Neural processing of olfactory stimuli in response to smell loss

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

Summary

ID

NL-OMON50783

Source
ToetsingOnline

Brief title
SensoSmell

Condition

- Other condition
- Central nervous system infections and inflammations

Synonym
anosmia; smell loss

Health condition

reukvermogen

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Brain activation, Electroencephalogram, Odors, Smell loss

Outcome measures

Primary outcome

Difference in event-related potentials in response to olfactory stimuli between

patients with smell loss and controls

Secondary outcome

Score on the Sniffin' Sticks test (smell test) of participants and its

correlation with N1 and P2 amplitudes of olfactory ERPs.

Study description

Background summary

The role of smell is of major importance in flavour perception and eating behaviour, sensing threats, social interaction and memory processes. The ability to smell greatly contributes to the quality of life. Loss of olfactory function is common and affects about 3-20% of the population. Risk of anosmia (inability to smell) and hyposmia (decreased ability to smell) can result from neurodegenerative diseases, trauma or infection. Olfactory deficits often go unnoticed, which highlights the importance of objectively measuring olfactory function in patients. Recently, EEG has gained clinical interest as a potential method to distinguish between patients with olfactory loss and healthy controls. How smell loss correlates with brain activation in response to olfactory stimuli still needs to be investigated.

Study objective

The primary objective of this study is to investigate the difference in brain activation in response to odour stimulation between patients and controls. The secondary objective is to investigate the relationship between smell ability

and brain activation in response to odour stimulation. We hypothesize that brain responses will decrease with severity of olfactory loss.

Study design

This is an observational study.

Study burden and risks

Participation includes one test session at Hospital Gelderse Vallei in Ede. Participants are asked to only drink water for two hours before the test session. At the start of the test session participants need to fill in a short questionnaire. During the test session olfactory function will be assessed using the UPSIT-40 (~30 minutes) and an EEG measurement (~60 minutes) will be performed. EEG is a widely used, non-invasive and safe way to measure brain activation. An EEG cap will be placed on the participants* head and electrodes will be connected by using gel and a tool to scratch a bit on the head. This may feel a bit cold and unpleasant. Participants are asked to sit still and not move their head during the EEG measurement. During the EEG measurement odour stimuli will be presented via an olfactometer, which tubes will be inserted ± 1 into the nostrils. The study is non-therapeutic to the participants. The risk associated with participation is minimal.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

For patients:
* Labelled as hyposmic or anosmic according to a standardised olfactory test
* Smell loss due to a viral infection
* Aged between 18-65 years
* Have normal/ corrected to normal eyesight
* Willing to follow the study procedures
* Having given written informed consent
* Righthanded

For controls:
* Self-reported healthy
* Labelled as normosmic according to a standardised olfactory test
* Aged between 18-65 years
* Have normal/ corrected to normal eyesight
* Willing to follow the study procedures
* Having given written informed consent
* Matched on sex to patient
* Matched on age (within +/- 3 years) to patient
* Righthanded

Exclusion criteria

* Having congenital anosmia (because olfactory networks will be different from people who have been able to smell)
* Having suffered from head trauma
* Having chronic (neurological) diseases which impact brain functioning (e.g. mental health disorder, epilepsy)
* Having fluctuating smell ability
* Being deaf (or having hearing problems) or blind
* Being an employee at the division of Human Nutrition and Health at Wageningen University
* Performing a thesis or internship at the chair group Sensory Science and

Eating Behaviour at the division of Human Nutrition and Health at Wageningen University

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2021
Enrollment:	40
Type:	Anticipated

Medical products/devices used

Generic name:	electroencephalogram
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	24-11-2021
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL75270.028.21