Morphology of olfaction-related brain regions and brain functionality in response to odor exposure in healthy participants

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To investigate brain morphology and brain activation in response to odor stimulation in participants with a normal smelling ability.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON49925

Source
ToetsingOnline

Brief title
Smell it! study

Condition

- Other condition
- Central nervous system infections and inflammations

Synonym
anosmia; smell loss; smelling ability

Health condition

reukvermogen

Research involving

Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Subsidie van Ziekenhuis Gelderse Vallei

Intervention

Keyword: MRI, odor, olfactometer, smelling ability

Outcome measures

Primary outcome

1) volume of olfaction-related brain areas; 2) activation of brain areas during

odor stimulation compared to the control condition.

Secondary outcome

1) olfactory function and its relation with the primary study parameters; 2)

activation of functional brain networks

Study description

Background summary

Olfaction is important in daily life. While olfactory loss is not often discussed, 3 to 20% of the general population is affected by olfactory loss. Previous studies showed that olfactory loss can affect both brain morphology of olfaction-related areas and brain response to odor stimulation within patients. To better understand how olfactory loss affects the processing of odors in the brain, we need more knowledge on how odors are processed in the brain of individuals with a normal sense of smell.

Study objective

To investigate brain morphology and brain activation in response to odor stimulation in participants with a normal smelling ability.

Study design

This is an observational study in healthy participants. For all participants, two visits will be planned. During a training session (1h) at Wageningen University, Wageningen, an olfactory and taste test will be performed (40 minutes). Participants who pass the olfactory test will be familiarized with the test situation that will be used during the study day (20 minutes) using a dummy MRI scanner. The study day (1.5h) includes a visit to the MRI facilities in Hospital Gelderse Vallei, Ede. Participants fill in a safety questionnaire and a demographics questionnaire (10 minutes), and undergo an MRI measurement (60 minutes). The MRI measurement consists of two subparts: anatomical imaging of the brain (~20 minutes) and a functional session including a paradigm during which subjects are presented with odors (~30 minutes).

Study burden and risks

The study is non-therapeutic to the subjects. No immediate benefits for the subjects are expected from participation in this study. The risk associated with participation is negligible. The subjects* burden is as follows, regarding time: the training session will take approximately 1h; the experimental session will take approximately 1.5h, including one hour inside the MRI scanner. MRI is an eminently safe technique; there are no risks that have been associated with the acquisition of MRI data per se. The MRI-scans in this study are not made with the intention to diagnose pathologies, however, chance findings of pathology may occur. Participants will be informed of this possibility and need to be willing to receive information about incidental findings of pathology. Participants can leave the study at any time for any reason if they wish to do so without any consequences.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Self-reported healthy
No known smell disorder
No history of head trauma
No neurological disorders (like Alzheimer*s or Parkinson*s disease)
Labelled as having a normal sense of smell according to our standardized clinical olfactory test Sniffin* Sticks) (score >= 30.5 points out of 48 points)
Age between 18-75 years
Have normal eyesight or an eye deviation that can be corrected with glasses or contact lenses.
Willing to comply with the study procedures
Willing to be informed about incidental findings of pathology and approving of reporting this to their general physician
Having given written informed consent (see E1.Informatiebrochure)

Exclusion criteria

Having a contra-indication to MRI scanning (including, but not limited to):
o Being pregnant
o Pacemakers and defibrillators
o Intraorbital or intraocular metallic fragments
o Ferromagnetic implants
o Claustrophobia

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-02-2022
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	14-12-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL78132.091.21