The transition into habitual smoking in high-risk adolescents

Published: 18-07-2016
Last updated: 16-04-2024

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

Summary

ID

NL-OMON46318

Source
ToetsingOnline

Brief title
The transition into habitual smoking in high-risk adolescents

Condition

- Other condition

Synonym
Addiction, Nicotine Dependence

Health condition

nicotine dependence

Research involving
Human

Sponsors and support

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

Intervention

Keyword: adolescents, fMRI, habit formation, Smoking

Outcome measures

Primary outcome

The main study parameter for RQ1 is the number of smoked cigarettes per day at baseline, 6, and 12-month follow-up. The main study parameter for RQ2 is brain activation in the ventral and dorsal striatum in response to smoking cues at baseline and at 1-year follow-up. Inclusion of participants will end when the planned number of participants finished the first EMA and baseline measurements. The study will end when the planned number of participants finished all study procedures.

Secondary outcome

- Fagerström test for Nicotine Dependence (FTND) to measure nicotine dependence.

- Hooked on nicotine checklist (HONC) to measure the development of symptoms of nicotine dependence.

- The Autonomy Over Tobacco Scale (AOTS) to assess autonomy over smoking and cue-induced craving.

- Self - Report Habit Index (SRHI) to measure habit behaviour regarding smoking.

- Pleasure of smoking questionnaire (PSQ) to measure to which extend

participants experience pleasure from smoking.

- Task performance on tthe digit span test and the Two-Step task

Study description

Background summary

Despite serious well-known health risks, 31% of Dutch adolescents have tried smoking, and 21% of 18 year olds smoke on a daily basis. While various addiction models explain the continuation of substance dependence, the transition from experimental to dependent substance use remains largely unexplained. The current project aims to bridge this gap by developing a neurocognitive model describing the mechanisms critically involved in the transition from experimental to dependent smoking in low educated high-risk adolescents.

Study objective

The current project has two main objectives:
Research question 1 (RQ1): Is the transition from experimental to dependent smoking in high-risk adolescents predicted by the strength of goal-directed and impulse control systems as well as habit propensity? It is hypothesized that experimental smokers with a stronger habit propensity and weaker goal-directed and impulse control systems are more likely to develop nicotine dependence.
Research question 2 (RQ2): Is the transition from experimental to dependent smoking associated with a shift from goal directed behaviour through positive reinforcement (i.e., activation in the ventral striatum to smoking cues) to a habitual response (i.e., activation in the dorsal striatum to smoking cues)? It is hypothesized that transition into dependent smoking is associated with a shift from ventral to dorsal striatal reactivity to smoking cues in a smoking cue-reactivity paradigm.

Study design

A three-wave longitudinal study design will be employed. At baseline and at 1-year follow-up all the relevant brain systems will be measured using fMRI. Additionally, smoking behaviour will be measured using ecological momentary assessments (EMA) at baseline. An online questionnaire about smoking behavior will completerd 6 months after the baseline measurements by the experimental smokers. This longitudinal design allows us to use baseline fMRI measures to predict the development of smoking behaviour over a 1-year time period. At 1-year follow-up, all relevant brain systems will be measured again to answer RQ2. For this aim brain activation at baseline and 1-year follow-up will be

compared in those participants who develop nicotine dependence. A control group of non-smokers will be included to investigate baseline differences in brain activation between experimental smokers and non-smokers in order to contribute to the development of a neurocognitive developmental model of addiction.

Study burden and risks

For the current study, participants will complete (online) questionnaires, perform cognitive tasks on a computer and will undergo an MRI scanning session two times. MRI measurements themselves do not pose any risk, with regards to possible physical risks, if appropriate precautions are made. Furthermore participation in the current study will only cause limited burden. No benefits are related to participation in the current study. The inclusion of 12-18 years old participants is necessary given that smoking is generally initiated during this age period, especially in high-risk populations such as students following low-education levels. Overall, we feel that the knowledge we gain through this project, as well as the risk-free nature of this study, justifies the efforts of the participants. The control group will only complete fMRI baseline measures and cognitive tasks and questionnaires at baseline.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Experimental smokers
1) Smoked 5-500 cigarettes lifetime
2) Smoked in the last 6 months
3) Never smoked on a daily basis;Controls
1) Never smoked a complete cigarette;All participants
1) Age 12-18

Exclusion criteria

All participants
1) Use of psychoactive medication that cannot be stopped for 24 hours before scanning
2) fMRI contraindications
3) A history of neurological disease

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	16-04-2017
Enrollment:	147
Type:	Actual

Ethics review

Approved WMO Date:	18-07-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	11-08-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	18-09-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	20-03-2018
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	NL57111.091.16