Prevention of passive smoking exposure in children with a high risk of asthma: the results of an individualized, tailored intervention.

No registrations found.

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

Summary

ID

NL-OMON24711

Source NTR

Health condition

secondhand smoke, passive smoking, children, asthma

Sponsors and support

Primary sponsor: Maastricht University, CAPHRI School for Public Health and Primary Care, Maastricht.

Source(s) of monetary or material Support: Netherlands Asthma Foundation

Intervention

Outcome measures

Primary outcome

The total number of passive smoking cessation, and the urine cotinine levels of the children and parents.

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Secondary outcome

1. Nicotine levels in the house. Passive sampling diffusion monitors will be placed in the participants' homes. Sampling will be measured at 0, 3, 6, 9, and 12 months of follow-up;

2. Number of reported smoked cigarettes/week at home and stopping active smoking, will be measured by a standard questionnaire;

3. Questionnaire on respiratory complaints and infections;

4. Quality of life, measured with FSII questionnaire;

5. The children's' lung function will be measured at home at 0, 3, 6, 9, and 12 months of follow-up;

6. Questionnaire at the end of the study (12 months) concerning the participants' evaluation of the intervention.

Study description

Background summary

Exposure to passive smoking is a huge problem worldwide. Especially children at risk for asthma are sensitive to the effects of passive smoking exposure. The WHO estimates that worldwide about 50% of children are exposed to passive smoking. The health effects of passive smoke exposure in children are huge: on average, they have 30-40% more respiratory infections, a higher chance on asthma-like symptoms and more severe asthma, more episodes of acute bronchitis, a two times higher risk on 'Sudden Infant Death Syndrome, and even more meningococcal septic shock syndrome. From earlier studies in the Netherlands (PIAMA, PREVASC, RAKKER) it is evident that 30% of children at high risk for asthma are exposed to passive smoking. We recently found that children aged 0-2 years with a first degree family member with asthma had a 6 to 7 times higher risk on 'wheezing ever' or attacks of wheezing' than children without asthma in the first degree. This underlines the importance of effective prevention of second-hand smoking at home in the group of vulnerable children. Prevention of passive smoking is not easy to accomplish. However, from the literature, it can be derived that an individualized, subject-tailored program with repeated contacts, attention for barriers and needs of parents, motivational interviewing, and confrontational feed-back about urine cotinine levels has a high chance on being effective. Such an intervention incorporates successful aspects of earlier intervention studies on this topic. The current study aims at testing an innovative, implementable, effective intervention strategy towards stopping of passive smoke exposure in children at risk for asthma. Sudy design: one-year follow-up randomized controlled intervention study. The primary research questions are:

1. What is the effectiveness of an intervention program towards stopping of passive smoke exposure in children with a positive family history of asthma in the first degree? Does stopping passive smoking persist after the intervention?

2. What barriers do parents encounter with stopping of passive smoking and how can we overcome these barriers?

Study objective

An effective intervention towards stopping passive smoke exposure in children is possibly by means of an individualized program with counseling, education, motivational interviewing, and confrontational interviewing with feedback about the urine cotinine levels of the children.

Study design

- 1. September 2009 December 2009: Recruitment;
- 2. February 2010 April 2010: Pilot;
- 3. September 2010 February 2012: Intervention.

Intervention

The participants (N=270 families with one child per family) will be randomized according to clusters into two groups: a control group receiving 'standard usual care', and an active intervention group with an intervention strategy during 6 months. The intervention is given by a trained practice nurse and consists of motivational interviewing, behavioral counseling about stopping passive smoking, and feedback on the urine cotinine of the children.

Contacts

Public

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Eligibility criteria

Inclusion criteria

- 1. Children aged 0-13 years exposed to passive smoking by one or both parents;
- 2. At least one first-degree family member suffering from GP-registered asthma.

Exclusion criteria

- 1. Children who are actively smoking themselves;
- 2. Mental retardation or syndromes;
- 3. Congenital disorders;
- 4. Children with chronic respiratory diseases like asthma, BPD, cystic fibrosis;
- 5. Children and parents already receiving professional support for smoking cessation.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	09-01-2010
Enrollment:	890
Туре:	Anticipated

Ethics review

Positive opinion	
Date:	23-09-2009
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 37213 Bron: ToetsingOnline Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL1906
NTR-old	NTR2023
ССМО	NL26349.068.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON37213

Study results

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Summary results

N/A