal data for this study. The research data collected up to the moment you withdraw your consent will still be used in the study.

Learn more about your rights when processing data

For general information about your rights in relation to the processing of your personal data, please visit the website of the Dutch Data Protection Authority. For questions or complaints about the processing of your personal data, we recommend that you first contact the research location (Wageningen University). You can also contact the institution's Data Protection Officer, Mr. WFEM (Frans) Pingen, whose contact details can be found in Appendix A.

Registration of the study

Information about this study is also included in an overview of medical-scientific studies, the Netherlands Trial Register [NTR (trialregister.nl)]. This overview will not contain any data that can be traced back to you. After the completion of the research the website may show a summary of the results. You can find this study in the NTR under the registration number Trail NL7963.

12. Insurance of test subjects

Insurance has been provided for everyone participating in this study. The insurance covers damage caused by the research. Not all damages are covered. In Appendix B you will find more information about the insurance. It also states to whom you can report damage.

13. Informing your general practitioner (GP)

In principle, your GP will not be informed of your participation in this study. However, as described on page 9, if there is a chance finding, the researchers will contact a radiologist for further assessment of the scan. In that case, you and your GP will be informed of such a finding. You cannot participate in the study if you do not have a GP.

14. Reimbursement for participation

If you participate in the entire study, you will receive a compensation of €50. If after the screening session it appears that you are not suitable for participation in the study, you will receive a compensation of 5€ in the form of a VVV gift card. If you stop before the research is completed, you will receive a lower compensation.
The compensation will be reported to the tax authorities as income. Be aware that it may take about 2-4 months after the completion of the study before the reimbursement is available on your bank account.

15. Do you have questions?

If you have any questions, please contact the research team. For independent advice about participating in this study, you can contact the independent physician, Dr. J. Nikken (radiologist). He knows a lot about the study, but has nothing to do with this study. If you have any complaints about the study, you should contact the complaints officer, Eveline Waterham. All details can be found in Appendix A: Contact details.

16. Signing of the consent form

When you have had sufficient time to think about it, you will be asked to decide if you want to participate in the study. If you give your consent, we will ask you to confirm it in writing on the accompanying consent form (see Appendix C). Your written consent indicates 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 statement.

Thank you for your attention.

17. Appendices to this information brochure

A. Contact information
B. Insurance information
C. Consent form

Appendix A: contact information for Wageningen University

Research team
Coordinating researcher: Ina Hellmich
Project leader: Dr. Sanne Boesveldt
Research physician: Drs. Myrthe Naaktgeboren
Division of Human Nutrition and Health, Wageningen University
E-mail: brainappeal@wur.nl
Telephone: +31 (0)6 29646991

Visiting address information meeting and screening
Wageningen University
Helix (gebouw 124)
Stippeneng 4
6708 WE Wageningen

Visiting address test session
Hospital Gelderse Vallei (ZGV)
Willy Brandtlaan 10
6716 RP Ede

Website:
https://www.wur.nl/nl/Waardecreatie-Samenwerking/Voedingsonderzoek-WUR/Show-Voedingsonderzoek/BrainAppeal-studie.htm

Independent practitioner:
Dr. J. Nikken, radiologist, Hospital Gelderse Vallei
E-mail: NikkenJ@zgv.nl
Please clearly inform the practice assistant or state in the e-mail which study it concerns.

Complaints Officer:
Eveline Waterham
Department of Human Nutrition and Health, Wageningen University
E-mail: eveline.waterham@wur.nl

Data Protection Officer of the institution:
Frans Pingen
E-mail: privacy@wur.nl
Website: https://www.wur.nl/nl/show/Reglement-bescherming-persoonsgegevens.htm

Appendix B: information about the insurance

Wageningen University & Research has taken out insurance for everyone who participates in this research. The insurance covers damages resulting from participation in the research. This applies to damage during the research or within four years of the end of your participation in the research. You must report any damage to the insurer within those four years.

The insurance does not cover all damages. At the bottom of this text you will find a short description of the damages that are not covered.
These provisions are in the Medical Research Involving Human Subjects Act. This decree is on https://english.ccmo.nl/, the website of the Central Committee on Research Involving Human Subjects (see 'Publications' and then 'Decree 2014 containing rules for compulsory insurance in medical research involving human subjects and explanatory memorandum').

In case of damage, you can contact the insurer directly.

The insurer of the study is:	
Name:	HDI- Global SE, the Netherlands Management for the Netherlands
Address:	PO Box 925, 3000 AX Rotterdam
Phone number:	020 5650654
Email:	info@hdi-gerling.nl
Policy number:	V-055-862-396-3 / V0100109572
Contact person:	M. Wijnsma (Amsterdam office)

The insurance provides coverage of up to a maximum amount of € 650,000 per participant, with a maximum of € 5,000,000 per research. A maximum of €7,500,000 applies to all Wageningen University & Research research per insurance year.

The insurance does **not** cover the following damage:

- damage caused by a risk of which you were informed in the written information. This does not apply if the risk occurs more seriously than was foreseen or if the risk was very improbable;
- damage to your health that would also have occurred if you had not taken part in the study;
- damage as a result of not (fully) complying with directions or instructions;
- damage to your offspring as a result of a negative effect of the research on yourself or your offspring;
- damage as a result of research into existing treatment methods.

Appendix C: consent form for test subject

BrainAppeal study

- I read the subject information. I was also able to ask questions. My questions were adequately answered. I had enough time to decide whether to participate.
- I know that participation is voluntary. I also know that I can decide at any time not to participate or to stop the study. I do not have to give a reason for doing so.
- I know that for the purpose of monitoring the study some people may have access to all my data. These people are listed in this information letter. I give permission for that access by those people.
- I consent to the collection and use of my data to answer the research question in this study.
- I know that data about me that are of importance 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.
- I know that the MRI images are not intended to be used for diagnosis.
- I consent to informing my physician and myself of unexpected findings based on the MRI scans that are (or may be) important to my health.
- For women: I know that I am not allowed to become pregnant during the study.
- I give permission for my data to be kept for 15 years after this study.
- I want to participate in this study.

Subject name: _____

Signature: _____ Date : __ / __ / __

I certify that I have adequately informed this subject about the aforementioned study. If any information becomes known during the study that could affect the subject's consent, I will inform him/her in a timely manner.

Investigator (or his/her representative) name: _____

Signature: _____ Date: __ / __ / __

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