

# De implementatie van een effectieve interventie om te stoppen met roken voor ouders.

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<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Werving gestart
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Interventie onderzoek

## Samenvatting

### ID

NL-OMON21061

### Bron

NTR

### Verkorte titel

N.A.

### Aandoening

Smoking parents of children aged 0 - 12 years.

Rokende ouders van kinderen tussen de 0 en 12 jaar.

### Ondersteuning

**Primaire sponsor:** Trimbos Institute

**Overige ondersteuning:** Dutch Cancer Society

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

## **Primaire uitkomstmaten**

The primary outcome measures is 7-day point prevalence abstinence at three months post-intervention.

## **Toelichting onderzoek**

### **Achtergrond van het onderzoek**

The aim of this study is to conduct an implementation 2-arm randomized controlled trial to examine the effectiveness of a proactive telephone counseling for smoking parents (N = 144) in the Netherlands. By using two different implementation routes (i.e., through [youth] healthcare and via a mass media approach) we will examine facilitators and barriers for these implementation routes, test whether these implementation routes have a differential effect on the effectiveness of the intervention, and test the cost-effectiveness of the intervention. Finally, an implementation will be developed that provides information on how this intervention can be implemented in the most optimal manner.

### **Doel van het onderzoek**

It is important that parents quit smoking, as this has serious detrimental effects on their own health and their children's health. The majority of parents want to quit smoking. However, many quit attempts are unsuccessful. Recently a proactive telephone counseling intervention for smoking parents was examined and found to be highly effective in the Netherlands. Therefore, it is time that this intervention will be implemented on a large scale.

The purpose of this study is to set up an implementation randomized controlled trial to:

1. obtain information about the recruitment success of two different implementation routes (i.e., through [youth] health care professionals and via a mass media approach [i.e., online mass media and mass mailings through primary schools]). In addition, a process evaluation for both implementation routes will be conducted;

2. test the (cost)effectiveness of the intervention and the extent to which the implementation routes have a differential effect on the main outcome;
3. to develop an implementation plan based on the information obtained from the various analyses and process evaluation.

### **Onderzoeksopzet**

All outcome measures will be assessed in online questionnaires.

The primary outcome measures will be assessed at three months post-intervention.

Secondary outcome measures:

- 1) occurrence of at least 24 hours abstinence at some point during the study will be assessed at three months post-intervention;
- 2) 4-week quitter will be assessed at three months-post intervention;
- 3) increase in motivation to quit will be assessed at baseline and three months post-intervention;
- 4) number and duration of quit attempts will be assessed at baseline and, three months post-intervention, and twelve months post-intervention;
- 5) use of and adherence to nicotine replacement therapy will be assessed at three months post-intervention;
- 6) implementation of smoking restrictions at home will be assessed at baseline and three months post-intervention;
- 7) change in smoking-related cognitions will be assessed at baseline and three months post-intervention.

### **Onderzoeksproduct en/of interventie**

In the telephone counseling condition parents receive proactive telephone counseling based on MI and cognitive-behavioural skill building. Each parent receives up to six counselor-

initiated phone calls (approximately 20 minutes) across a period of three months. In addition, they receive a supplementary brochure on smoking cessation, which is designed for this study as tailored supplementary material.

In the control condition parents receive within two weeks after baseline assessment a standard brochure on smoking cessation. This brochure is a 16-page colour-printed booklet.

## Contactpersonen

### Publiek

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 1) being at least a weekly smoker;
- 2) being a parent/caretaker of a child between 0 and 18 years old;
- 3) having the intention to quit smoking (currently or in the future);

4) giving informed consent for participation.

## **Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)**

Women who are pregnant will be excluded. Telephone counseling will be offered to them.

## **Onderzoeksopzet**

### **Opzet**

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Enkelblind
Controle:	Geneesmiddel

### **Deelname**

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	15-09-2016
Aantal proefpersonen:	144
Type:	Verwachte startdatum

## **Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)**

**Wordt de data na het onderzoek gedeeld:** Nog niet bepaald

## **Ethische beoordeling**

Positief advies	
Datum:	19-09-2016
Soort:	Eerste indiening

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

Register	ID
NTR-new	NL5904
NTR-old	NTR6092
Ander register	- : 2015-7944

# Resultaten

## Samenvatting resultaten

N.A.