Validation of the Dutch Language Asthma Control Test (ACT) and Child-ACT for internet use among adolescents (ACT) and parents and children (Child-ACT)

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The aim of the proposed study is to conduct an evaluation of the validity of web-based completion of the (Child-) ACT on the basis of comparison with paper-based completion and to test reproducibility of both web-based and paper-based version....

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

Summary

ID

NL-OMON31860

Source
ToetsingOnline

Brief title
geen

Condition

- Bronchial disorders (excl neoplasms)

Synonym
asthma

Research involving
Human

Sponsors and support

Primary sponsor: Amphia Ziekenhuis

Source(s) of monetary or material Support: GlaxoSmithKline,grant van GSK voor realisatie webdesign

Intervention

Keyword: Asthma Control Test, children, internet, questionnaire

Outcome measures

Primary outcome

The primary goal of the present study is to evaluate the concordance of web version of the ACT and the paper version. Both tests will be performed within a period of 3-5 days in a randomized order using numbered sealed envelopes according to a computer generated sequence stratified by centre. This will be done separately for the two types of ACT (for children 4-11 years and for children 12 years or above). After the return of a signed informed consent, a patient study number will be given and the randomisation code will become available from the corresponding envelope. A logbook will be kept for numbers of patients not able or willing to participate (specifications: *no computer available* or *other reasons*).

All statistical analyses will be done separately for the two age groups.

Using Anova for cross-over studies it will be investigated whether differences, if any, depend on the order of administration of the two versions for the first and 2nd ACT questionnaire. The agreement between the web version and the paper version will be quantified by calculating intra-class correlation coefficients.

Graphical presentation of agreement between the 2 versions will be done by Bland & Altman plots. It is expected that there is a good agreement between both versions. With a sample size of 75 for each age category, and an observed

correlation coefficient of 0.80, the 95% confidence interval for the correlation coefficient will range from 0.70 to 0.87. In case of an observed correlation coefficient of 0.85, the 95% confidence interval for the correlation coefficient will range from 0.77 to 0.90. These limits are considered sufficiently narrow. Analyses will be restricted in the first instance to those children who have stated at the second test that their asthma has not changed as compared to the day at which they completed the first assessment.

Similar methods will be used for the comparison of the 2nd and third ACT assessment within each group (second and third assessment using paper or using the Web). Primary analysis will focus on patients who have stated at the third questionnaire that their asthma had not changed since the day of completion of the previous 2nd questionnaire.

Inclusion for each age category will continue until the target number of 75 evaluable cases for assessment 1 and 2 is met.

Secondary outcome

Acceptance of both versions of the (Child-) ACT will be evaluated by an additional short questionnaire after the second (Child-) ACT.

Comparison of the results of (Child-) ACT with current recommendations of control status as defined in GINA guidelines and comparison with a well validated questionnaire (ACQ) for the children 12 years and older.

Study description

Background summary

The Asthma Control Test (ACT) is a simple 5-item questionnaire, which has been shown useful in the detection of poorly controlled asthma in adults and children above the age of 12. An ACT-score of 19 or less showed a sensitivity and specificity of 71% to detect poorly controlled asthma. More recently a 7-item Childhood ACT has been validated in children from the age of four. A cut-off point of <=19 was selected to indicate uncontrolled asthma (sensitivity 74%, specificity 68%).
Based on epidemiological data, also in Western European countries, still a substantial proportion of adults as well as children with asthma are not optimally controlled.
Recently, the newest GINA guidelines for the management of asthma introduced the level of asthma control as the basis for adjusting asthma medication. Based on the following characteristics: daytime symptoms, limitations of activities, nocturnal symptoms, need for reliever medication, lung function and exacerbations, the patient is categorised as either well controlled, partly controlled or uncontrolled. This concept of optimizing control status was used in a worldwide large scale asthma study in 3421 adults and adolescents and resulted in a large proportion of patients reaching *totally controlled* or *well-controlled* level. A practical disadvantage of this approach is that for a correct categorisation of the patient*s control level detailed and continuous information on symptoms and use of reliever medication are necessary. Furthermore patients as well as doctors tend to overestimate their level of asthma control and the effect of medication changes on it. The use of a simple and valid questionnaire for estimating the level of control and guiding treatment would overcome these problems. Using modern communication technology as the internet, a web-based questionnaire may result in improvement of control status of asthma patients without the need to increase direct contacts between patients and their physicians. Yet, on the internet children and their parents are already invited to do the (Child-) ACT and discuss the results with their doctor.
We therefore state that validation of the web-based version is a necessary step before using web-based (Child-) ACT in paediatric practice. Furthermore the Asthma Control Test will be compared with GINA recommendations for asthma control.

Study objective

The aim of the proposed study is to conduct an evaluation of the validity of web-based completion of the (Child-) ACT on the basis of comparison with paper-based completion and to test reproducibility of both web-based and paper-based version. Additionally, patients* subjective evaluation of the acceptability will be explored.
For children aged 4 to 11 years old the Children Asthma Control Test will be performed, for children from the age of 12 to 18 years old the Asthma Control

Test will be performed.
A secundary objective of this study is to compare the results of the Asthma Control Test with the current recommendations on asthma control by GINA guidelines and to compare the resulst of the Asthma Control Test in children 12 years and older with the Asthma Control Questionnaire by Juniper.

Study design

Randomised cross-over design of a paper and webbased version of the (Child-)ACT followed by a repeat (Child-)ACT of the last version (either paper or webbased). After the second (Child-)ACT an additional questionnaire on acceptance will be sent.
Children will be recruited from the outpatient departments of the participating centres. Children and/or parents will receive an information sheet and consent form upon their regular visit to their paediatrician/paediatric pulmonologist. At that visit the aim and impact of the study will be explained. If necessary, additional information can be obtained by a telephone call to the paediatrician/paediatric pulmonologist or specialised paediatric asthma nurse. For practical reasons, children and/or parents are asked to return the consent form by postage free envelope, either signed if they agree to participate or unsigned if they are not willing to participate.
Randomisation will be stratified by centre and age-group (4-11 or 12-18), using a random numbers list with either code A (paper- web) or B (web - paper) for each number. Codes are placed in sealed numbered envelopes and for the separate age groups supplied to each centre. After the return of a signed informed consent, a patient study number will be given and the randomisation code will become available from the corresponding envelope.

Study scheme
Upon receipt of a signed informed consent, depending on randomisation, either a paper-based (Child-)ACT will be sent by post or an invitation by mail will be sent to fill in the web-based (Child-)ACT. The paper-based (Child-) ACT has to be returned in a postage free envelope. Upon receipt of either the paper-based or web-based questionnaire, the opposite version will be sent out, according to the cross-over design. Before answering this second (Child-) ACT patients will be asked whether their asthma is unchanged, improved or worsened compared to the time at which they answered the first (Child-) ACT. One week after receipt of both versions of the (Child-) ACT either a paper-based or web-based (Child-) ACT will be sent, conform the latest version of the (Child-) ACT, also beginning with the question whether their asthma has changed during the last week. Furthermore, the questionnaire on acceptance will be sent. Active guidance by specialised paediatric asthma nurses will take place in order to receive both versions of the questionnaire within a time span of preferably 5 days.
For the second part of the study, patients will be sent an web-based diary card upon receipt of their (re-test) (Child-) ACT. Data can be submitted up to 2 days later. After completion of this 4-week diary card another (Child-) ACT

will be sent webbased and ACQ for children 12 years and older.

Study burden and risks

The time for completion of the ACT as well as the Child ACT is maximum 5-10 minutes.
The 4-week webbased diary will take maximum 2-5 minutes per day. Data can be filled in up to 2 days later.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

age 4-18 years
asthma
internet access
ability to understand Dutch language

Exclusion criteria

chronic lung disease, other than asthma

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-11-2008
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	15-07-2008
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)
Approved WMO Date:	16-10-2008

Application type:	Amendment
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)

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	NL22725.101.08