# Stress and smoke free pregnancy: Development and evaluation of an e-health intervention aimed at stress reduction and smoking cessation in pregnant women

Published: 10-05-2019
Last updated: 15-05-2024

The main goal of the current project is to adapt an existing stress reduction intervention (an e-health application) to the needs of women with a lower educational level and/or low SES, to enrich it with additional smoking cessation components, and…

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Lifestyle issues |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON48709

**Source**
ToetsingOnline

**Brief title**
Stress and Smoke Free Pregnancy

### Condition

- Lifestyle issues

**Synonym**
nicotine dependence, smoking addiction

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Vrije Universiteit
**Source(s) of monetary or material Support:** FNO (Fonds Nuts Ohra) Zorg voor Kansen;in het kader van het programma Gezonde Toekomst Dichterbij

## Intervention

**Keyword:** e-health intervention, pregnancy, smoking cessation, stress reduction

## Outcome measures

### Primary outcome

Main objectives of the study are, ultimately, smoking cessation (or reduction), stress reduction, and higher self-perceived health among women with a lower educational level and/or low SES.

### Secondary outcome

Secondary objectives are a greater self-regulation and resilience with regard to smoking, a sense of control in stressful situations, increased awareness of responsibility for the child's health, better child attachment, and (enhanced) intrinsic motivation to maintain behavioral change. We expect participants to find the intervention attractive and easy to use, and attractiveness and user friendliness to be positively associated with participant motivation to use HRV biofeedback.

# Study description

### Background summary

Smoking during pregnancy has many adverse health consequences for the (unborn) child, is closely linked with stress, and particularly prevalent among women with a lower educational level and/or low socioeconomic status (SES). Since most smoking cessation interventions have not been proven effective within this

subpopulation of pregnant women, it is important to provide suitable smoking cessation interventions for this target group.

## Study objective

The main goal of the current project is to adapt an existing stress reduction intervention (an e-health application) to the needs of women with a lower educational level and/or low SES, to enrich it with additional smoking cessation components, and to explore the effectiveness of this intervention/app with regard to smoking, perceived stress and perceived health within the target group. The intervention/app will also be tested with regard to secondary parameters (e.g. self-regulation, resilience and sense of control in stressful situations) and user experience (i.e. frequency and ease of use, attractiveness, and motivation).

## Study design

The study design is a pretest-posttest design with follow-up three months postpartum. Pregnant women will be asked to fill out three brief online questionnaires; one at enrolment (T0), one directly after the intervention (T1; eight weeks after T0) and one three months postpartum (T2). Main indicators are smoking pattern, perceived stress, and perceived health. Secondary indicators include (among others) appeal and usability of the application.

## Intervention

The intervention/app is an adaption and extension of an existing e-health intervention/app (*Time2Breathe*) aimed at stress reduction and comprising a specific module on pregnancy. This prototype contains stress reducing breathing techniques by means of visual heart rate variability (HRV)-biofeedback, and psycho-education regarding stress, relaxation, heart rate variability (HRV)-biofeedback, and pregnancy. This prototype will be adapted in order to meet the needs of the target group, and expanded with additional content regarding smoking cessation support, self-regulation, and a tailored quit plan. In this process, co-creation (i.e. input from the target group) will be used through an iterative process.

## Study burden and risks

Considering the low frequency of filling out questionnaires, limited length of the questionnaires, and nature of the items in the questionnaires, this study does not nudge towards a (temporary) change in participants' normal everyday life. Given the low intrusive nature of its items we do not expect the questionnaire to have any (psychological) impact on the participants. Therefore, in line with the examples and clarifications presented in de CCMO-notitie 'Gedragswetenschappelijk onderzoek en de WMO' (2001), participants

in this study are not subjected to procedures nor required to follow rules of behaviour.

No risks are expected with participation, since the intervention (application) contains information that is based on the current, evidence-based stop-smoking counselling for pregnant women in the Netherlands. No harmful or adverse effects are known with respect to HRV-biofeedback. In addition, no pharmaceuticals or drugs are promoted and no invasive treatment will be used. Participation in the study will not lead to department from, or delay of standard treatments or diagnostics.

Smoking cessation and stress reduction benefits both the mother and the (unborn) child. We therefore consider participation in the research advantageous for all smoking pregnant women. We ultimately believe that the benefits of participating in the research by far outweigh any burden or risks.

## Contacts

**Public**
Vrije Universiteit

van der Boechorststraat 7
Amsterdam 1081 BT
NL
**Scientific**
Vrije Universiteit

van der Boechorststraat 7
Amsterdam 1081 BT
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

**Age**

Adults (18-64 years)
Elderly (65 years and older)

### Inclusion criteria

- 18 years or older;
- Female;
- Pregnant (27 weeks maximum);
- Current smoking status <= smoking (not necessarily on a daily basis, and independently of the number of daily smoked cigarettes).

### Exclusion criteria

See remarks under 'Additional comments'.

## Study design

### Design

**Study type:** Interventional

| | |
|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Prevention |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-01-2018 |
| Enrollment: | 50 |
| Type: | Actual |

### Medical products/devices used

| | |
|---|---|
| Generic name: | e-health smoking cessation intervention |
| Registration: | No |

# Ethics review

| | |
|---|---|
| Approved WMO Date: | 10-05-2019 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 11-07-2019 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

ID: 25629
Source: NTR
Title:

## In other registers

| Register | ID |
|---|---|
| CCMO | NL63025.029.17 |
| OMON | NL-OMON25629 |