Validation of the Paediatric Electronic quality of Life Instrument for Childhood Asthma in the Netherlands.

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The objective of this project is to establish the validity, reliability and responsiveness of a self-administered electronic asthma-specific quality of life instrument for childhood asthma. Since the Pelican instrument is developed to evaluate HRQL...

Ethical review	Approved WMO
Status	Pending
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Observational non invasive

Summary

ID

NL-OMON32237

Source
ToetsingOnline

Brief title
Pelican project

Condition

- Bronchial disorders (excl neoplasms)

Synonym
asthma, bronchial asthma

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Nederlands Astmafonds

Intervention

Keyword: Asthma, pediatric, Quality of Life, Validation

Outcome measures

Primary outcome

The Pelican instrument should have the following (clinimetric) characteristics:

has a high internal consistency and is able to detect relevant changes in HRQL

within an individual child aged 6 to 12 years (evaluative capacity of the

instrument). Moreover, the validity of the individualised part of the

instrument should be good and the instrument is comprehendible, serviceableness

and acceptable according to the children.

Secondary outcome

The Pelican instrument should have the following (clinimetric) characteristics:

is able to discriminate between relevant groups; is valid based on

cross-sectional construct validity; is reliable and valid for children with

asthma aged 4 or 5. Next the influence of a reminder on the reliability of the

children*s answers will be evaluated.

Study description

Background summary

Health-related quality of life (HRQL) is the complex of all aspects of an individual*s subjective experience that relate both directly and indirectly to health, disease, disability and impairment. Assessment of HRQL for children with asthma in daily care may facilitate shared decision-making and contribute to patient-centered care, which could result in improvement adherence to treatment, asthma control, HRQL and satisfaction with received care. Currently there is no appropriate pediatric asthma-specific HRQL instrument for use in daily care that is feasible for daily care. In a recent study we have developed

an electronic HRQL instrument to fill this gap. This so-called *Pelican* instrument is designed as a webbased computer game.

Study objective

The objective of this project is to establish the validity, reliability and responsiveness of a self-administered electronic asthma-specific quality of life instrument for childhood asthma. Since the Pelican instrument is developed to evaluate HRQL in daily care it is especially important that the Pelican instrument is able to detect relevant changes in HRQL within a child.

Study design

Clinimetric study (no intervention) with a follow up of 2-months for asthmatic children (3 visits) and one visit for the reference population.

Study burden and risks

Minors are asked to participate in this non-therapeutic trial. Since the Pelican-instrument is an instrument developed to assess the HRQL of asthmatic children, it is not possible to use other subjects (like adults). The results of this trial could result in benefits for children with asthma in general. The risk of participation is negligible. The children (and parents) are asked to fill out questionnaires. Moreover, the fraction of exhaled nitric oxide and lung function is assessed. For the lung function assessment salbutamol is used. In general, children with asthma use salbutamol or similar medication to relieve symptoms. Though very infrequent, the use of salbutamol can result in some side-effects.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

For the asthmatic children
* age 4 to 12 years
* signed informed consent by parent (or caretaker)
* child agrees to participate in the study
* at least two prescriptions for inhaled asthma medication during the previous year
* use of inhaled asthma medication for at least six weeks during the previous year
* physician-diagnosed asthma (a symptom diagnose asthma by a physician in case the child is 4 or 5 years old) ;For the healthy individuals (reference population)
* age 6 to 12 years
* signed informed consent by parents (or caretakers)
* child agrees to participate in the study

Exclusion criteria

For all children
* comorbid condition that significantly influences HRQL
* child does not master the Dutch language sufficiently
* not being able to attend a regular school class

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2008
Enrollment:	275
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL23004.091.08