Environmental tobacco exposure (ETS) as a pathway to youth addiction

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

Summary

ID

NL-OMON46046

Source
ToetsingOnline

Brief title
Effects of ETS on the development of nicotine addiction

Condition

- Other condition

Synonym
Addiction

Health condition

Rookgerelateerde aandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universiteit Nijmegen
Source(s) of monetary or material Support: KWF

Intervention

Keyword: Adolescents, EEG/fMRI, Environmental tobacco smoke (ETS), Longitudinal

Outcome measures

Primary outcome

At each wave and during the three weeks of EMA data collection the primary outcome variables will be the PBS: feelings of craving, cue-triggered wanting to smoke, nicotine dependence and behavioral mood and concentration symptoms. These outcomes will be measured by using well-validated questionnaires to measure the occurrence and development of PBS.

The primary outcome variable for the EEG study will be the magnitude of the ERP components. ERPs of smoking cue-reactivity (P3 and LPP), non-drug reward sensitivity (P3, FRN and LPP) and impulse control (N2 and P3) will be measured.

The primary outcome variable for the fMRI study will be the changes in brain functioning over time in specific brain regions of interest (ROIs) involved in smoking cue-reactivity, non-drug reward sensitivity and impulse control in novice smokers. Brain activity in ROIs of smoking cue-reactivity (NA, amygdala and ACC), non-drug reward sensitivity (NA and vmPFC) and impulse control (IFG, ACC and dlPFC) will be measured immediately after the EMA and once again two years later.

Secondary outcome

Not applicable

Study description

Background summary

Research has shown that exposure to environmental tobacco smoke (ETS) leads to the uptake of nicotine in the body, and a growing number of studies suggest that this may possibly result in neuro-physiological changes in the brain and altered psycho-behavioural responses to nicotine in never- and novice-smoking adolescents. Psycho-behavioural responses or psycho-behavioural symptoms (PBS) are symptoms that develop in response to nicotine dependence (e.g., tolerance to aversive effects of nicotine, sensitization to rewarding effect of nicotine, withdrawal symptoms after the effects of nicotine wear off). Recently it has been shown that in never-smoking adolescents, a higher number of smokers in the social environment is associated with self-reported PBS indicative of nicotine dependence. In addition, exposure to ETS is associated with increased rewarding sensations in response to the first dose of nicotine in adolescents who recently initiated smoking. These studies indicate that exposure to ETS may result in the development of psycho-behavioural symptoms indicative of nicotine dependence in never-smokers and in an increased vulnerability to develop nicotine dependence in novice smokers.
Although previous research indicates a relationship between ETS exposure and PBS indicative of nicotine dependence in both non-smokers and novice smokers, it has never been investigated whether ETS exposure actually precedes the occurrence of PBS. Moreover, the potential underlying neurobiological mechanisms through which ETS might predispose both never smokers and novice smokers towards addiction are unknown.
Therefore, the proposed project aims to test whether PBS among adolescent non-smokers and novice smokers are indeed the result of ETS. Furthermore, the proposed project aims to investigate the underlying neurobiological mechanisms through which ETS predispose adolescents towards addiction.

Study objective

With this study we aim to investigate the occurrence and development of PBS indicative of nicotine dependence in never smokers and novice smokers and the underlying neurobiological mechanisms as a function of the level of ETS exposure. Therefore, we specified the following main objectives:
1) To test whether ETS exposure precedes the occurrence of psycho-behavioural symptoms (PBS) indicative of nicotine dependence.
2) To investigate the role of ETS on time period and the process in which smoking initiation occurs and potentially progresses into more established levels of smoking and more severe levels of PBS.
3) To investigate the association of ETS exposure with brain activation during smoking cue-reactivity, non-drug reward sensitivity and impulse control in never smokers by means of event-related potentials (ERPs) measured with EEG.

4) To investigate the association of ETS exposure with changes in brain functioning over time in specific brain regions of interest (ROIs) involved in smoking cue-reactivity, non-drug reward sensitivity and impulse control in novice smokers using fMRI.

Study design

To determine whether ETS exposure precedes the occurrence of PBS, this study will use Ecological Momentary Assessments (EMA) for a period of three weeks at the start of the study. To investigate the role of ETS on the time period and the process in which smoking initiation occurs and potentially progresses into more established levels of smoking and PBS, this study will have a three wave longitudinal design (1 year with six-month intervals). During both the three waves of the longitudinal study and the EMA study, self-report questionnaires assessing smoking patterns, dependence symptoms, and ETS exposure will be filled out. These questionnaires provide more information on adolescents* exposure to ETS, development of PBS, own smoking behavior, as well as smoking behavior of their parents, siblings and friends.
To investigate the underlying neurobiological mechanisms through which ETS predisposes adolescents towards addiction, we will use EEG measurements in never-smoking adolescents and we will use fMRI measurements in novice smoking adolescents at two time points, once at the start and once again one year later. Brain activation during smoking cue-reactivity, non-drug reward sensitivity and impulse control will be measured by means of event-related potentials (ERPs) measured with EEG and within specific regions of interest (ROIs) measured with fMRI. This brain activity will be related to the amount of exposure to ETS.

Study burden and risks

There is no risk during both the EMA study and the longitudinal study as participants will only be asked to fill out questionnaires and provide saliva samples. Furthermore, fMRI and EEG are safe and non-invasive methods for measuring brain activity. However, the noise and the relative confined space of the MRI scanner may cause some level of discomfort to some subjects. The study has no therapeutic goals; there are no benefits for the participants. The participants in this study will be aged between 12-18 years old to appropriately follow the initiation of smoking and potentially progresses into more established levels of smoking and development of PBS. Overall, the knowledge we gain through this project, as well as the risk-free nature of this study, justifies the efforts of the participants.

Contacts

Public
Radboud Universiteit Nijmegen

Montessorilaan 3, kamer 06.23
Nijmegen 6525 HR
NL
Scientific
Radboud Universiteit Nijmegen

Montessorilaan 3, kamer 06.23
Nijmegen 6525 HR
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)

Inclusion criteria

Inclusion Criteria Experimental Smokers:
- Smoked between 5-500 cigarettes
- Smoked in the past 6 months
- Never smoked daily
- Aged between 12 en 18 years old

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded
o Head Injury
o Regular use of other addictive substances other than nicotine
o Use of (psychoactive medication)
To take part in the fMRI study the subjects need to be free from metal in or outside the body. Therefore, he or she will be excluded if he or she meets any of the following criteria:

Standard exclusion criteria for MRI scanning
o* Metal objects or fragments in the body that cannot be taken out
o* Active implants in the body
o* Using medical plasters
o* Epilepsy
o* Previous head surgery
o* Pregnancy
o* Claustrophobia

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-03-2017
Enrollment:	225
Type:	Actual

Ethics review

Approved WMO Date:	14-07-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	05-09-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	

Date:	22-03-2018
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	NL55542.091.15