The characterising flavours of tobacco

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Primary Objective: To determine whether a tobacco product (cigarettes and roll-your-own tobacco) imparts a characterising flavour/odour.Secondary Objective: Do the characterising flavours/odours of the tobacco products as determined through panel...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON42216

Source ToetsingOnline

Brief title The characterising flavours of tobacco

Condition

• Other condition

Synonym Addiction, habituation

Health condition

verslaving

Research involving Human

Sponsors and support

Primary sponsor: Wageningen Universiteit Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: Flavour, Tobacco

Outcome measures

Primary outcome

The descriptive flavour profiles of cigarettes with and without characterising

flavour/odour (i.e. tobacco descriptors and their intensity, VAS-scale

measurement)

Secondary outcome

Does the descriptive flavour/odour profile of the tobacco judged by the

professional panel correspond with additives found by chemical analyses of

tobacco products.

Study description

Background summary

Smoking leads to severe health problems for both smokers and their environment (1, 2). Most smokers become addicted to tobacco during secondary school, with determinants of youth smoking varying from individual factors to wider social influences (3, 4). One of these determinants is the so-called product attractiveness of tobacco products, therefore, tobacco product attractiveness and its impact on dependence should be taken into account when considering regulatory measures, as tobacco products are commonly made to be attractive in order to encourage their use (5, 6).

Attractiveness can be defined by intrinsic sensory attributes such as taste, smell and mouth feel (7) and extrinsic factors such as marketing, packaging and pricing (8).

The current study focuses on intrinsic factors, in particular additives that give a characterising taste and smell to tobacco products. Studies have shown that in addition to the pharmacological effects of nicotine, sensory product characteristics such as taste, smell, and respiratory tract sensations (mouth feel, impact) play a major role in smoking satisfaction, product acceptance, and the desire to smoke (9, 10).

Regarding taste and aroma, cigarette smokers identify flavour as an important

factor in the pleasure derived from smoking and for their choice of cigarette brand (11-13). Dutch survey data also indicate that taste and smell are important determinants of brand preference among adolescent smokers (14). For instance, the sweetness of cigarette smoke appeared closely related to satisfaction and pleasantness (15).

Many chemosensory studies are performed by the tobacco industry with the aim to control sensory characteristics in a favourable way (16). For example, additives referred to as ameliorants such as sugars, cocoa and liquorice (17) are used to reduce sharpness and irritation caused by tobacco smoke as this positively influences adolescent product perceptions (18), and may facilitate experimenting and smoking initiation (5, 19).

To protect the health of European citizens, in particular, to reduce the smoking prevalence among young people, the new EU Tobacco Product Directive prohibits cigarettes and roll-your-own tobacco having a characterising flavour other than one of tobacco. Examples of flavours added to tobacco are fruit flavours, chocolate and menthol. The new EU Tobacco Product Directive aims to discourage young people, attracted by flavoured products, from taking up smoking.

Some countries already implemented legislation aiming at decreasing product attractiveness via flavour regulation, for example upper limits are set for aroma additives in France and in Canada many different additives are prohibited. However clear methods to determine whether a tobacco product imparts a characterizing flavor are yet to be developed. From chemical research we can derive information about the natural ingredients and additives of tobacco, which comes down to a list of 460 additives (20). However it is difficult to assess the combined and individual effect of each additive on the flavour of tobacco, therefore the focus in this study is on the characteristics of the entire product. Characterising flavour is defined by the European Commission (Consumer, Health & Food Executive Agency) as * a clearly noticeable smell or taste other than one of tobacco, resulting from an additive or a combination of additives, including, but not limited to, fruit, spice, herb, alcohol, candy, menthol or vanilla, which is noticeable before or during the consumption of the tobacco product;* In this definition, *tobacco* means: *leaves and other natural processed or unprocessed parts of tobacco plants, including expanded and reconstituted tobacco.*

Characterising the flavour of a tobacco product is subjective; therefore it requires sensory information from consumers and/or trained judges. In order to do so, we will compare brands with so-called characterising flavours to brands without characterising flavours, including cigarette brands with no additives. Comparison will be done by a semi trained panel making a descriptive flavour/odour profile of each roll-your-own of cigarette brand included in this study.

Study objective

Primary Objective: To determine whether a tobacco product (cigarettes and

roll-your-own tobacco) imparts a characterising flavour/odour.

Secondary Objective: Do the characterising flavours/odours of the tobacco products as determined through panel testing correspond with findings of chemical analyses of the same tobacco products.

If the chemical analysis of tobacco is in line with the flavour profile of the expert panel, the expert panel could in the future be replaced by chemical analysis to determine cigarette flavour. Performing a chemical analysis is beneficial in many ways, as this technique is not harmful for people, not subjective and less time- and cost- intensive.

Study design

This study falls within the classification of sensory research and aims to determine the characteristic flavours of tobacco. A descriptive flavour profiling analysis will be performed by an expert panel. The study consists of three phases, a screening phase, training phase and test phase. All study sessions will take place in sensory booths at Wageningen University (Biotechnion building 307, second floor). The study population consists of smokers and non smokers. Included panel members have to be available for at least 3 months.

The study phases:

- Phase I: Screening
- Phase II: Training
- Phase III: Testing

Phase I: Screening of potential candidates

All potential participants will be screened on basic olfactory skills. The screening consist of 2 sessions, during the first 1hour screening odour recognition and the ability to rate odor intensity will be measured. During the second screening olfactory sensitivity will be measured with use of the sniffin sticks, duration will be approximately 2 hours.

Phase II: Training of selected panel members

This phase consist of 14 training sessions in which participants need to be committed to two, 1.5 hour training sessions a week, for seven consecutive weeks. During the training sessions panel members will rate different kinds of cigarettes and will judge flavour attributes through smelling unburned Tobacco products.

Phase III: Testing of different tobacco products

During the testing phase panel members will evaluate tobacco in the same manner as practiced during the training phase (training 7) In total we will include twenty tobacco brands including roll-your-own tobacco and filter cigarettes and one reference (pure tobacco). These tobacco products will be tested in a

randomized block design. In a single session the 18 panel members will only evaluate ten tobacco products. However, the tobacco products will be evaluated in triplicate. Therefore, the panel members must attend six sessions to evaluate all the samples in triplicate.

Intervention

not applicable

Study burden and risks

The negative health effects of smoking are widely known (1, 27). Therefore the assessment of the Tobacco products will be done by smelling unburned tobacco products.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age Adults (18-64 years)

Inclusion criteria

- 18-55 years born between 01-06-1959 and 17-02-1997
- Has Dutch as a mother tongue
- Generally considered to be healthy (see F1 questionnaire)
- Available for a minimum period of 3 months.

Exclusion criteria

- Using medications that are known to affect smell perception
- Pregnant or having plans to get pregnant
- Is lactating
- Having problems with smelling, hearing or sight.

Study design

Design

Study type: Interventional	
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	17-02-2015
Enrollment:	18
Туре:	Actual

Ethics review

Approved WMO Date:

03-12-2014

Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	05-03-2015
Application type:	Amendment
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 CCMO ID NL50772.081.14