Smoking Topography Study 2016

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How is a smokers* smoking behavior and topography influencing exposure to cigarette smoke constituents?Primary Objectives: - What is the individual smoking topography of a smoker smoking his usual brand, and does this change between cigarettes over...

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

Summary

ID

NL-OMON42805

Source
ToetsingOnline

Brief title
STS 2016

Condition

- Other condition

Synonym
Not applicable

Health condition

Gedrag

Research involving
Human

Sponsors and support

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

Intervention

Keyword: natural smoking behaviour, Smoker, Smoking topography

Outcome measures

Primary outcome

Monitoring *habitual* smoking behavior, regarding the moments during the day the cigarettes are smoked, and how they are smoked (smoking topography) differing per cigarette.

Output: a table with smoked cigarettes per participant with the associated nicotine and CO(Hb) measurement, and the smoking topography of each cigarette (puff volume, puff duration, puff interval, puff flow).

Secondary outcome

Nicotine, cotinine, COHb and leukocyte differentiation in blood per time points per participant.

COHb measured with the finger sensor.

Nicotine, cotinine, kreatinine and ureum in urine per time points per participant.

Smoking-related DNA adducts in saliva per time points per participant.

VOCs (1,3butadiene and benzene) and aldehydes (formaldehyde, acetaldehyde, acrolein) in breath per time points per participant.

Metabolic state parameters (ASAT, ALAT, bilirubin, sodium, potassium, urea, TSH, CRP) only measured in baseline samples per participant.

Study description

Background summary

In 2005, the World Health Organization Framework Convention on Tobacco Control (WHO FCTC) was established with the aim for a regulatory strategy as a response to the globalization of the tobacco epidemic. One of their non-price measures to reduce the demand for tobacco includes article 9: Regulation of the contents of tobacco products. Cigarette product regulation is currently based on tar, nicotine and carbon monoxide (TNCO) levels in cigarette smoke, which are indicated on the package. This is not sufficient, since cigarette smoke includes more than 7000 chemicals. There are aldehydes, VOCs, PAHs, nitrosamines, metals and so much more measured in cigarette, causing tobacco-related diseases.
In the future, regulation of these harmful cigarette constituents should be based on more chemical classes, as the WHO suggested. However, in order to introduce such class-based regulation, a scientific base is needed to define upper limits of allowed amounts of chemicals (groups) in cigarette smoke emissions and to ensure decreased harmful effects due to cigarette smoking. To date, the causality between human exposure to specific cigarette smoke compounds and the harmful effects is unknown. The first step in closing the gap in knowledge between cigarette smoke exposure and developing tobacco-related diseases includes a proper determination of human exposure to cigarette smoke chemicals. Unfortunately, there is a lack of methodology to determine cigarette smoke exposure in humans. The goal of this pilot study is to characterize natural human smoking behavior. The smokers* exposure to cigarette smoke emissions is determined by the smoking behaviour, which includes 1) the way a cigarette is smoked, called smoking topography, and 2) holding cigarette whereby ventilation holes may be blocked by rolling the cigarette between the smokers* fingers.
In a laboratory setting, this is combined in a smoking regime used in smoking machine experiments. For example, TNCO indicated on packages, is measured with machine smoking following a standard International Organization for Standardization (ISO) method, and differs per brand. However, smoking topography data in human studies show a more intense human smoking behavior. Therefore, a more intense regime with longer and more often puffs, such as the Health Canada Intense (HCI), was also introduced. Although such changes in the setup of the machine smoking experiments make it a useful tool for product comparison, this approach remains a poor predictor for a smokers' exposure. Hence, we do know that smokers have their own smoking topography, and that this process differs per cigarette and situation. In other words, the smoker doses himself and this cannot be mimicked on a smoking machine. The question arises which factors lead to a certain manner of smoking. Smokers smoke to gain nicotine, with additional production of carbon monoxide (CO). Inhalation of too much CO gives the smoker an unpleasant negative sensation, which leads to an adaptive way of puffing in order to prevent this. Of course, smoking is also accompanied by the inhalation of harmful chemicals, but the smoker is not aware of this during smoking and therefore does not adapt his smoking topography with

respect to that exposure. We hypothesize that a personal smoking profile is based on withdrawing as much nicotine as possible while maintaining the additionally produced CO at levels that do not induce adverse effects.
The current study aims at measuring smoking in a habitual rhythm without imposing it as has been done thus far. With this, the smoking topography per cigarette can be measured. Because the smoker can smoke when he wants, the craving, or maybe just the habit to smoke at a certain point at the day, can be recorded. During the day, blood, exhaled air, urine and saliva will be sampled to measure nicotine, carbon monoxide, but also other cigarette smoke compounds and their metabolites.
In the future, the personal smoking regimes of the participants will be mimicked with machine smoking experiments, which results in the exact exposure for that person based on when he smoked that cigarette. To link the observed smoking behavior to the underlying biological mechanisms, this study is also designed to measure exposure biomarkers in body fluids of smokers, such as nicotine, the most abundant cigarette smoke chemicals and both their metabolites.

Study objective

How is a smokers* smoking behavior and topography influencing exposure to cigarette smoke constituents?

Primary Objectives:
- What is the individual smoking topography of a smoker smoking his usual brand, and does this change between cigarettes over the day?
- Can we connect the nicotine and carbon monoxide levels in blood and/or urine with the smoking behavior over the day?
Secondary Objectives:
- Which (metabolites of) toxicants present in cigarette smoke can also be found in exhaled air, saliva, urine and blood of smokers?

Study design

The Smoking Topography Study 2016 is an observational study, with the duration of 2,5 weeks in total. Participants will stay for 36 hours, including two nights, with a temporary residency at the Apart Hotel Randwyck.
In this study it is important that the participants are able to smoke cigarettes *ad libitum*. Because it is impossible to monitor this smoking topography at all times at home, we have to measure the smoking at a research location. Therefore, this study includes two times overnight staying at the Apart Hotel Randwyck in a homelike atmosphere where standardized meals are served and cigarettes can be smoked when and how the participant desires. The smoking topography of every smoked cigarette will be monitored through the CRESSmicro device, which records the puff length, the puff interval, the puff flow and the puff volume. Furthermore, the exact time point of smoking (i.e.

the moment the cigarette is lit) is noted in the experiment time table.
Due to this setup, the smoking topography measurements do not take place at scheduled time points and therefore only one participant at the time will be measured. Total duration of the study will be 2,5 weeks, including 5 smoking individuals.
Participants are their own control by measuring baseline samples (t=baseline). This sampling takes place immediately after waking up and thus before the first cigarette is smoked. These baseline measurements include urine, exhaled air, blood and saliva.
Goal of the study is to follow the smoker in his personal daily life smoking schedule. They can smoke when they want or feel the urge to smoke. Therefore, the sampling time points and the amount of cigarettes smoked are unknown per participant. Despite the unknown time points on forehand, smoking topography of every single cigarette in the next 24 hours is measured. During the whole experiment, we make use of experimental time. Lighting the first cigarette of the day is the start of the experiment and noted as time point 0 (t=0). This is probably shortly after the baseline measurements.
All spent cigarette butts are collected in separate plastic bags per participant with the experimental smoking time noted. Because it is very important not to interfere with the daily life smoking schedule, the experiment day is divided into timeslots for urine and a fixed time point for saliva sampling.
Urine will be collected during four time periods. The first time point includes the baseline measurement before the first cigarette is smoked. Next, all urine between t=0 and t=6 hours is collected in one beaker, urine between t=6 and t=12 is collected in a beaker and finally the same for all urine between t=12 and t=24 hours in another beaker. The participant is asked to empty his bladder just before the timeslots end. This results in 4 urine samples per participant.
Saliva is withdrawn at t=baseline, and at t=0 (immediately after the first cigarette), t=6, t=12 and t=24. This results in five saliva samples per participant.
The exhaled air and blood samples are collected immediately after smoking a cigarette to have the most accurate measure associated with the cigarette smoking. However, the smoking time points are uncertain due to the chosen setup of this study. However, since all smokers included smoke around 20 cigarettes a day, they will at least smoke every 2 hours. Therefore, we have made time periods of 2 hours in which the first cigarette smoked is used for sampling blood and exhaled air, immediately after finishing smoking. The time periods are within one urine collection period, to avoid different samplings within a short time that can interfere with the habitual smoking of the participant.
At baseline, the participant is asked to exhale via a mouthpiece whereby the exhaled air is collected in a Tedlar bag. The exhaled air just before and after finishing smoking the first cigarette is collected (t=0). The same is done immediately after the first cigarette between t=1 and t=3, between t=3 and t=5, between t=7 and t=9 and between t=9 and t=11. This results in 13 exhaled air samples per participant.
To avoid multiple punctures, the participants get a peripheral venous catheter

at baseline, after which the baseline blood sample is withdrawn. The next blood sample is withdrawn just before and after finishing smoking the first cigarette (t=0). Then, the same sampling points are used as for exhaled breath sampling, i.e. just before and immediately after the first cigarette between t=1 and t=3, between t=3 and t=5, between t=7 and t=9 and between t=9 and t=11. This results in 13 blood samples per participant.

Study burden and risks

The participating smokers smoke according to their habitudinal smoking pattern, and are therefore not increasingly exposed to the harmful health effects of cigarette smoking. The invasive part of the study is their stay for two nights and a day in a hotel, and the sampling of blood, saliva, urine and exhaled air.

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

A subject must meet all of the following criteria:
- Male
- 25-34 years old (birth year 1981 * 1990)
- Caucasian
- At least 3 years smoking Marlboro as usual brand
- Used to smoke between 13 and 25 cigarettes a day (around a package/day)

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation:
- Heavy smoker (minimum of 25 cigarettes/day)
- Smokes more than one brand on a regular base.
- Amount of cigarettes per day varies ±10, between days
- Daily medication use
- Experienced adverse effects due to smoking
- Suffering chronic illness

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-02-2016
Enrollment:	5
Type:	Actual

Ethics review

Approved WMO Date:	30-12-2015
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL55676.068.15
Other	onder constructie

Study results

Date completed:	26-02-2016
Actual enrolment:	5