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

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The current proposal aims at testing an innovative, implementable, effective intervention strategy towards stopping of passive smoke exposure in children at risk for asthma.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON37213

Source
ToetsingOnline

Brief title
Prevention of passive smoking exposure in children.

Condition

- Other condition
- Respiratory disorders NEC
- Lifestyle issues

Synonym
second-hand smoking exposure

Health condition

passief roken

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Nederlands Astmafonds

Intervention

Keyword: children, passive smoking, prevention

Outcome measures

Primary outcome

Primary outcome measures include urine cotinine levels of the child and the

parents, stopping of passive smoking, and number os smoked cigarettes/week at

home.

Secondary outcome

Secondary outcome measures are respiratory complaints and infections, nicotine

levels a home, quality of life, and lung function.

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.

Study objective

The current proposal aims at testing an innovative, implementable, effective intervention strategy towards stopping of passive smoke exposure in children at risk for asthma.

Study design

One-year follow-up randomised controlled intervention study.

Intervention

The participants will be randomised in 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, behavioural counselling about stopping passive smoking, and feedback about the urine cotinine of the children.

Study burden and risks

The nature and extent of the burden associated with participation is limited to six counselling sessions with the practice nurse, each lasting no longer than 60 minutes, and questionnaires on smoking behaviour, quality of life, respiratory symptoms and infections, measured at baseline, 3, 6, 9, and 12 months. These questionnaires will not take longer than 20-30 minutes to complete. Furthermore, parents* and children*s urine samples will be collected at baseline, 3, 6 ,9, and 12 months. The household nicotine level at baseline and 12 months, and the children*s lung function will be measured at baseline, 3, 6, 9, and 12 months. There are no risks associated with participation. The intervention and other study measures are non-invasive. The intervention is more likely to have a beneficial effect on the participants, helping the cessation of second-hand smoking at home in children with a high risk on asthma.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Children aged 0 to 13 years, with passive smoking exposure and a positive family history of asthma in the first degree relatives.

Exclusion criteria

mental retardation, respiratory diseases, children who smoke themselves, parents receiving treatment for passive/active smoking cessation

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2010
Enrollment:	711
Type:	Actual

Ethics review

Approved WMO Date:	18-08-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	07-09-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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: 22062
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL26349.068.09
OMON	NL-OMON22062
OMON	NL-OMON24711