

# Electronic cigarettes: An intervention for dual-users

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON23863

### Source

Nationaal Trial Register

### Health condition

Smokers

## Sponsors and support

**Primary sponsor:** Initiator: KU Leuven

No sponsor

**Source(s) of monetary or material Support:** Performer of study

## Intervention

## Outcome measures

### Primary outcome

The most important outcome measures in this study are the answers on the questionnaires (number of tobacco cigarettes that are still smoked and the comparison between the two groups) and the eCO-measurement.

### Secondary outcome

Secondary outcome measures are the other answers to the questionnaires, e.g.: in which

situations do people still smoke tobacco cigarettes, which amount of e-liquid do people still use, etc.

## Study description

### Background summary

This study conducts a psycho-educational intervention (face-to-face vs. online) with dual-users who have the intention to completely and exclusively switch to vaping e-cigs within six months. By comparing this group to a control group/waiting group of dual-users with whom the intervention will be conducted after three months of waiting, we obtain an answer to the question if psycho-education can facilitate completely switching to vaping and if so, which factors are of importance for this change. The psycho-education is based on differences found in previously conducted research between exclusive vapers and dual-users. The psycho-education will contain the following elements: (a) providing correct information about the expected health effects of “dual use” vs. completely switching (pros and cons for both short as long term), including corrective information about the harm of nicotine, (b) broadening practical knowledge about the different kinds of e-liquids and e-cigs and the optimal use of these, and (c) components aimed at increasing motivation (offering perspective on success) and self-efficacy (how to handle situations in which people still smoke tobacco cigarettes). Whether the intervention eventually helped will be examined by using questionnaires that identify smoking/vaping behaviour and by biological validation of smoking cessation through eCO-measurements.

Recruting countries: Belgium

### Study objective

Some smokers manage to quit completely by exclusively switching to e-cigs. However, some e-cig users tend to keep smoking their regular tobacco cigarettes (possibly less than before) in combination with their e-cig. The term “dual use” refers to this combined use of e-cigs and tobacco cigarettes. Dual use can have health benefits if the dual-user smokes less tobacco cigarettes than before, but these benefits are relatively limited in comparison to the health benefits that are obtained from completely switching to e-cig use; and thus completely quitting smoking. This study conducts a psycho-educational intervention with dual-users who have the intention to completely and exclusively switch to vaping e-cigs within six months. The intervention will be carried out in two parallel versions, namely a face-to-face version and an online version. By comparing each group to a control group/waiting group of dual-users with whom the intervention will not be conducted (at first, see below), we obtain an answer to the question if psycho-education can facilitate completely switching to vaping and if so, which factors are important for this influence. We will also be able to study possible differences in effectiveness between the face-to-face and online intervention.

### Study design

#### a) Intervention group

- Moment 0: intake (questionnaires + eCO-measurement)
- Moment 1: short after intake: intervention (questionnaires + eCO-measurement)
- Moment 2: 3 months after intervention: follow-up 1 (questionnaires + eCO-measurement)
- Moment 3: 6 months after intervention: follow-up 2 (questionnaires + eCO-measurement)

#### b) Control/Waiting group

- Moment 0: Intake (questionnaires + eCO-measurement)
- Moment 1: 3 months after intake: intervention (questionnaires + eCO-measurement)
- Moment 2: 6 months after intake = 3 months after intervention: follow-up 1 (questionnaires + eCO-measurement)
- Moment 3: 9 months after intake = 6 months after intervention: follow-up 2 (questionnaires + eCO-measurement)

### **Intervention**

The study conducts a psycho-educational intervention with dual-users who have the intention to completely and exclusively switch to vaping e-cigs within six months. The intervention will contain the following elements: (a) providing correct information about the expected health effects of “dual use” vs. completely switching (pros and cons for both short as long term), including corrective information about the harm of nicotine, (b) broadening practical knowledge about the different kinds of e-liquids and e-cigs and the optimal use of these, and (c) components aimed at increasing motivation (offering perspective on success) and self-efficacy (how to handle situations in which people still smoke tobacco cigarettes). Whether the intervention eventually helped will be examined by using questionnaires that identify smoking/vaping behaviour and by biological validation of smoking cessation through eCO-measurements.

The participants are randomly assigned to either the intervention group or the control/waiting group:

The intervention group will have three contact moments (after intake). During the first contact the actual psycho-education will take place. The first and second follow-up will take place after three and six months after the intervention. During each contact participants are asked to fill out the questionnaires and to perform an eCO-measurment. For the second follow-up, the questionnaire will be expanded with questions about which aspects of the interventions they thought were helpful or not.

The control/waiting group will also have three contact moments (after intake), but these are

later in time in comparison to the intervention group. Their first contact, at which the psycho-education is conducted, takes place three months after intake. Six and nine months after intake (respectively three and six months after intervention), the second and third contact take place. During each contact the same questionnaires and eCO-measurements as in the intervention group are conducted.

Parallel to the face-to-face group, the online intervention group will also be divided into an intervention and control/waiting group. All measurements will take place at the same time points as described earlier for the face-to-face group, except for the eCO-measurements (these will not take place for the online version). Questionnaires will be filled out online in a secure environment (Qualtrics). The online intervention will be provided in a secure web environment.

This design allows us to (a) compare the effects on smoking/vaping behaviour between the two groups after three months (three months after intervention vs. three months waiting) and thus possibly to decide on causality and (b) follow the evolutions in both groups until six months after the actual intervention (measurements after six respectively nine months in intervention and control/waiting group) and (c) to compare the effects of the face-to-face and online intervention on the evolution in smoking/vape behavior .

## Contacts

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### **Scientific**

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## Eligibility criteria

### Inclusion criteria

Dual-users (people who smoke tobacco cigarettes and vape e-cigs) who have the intention to completely and exclusively switch to vaping e-cigs within six months.

## Exclusion criteria

Non-smoker + Dual-users who use e-cigarettes for less than three months

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-03-2018
Enrollment:	100
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	12-01-2017
Application type:	First submission

## 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
NTR-new	NL6077
NTR-old	NTR6224
Other	: SMEC G- 216 12 724

## Study results