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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21061

Source
NTR

Brief title
N.A.

Health condition

Smoking parents of children aged 0 - 12 years.

Rokende ouders van kinderen tussen de 0 en 12 jaar.

Sponsors and support

Primary sponsor: Trimbos Institute
Source(s) of monetary or material Support: Dutch Cancer Society

Intervention

Outcome measures

Primary outcome

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

intervention.

Secondary outcome

Secondary outcome measures include:

1) occurrence of at least 24 hours abstinence at some point during the study;

2) 4-week quitter (defined as "has not smoked even a single puff on a cigarette in the past 2 weeks" assessed 4 weeks after the designated quit date);

3) increase in motivation to quit;

4) number and duration of quit attempts;

5) use of and adherence to nicotine replacement therapy;

6) implementation of smoking restrictions at home;

7) change in smoking-related cognitions (e.g., social norms, attitudes towards smoking, and self-efficacy)

Study description

Background summary

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.

Study objective

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 attemts 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.

Study design

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.

Intervention

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.

Contacts

Public
Da Costakade 45
Tessa Scheffers-van Schayck
Postbus 725 - 3500 AS Utrecht
Utrecht 3521 VS
The Netherlands
-
Scientific
Da Costakade 45
Tessa Scheffers-van Schayck
Postbus 725 - 3500 AS Utrecht
Utrecht 3521 VS
The Netherlands
-

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-09-2016
Enrollment:	144
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	19-09-2016
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	NL5904
NTR-old	NTR6092
Other	- : 2015-7944

Study results

Summary results
N.A.