

# Liking of e-liquid flavors: correlation between smelling and vaping

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Completed
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON46212

### Source

ToetsingOnline

### Brief title

Smell-e

### Condition

- Other condition

### Synonym

attractiveness, liking

### Health condition

perceptie

### 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, liking, smell

## Outcome measures

### Primary outcome

The primary study parameter is the correlation coefficient of liking of e-liquid flavors through smelling versus liking of e-liquid flavors through vaping, for smokers as well as for non-smokers.

### Secondary outcome

Secondary study parameters are:

- Difference in correlation coefficient of liking by smelling and liking by vaping between smokers and non-smokers.
- Correlation coefficients of intensity, familiarity, and irritation of e-liquid flavors by smelling versus vaping, for smokers as well as for non-smokers.
- Average (mean+SE) liking, intensity, familiarity, and irritation of the e-liquids used in this study, including differences (p-value) between e-liquids, for smelling as well as for vaping. In addition, a distinction will be made between male and female research subjects.
- Slope and intercept for the relation between liking by smelling and liking by vaping, within research subjects.
- Correlation coefficients between average liking, intensity, familiarity, and

irritation, for smelling as well as for vaping.

## Study description

### Background summary

It is well known that smoking is associated with severe health effects. Recently, the e-cigarette was introduced. Whereas smoking burns tobacco, the use of an e-cigarette (vaping) only heats e-liquids. E-liquids consist of a base liquid with flavorings and potentially nicotine. E-liquids are available in a high variety of flavors, which increase sensory appeal. Therefore, usage of the e-cigarette has exponentially increased over the past couple of years, and governments aim to regulate the availability of e-liquid flavors. Within Europe, no regulation on the availability of e-liquid flavors currently exists. In order to advice the government on how to regulate e-liquids flavors, research is required. On the one hand, certain flavors may help currently addicted adult smokers switch to potentially less harmful forms of nicotine-containing tobacco products. At the same time, e-cigarettes are the most commonly used tobacco product among middle and high school students, and flavors are identified as one of the top three reasons for use. Given these findings, governments need to be wary of the role flavors play in attracting youth to initiate on any tobacco product that could lead to regular use \* something that clearly should be avoided. No child should use any tobacco products, including e-cigarettes.

Regulation could focus on liking (and disliking) of particular e-liquid flavors and/or flavor categories among these different consumer groups (i.e., adults/adolescents; smokers/non-smokers). On behalf of the Dutch Ministry of Health, Welfare, and Sports, Wageningen University and RIVM collaborate in order to investigate sensory characteristics of e-liquids flavors within these target groups. In this way, we aim to obtain insight in attractiveness and preferences of different e-liquid flavors and addictive behavior - also within the brain. The Smell-e study is the first step in this 4-years research project. Eventually, we will advice the government in how to best regulate e-liquid flavors, contributing to the overall aim for a 'smoke-free generation'.

### Study objective

Research on e-liquid flavors could be performed through smelling or tasting (\*vaping\*) experiments. The main objective of the Smell-e study is to determine if there is a correlation between liking of e-liquid flavors through smelling and liking of e-liquid flavors through vaping, for smokers as well as for non-smokers. If we find a correlation between liking by smelling and liking by

vaping, we may be able to assess liking through vaping in future research by performing smelling experiments only. This removes potential health implications, and will save time, effort and money. In addition, performing smelling experiments allows to include youth as well (<18 years old). Results in flavor liking among this study population will be of huge importance to policy makers worldwide in developing their regulations on e-cigarette flavors in order to prevent tobacco use among non-smoking youth.

## **Study design**

The Smell-e study consists of an experimental within-research subjects design., in which the smell and taste of 25 e-liquids will be evaluated by smelling and vaping. The study consists of 4 test sessions (two smelling and two vaping sessions). Test sessions will take place in sensory booths of the Restaurant of the Future at Wageningen University. The order of sessions A \* D will be counterbalanced across research subjects. Sessions will be scheduled in accordance with panelists. Minimal time between two sessions is 1 week.

The screening session (30 minutes) will include olfactory screening using the Sniffin\* Sticks identification test. Research subjects with normal olfactory function according to this test will be included in the study. Research subjects will subsequently be trained in using an e-cigarette by vaping an unflavored e-liquid (maximal 5 puffs), and in using a visual analogue scale (VAS) by scoring liking of the unflavored e-liquid. This will avoid vaping results to be influenced by incorrect usage of the e-cigarette or VAS.

The test sessions consist of two smelling and two vaping sessions (each 60 minutes).

For the smelling sessions, 10 drops of each e-liquid will be put into a glass vial, which will be covered in tinfoil to avoid visual cues and labelled with a random three-digit code. In one smelling session, research subjects will smell 12 of the 25 e-liquid flavors. The other 13 e-liquid flavors will be assessed in the other smelling session. During the smelling session, research subjects will first assess each of the 12 or 13 samples in randomized order on liking (100mm VAS). Subsequently, they will assess each of the same samples in randomized order on intensity, familiarity, and irritation (100mm VAS). In this way, research subjects do not have to continuously switch between hedonic and analytical assessment for each sample. Research subject will smell each sample 2 times. A one-minute break will be incorporated between each sample to neutralize the research subjects\* smell and prevent adaptation.

For the vaping sessions, two sets of 25 e-cigarettes will be filled with each of the 25 e-liquids. The e-cigarette cartridge (which contains the e-liquid) will be covered in tinfoil to avoid visual cues and labelled with a random three-digit code. In one vaping session, research subjects will evaluate 12 of the 25 e-liquid flavors. The other 13 e-liquid flavors will be assessed in the other vaping session. During the vaping session, research subjects will first assess each of the 12 or 13 samples in randomized order on liking (100mm VAS).

Subsequently, they will assess each of the same samples in randomized order on intensity, familiarity, and irritation (100mm VAS). Each research subject will use 2 puffs for each sample. Research subjects themselves decide whether to inhale the vape over their lungs or whether to keep the vape only in their mouth before exhaling; as long as they inhale each sample in the same way.

## **Intervention**

Research subjects will be exposed to the odor of 25 e-liquids (divided over two smelling sessions) and the vapor of the same 25 e-liquids (divided over two vaping sessions).

## **Study burden and risks**

The burden for research subjects includes 6 visits to the university for the information meeting, screening, and four test sessions respectively. The study will take approximately 5.5 hours in total. During the information meeting, research subjects fill out the screening questionnaire. During the screening session, research subjects smell 16 odors (Sniffin' Sticks). During the test sessions, research subjects evaluate each sample on four aspects (liking, intensity, familiarity, and irritation) while they smell the sample twice (25 samples divided over 2 smelling sessions) and they take two puffs of each sample (25 samples divided over two vaping sessions).

The health risk associated with smelling is negligible. Potential risks associated with vaping can be divided into three parts: addictiveness, attractiveness, and toxicity.

The risks on addictiveness is not applicable, as we only use e-liquids without nicotine (this will be confirmed using chemical-analytical research). The risk of attractiveness of e-cigarette use will be minimized by using the most straightforward and least attractive e-cigarette model (far from the look of a regular tobacco cigarette and not the most popular e-cigarette model), selecting e-liquids with a low amount of vegetable glycerin (in order to minimize the amount of vapor clouds that is produced), and by performing the vaping experiments in laboratory setting (while vaping might be more associated with a social setting).

The vaping part of this study will be associated with a very low health risk, because research subjects will take a low number of puffs (50 in total, divided over two sessions) and because the e-liquids do not contain nicotine. The RIVM has published a report on health effects of e-cigarette exposure, of which we can conclude that potential health risks of the Smell-e study are very low. Only with a much higher exposure to e-cigarette vapor than the exposure of this study, users might be at risk of irritation or harm to airways and palpitations. In any way, these effects are less severe than the health effects that are associated with smoking of regular tobacco cigarettes (such as lung

cancer, heart attack, and stroke).

Potential health effects will be elaborated during the information meeting. A more detailed risk analysis is provided in chapter 13 of our research protocol.

## 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

- Good proficiency of the Dutch language
- Aged 18 to 55 years at the time of inclusion
- Healthy as defined by the F1 Screening questionnaire
- Normal olfactory function according to Sniffin\* Sticks identification test (>12 correct answers out of 16)

## Exclusion criteria

- Having ever used an e-cigarette
- Pregnancy (plans) or lactating
- Being allergic for any of the products under investigation in this study (e-liquid flavors)
- Being employed by the Division of Human Nutrition 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 of Wageningen University
- Participating in another medical-scientific study (except for EetMeetWeet)

## Study design

### Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

### Recruitment

NL	
Recruitment status:	Completed
Start date (anticipated):	13-11-2018
Enrollment:	48
Type:	Actual

## Ethics review

Approved WMO	
Date:	05-07-2018
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

## 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	NL65748.081.18

## Study results

Date completed: 13-12-2018

Results posted: 26-09-2019

### First publication

26-09-2019