Prevention of passive smoking exposure in children with a high risk of asthma.

No registrations found.

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

Summary

ID

NL-OMON22062

Source Nationaal Trial Register

Brief title PREPASE

Health condition

passive smoke exposure, environmental tobacco smoke, asthma, parents stopping passive smoke exposure, children

Sponsors and support

Primary sponsor: Maastricht Univrsity Medical Center - School for Public Health and Primary Care (CPAHRI) **Source(s) of monetary or material Support:** The Netherlands Asthma Foundation

Intervention

Outcome measures

Primary outcome

Primary outcome measure is the percentage of families with passive smoking cessation in children (measured via urine cotinine levels of the children and parental self-reports). Stopping passive smoking exposure at home is defined as the cessation of passive smoke

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exposure to children for at least 6 months after quit date. This can be achieved by parents smoking outside the house, by stopping active smoking or less ideal, smoking in a room where the child does not come.

Secondary outcome

Secondary outcome measures are respiratory complaints and infections, nicotine levels at home, quality of life and lung function of the children.

Study description

Background summary

Exposure to passive smoking is a huge problem world-wide. The WHO estimates that about 50% of children are exposed to passive smoking globally. The health effects of passive smoking 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 (SIDS)', and even more meningococcal septic shock syndrome. From earlier studies in the Netherlands (PIAMA, PREVASC, RAKKER) it is evident that even 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 and passive smoke exposure 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 passive smoking at home in this group of vulnerable children. The purpose of this study is to test the effectiveness of a new intervention. The intervention is an individualized, subject-tailored program with repeated contacts, including motivational interviewing, attention for barriers and needs of parents, and feedback on the children's urine cotinine levels and lung functions. Such an innovative approach is a further development of existing knowledge in the literature and has a high chance on being effective.

Study objective

An effective intervention towards stopping passive smoke exposure in children is possible by means of an individualized program with repeated counseling, education, motivational interviewing, and by promoting parental awareness with feedback about the lung function of the children and their urine cotinine levels.

Study design

Lung function and cotinine measurements will be done at time points 0, 3, 6, 9 and 12 months.

The intervention group will receive the intervention during 6 months; from time point 1

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month until 6 months.

Intervention

Two hundred families (1child per family) are randomized into two groups: a control group, and an active intervention group. Stratification for 'age' will occur. The control group receives 'usual care' with no extra visits or extra information about health effects of smoking, other than standard usual care according to the standards of the Dutch Society of General Practitioners (NHG). The active intervention group receives an intervention strategy given by two trained practice nurses at home. The intervention consists of 6 counseling sessions during six months, each lasting about 1hour. The intervention consists of motivational interviewing and feedback on the children's' lung function and urine cotinine measurements.

Contacts

Public

Research Institute CAPHRI, Dept. fo Pediatric Pulmonology PO Box 5800 Sasha Hutchinson Research Institute CAPHRI, Dept. fo Pediatric Pulmonology PO Box 5800 Maastricht 6202 AZ The Netherlands + 31(0) 43 - 3874282Scientific Research Institute CAPHRI, Dept. fo Pediatric Pulmonology PO Box 5800 Sasha Hutchinson Research Institute CAPHRI, Dept. fo Pediatric Pulmonology PO Box 5800 Maastricht 6202 AZ The Netherlands + 31 (0) 43-3874282

Eligibility criteria

Inclusion criteria

Children aged 0-13 years with passive smoke exposure at home and high risk of asthma (asthma in the first degree).

Exclusion criteria

- 1. Children who are currently smoking themselves;
- 2. Parents already receiving professional help for smoking cessation;

3. Children with diagnosis of: Asthma, congenital malformations of the airways or other chronic lung diseases like CF or BPD, mental retardation or syndromes, heart disease.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

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NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-03-2009
Enrollment:	200
Туре:	Anticipated

Ethics review

Positive opinion	
Date:	29-11-2010
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	NL2514
NTR-old	NTR2632
ССМО	NL26349.068.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON37213

Study results

Summary results N/A