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

Gepubliceerd: 29-11-2010 Laatst bijgewerkt: 19-03-2025

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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22062

Bron
Nationaal Trial Register

Verkorte titel
PREPASE

Aandoening

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

Ondersteuning

Primaire sponsor: Maastricht Univrsity Medical Center - School for Public Health and Primary Care (CPAHRI)
Overige ondersteuning: The Netherlands Asthma Foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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 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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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 month until 6 months.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2009
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	29-11-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 37213
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2514
NTR-old	NTR2632
CCMO	NL26349.068.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON37213

Resultaten

Samenvatting resultaten
N/A