Neural correlates of odor liking in food and e-cigarette context

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To determine the effects of context (food context vs. e-cigarette context), odor category (sweet vs. savory) and user group (smokers vs. non-smokers) on reward-related brain activation.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON52740

Source
ToetsingOnline

Brief title
BrainAppeal

Condition

- Other condition

Synonym
brain activation, brain signalling

Health condition

hersenactivatie

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: het Rijksinstituut voor Volksgezondheid en Milieu (RIVM)

Intervention

Keyword: e-cigarette, flavors, fMRI, liking

Outcome measures

Primary outcome

The primary study parameter is the brain response to odors in reward-related brain areas, measured with fMRI.

Secondary outcome

Secondary study parameters are quantitative ratings for odor liking, intensity of odor sweetness, intensity of odor savoriness, and willingness to try the e-cigarette/food product obtained using a continuous 100-unit visual analogue scale (VAS). Other secundary study parameters are questionnaires outcomes about reward sensitivity, impulsivity, sensitivity to food cues, smoking and vaping characteristics, and other parameters such as age, gender, history of e-cigarette use, and intention to quit smoking.

Study description

Background summary

Electronic cigarettes (e-cigarettes) were introduced a few years ago. Whereas smoking burns Tobacco, the use of an e-cigarette (vaping) only heats an e-liquid. E-liquids are available in thousands of different flavors, which contribute to product attractiveness. The availability of e-liquids in various flavors is positive as well as negative. On one hand, attractive e-liquid flavors may help currently addicted smokers to quit smoing and switch to

e-cigarettes, a product that is potentially less harmful. On the other hand, research showed that e-cigarette use is increasing among middle and high school students, and flavors are identified as one of the top reasons for use. Worldwide, governments have raised concerns about e-cigarette use among adolescents, which is why more knowledge about e-liquid flavors is necessary.

On behalf of the Dutch Ministry of Health, Welfare, and Sports, Wageningen University and RIVM collaborate in order to investigate e-liquid flavors in different user groups. Investigating brain processes provides more insight in the role of different odors/flavors in e-cigarette use. As the role of odors/flavors in eating behavior is well known, we aim to investigate it this is comparable to the role of odors/flavors in e-cigarette use. Focusing on neural processes involved will allow us to better understand why people like (flavored) e-cigarettes, how liking of e-cigarettes may differ from liking of food, and if this differs between user groups (e.g. smokers/non-smokers).

Results of our previous sensory study (Smell-e studie, METC protocol NL65748.081.18, Dutch Trial Register Trial NL7319 [NTR7535]) showed that the correlation coefficient between smelling and vaping for hedonic assessment of e-liquid flavors is strong, which justifies the use of orthonasal smelling in the current BrainAppeal study.

Study objective

To determine the effects of context (food context vs. e-cigarette context), odor category (sweet vs. savory) and user group (smokers vs. non-smokers) on reward-related brain activation.

Study design

This study has a 2x2x2 mixed design in which brain responses to sweet and savory odors will be measured in an e-cigarette and food context in smoking and non-smoking subjects.

Intervention

During fMRI, sweet and savory odors will be presented using an olfactometer. Accompanying visual cues will be used to create an e-cigarette and food context. Ratings for odor liking, intensity of odor sweetness, intensity of odor savoriness, and willingness to try the e-cigarette/food product will be collected on a 100-unit Visual Analogue Scale.

Study burden and risks

The study is non-therapeutic to the subjects; no immediate benefits are expected from participation in this study. The risk associated with

participation is negligible. In terms of time, the subject*s burden is as follows: both the information meeting and the screening/training visit will take approximately 30 minutes, and the experimental test visit will take approximately 1 hour and 10 minutes, of which subjects spend less than an hour in the scanner. To undergo an fMRI scan involves: exposure to loud noise, a moderate amount of physical restraint, as well as exposure to a strong magnetic field (3 Tesla) of which the subject is unaware, that is, the subject does not *feel* being in a magnetic field. During the scanning session, subjects will receive olfactory stimuli, embedded in a constant stream of odorless air which is heated to body temperature and humidified to 80% relative humidity.

Contacts

Public
Wageningen Universiteit

Stippeneng 4
Wageningen 6708WE
NL
Scientific
Wageningen Universiteit

Stippeneng 4
Wageningen 6708WE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Be susceptible to e-cigarette use (for definition, see *C1 Research Protocol*)

- Be smoker or non-smoker (for definition, see *C1 Research Protocol*)
- Normal olfactory function according to the Sniffin* Sticks identification test (>=12 correct answers out of 16)
- Good proficiency of the Dutch and/or English language
- Right-handed
- Aged 18-55 years at the time of inclusion
- Normal BMI (between 18.5-25 kg/m2)
- Healthy as defined by the *F1_1 General screening questionnaire*
- Willing to be informed about incidental findings of pathology and approving of reporting this to their general physician
- Willing to refrain from using drugs other than tobacco and alcohol for one week before the test session

Exclusion criteria

- Dislike the odors under investigation
- Allergic or hyper sensitive reaction to yoghurt
- The use of prescribed or non-prescribed medication in the month prior to the test session, other than occasional use of pain medication (such as paracetamol and NSAID*s) or oral contraceptives
- Have a history of drug or alcohol dependence
- Have a psychiatric, neurological, or eating disorder or chronic medical condition
- Be 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
- Participation in another medical-scientific study (except for EetMeetWeet)
- Claustrophobic (self-report)
- Having a contra-indication to MRI scanning, including but not limited to non-removable piercings, a pacemaker, or ferromagnetic implants
- Limited sight that is not corrected with contact lenses or cannot be corrected with our MRI safe glasses (maximum strength is +6 and -6)
- For women: lactating, being pregnant, or using a IUD as anti-conceptive (with exception of the Mirena IUD).

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-02-2022
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	16-09-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-03-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-04-2022
Application type:	Amendment
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	NL70699.081.19