SMASHING in adolescents: Self-Management of Asthma Supported by Hospitals, Information and communication technology, Nurses and General practitioners

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1. To improve patient's quality of life in a cost-effective way by a self-management programme guided by doctors and a specialist asthma nurse through information and communication technology. 2. To investigate whether a simple index of asthma...

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

Summary

ID

NL-OMON29705

Source
ToetsingOnline

Brief title
SMASHING-adolescents

Condition

- Bronchial disorders (excl neoplasms)

Synonym
asthma

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Astma Fonds

Intervention

Keyword: Adolescent, Asthma, Quality of Life, Self Care

Outcome measures

Primary outcome

The primary and secondary outcome are health related quality of life (PAQLQ)

and asthma control (ACQ), respectively.

Economic evaluation

The costs of usual care and ICT-supported care will be compared from a societal

perspective. In a cost-utility analysis, the difference in societal costs will

be related to the estimate difference in QALYs using acceptability curves. A

Markov model will be used to extrapolate the trial data to a 3 year period.

Secondary outcome

self-management behaviour

QALY (for cost-effectiveness analysis)

inhalation technique (assessed by nurse)

health care utilization

knowledge of asthma

lung function and daily symptoms

self-efficacy

asthma control by other instruments

Study description

Background summary

Self-management of asthma is of proven effectiveness, but is seldom done by patients. This study aims at making self-management easier by simplifying monitoring of symptoms and lung function, and by supporting decisions on increasing or decreasing medication.

Study objective

1. To improve patient's quality of life in a cost-effective way by a self-management programme guided by doctors and a specialist asthma nurse through information and communication technology.
2. To investigate whether a simple index of asthma control and/or patient characteristics can be used to predict efficiency of such a guided self-management programme in order to target cost-effective implementation.
3. To assess the characteristics and reasons for not participating of eligible patients.
4. To assess the agreement between actual and perceived control of asthma.

Study design

A randomised parallel trial with 2 arms and 1 year follow-up in 3 phases in order to compare ICT-supported care with usual care. The first phase aims at selecting eligible patients. The second phase serves as a baseline period and is solely aimed at collecting data on asthma control and behaviour and lifestyle, and predisposing, reinforcing and enabling factors. The third phase includes the intervention and evaluation period.

Intervention

The current intervention is additional to usual care and includes monitoring of symptoms and lung function and communication of results, feedback and reminders via internet and short message services on telephones. The service is supervised by a specialised nurse and facilitates discussion groups, a chat box and consultation via private messaging. Asthma self-management education and training sessions are given by a specialist nurse.

Study burden and risks

questionnaires on asthma control, total 15'-20' in phase 1

3x set of questionnaires, total 30'-45' for each set, in phase 2/3
*see p23, attachment 4 for details on assessment schedule

oral explanation about goal of phase 2/3 + check inhalation technique (total 1 hour)

2 education sessions of 1,5 - 2 hour (intervention group only)
3x 2 weeks daily symptomscore / lungfunction (1' to 3' each day)
52x weekly lungfunction + asthma-control questionnaire (online) invullen (3'-5' each week) (intervention group only)

no known risks

Contacts

Public
Leids Universitair Medisch Centrum

postbus 9600
2300 RC Leiden
Nederland
Scientific
Leids Universitair Medisch Centrum

postbus 9600
2300 RC Leiden
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)
Adolescents (16-17 years)

Inclusion criteria

* age 12-17 year
* doctors diagnosis of asthma
* mild to severe persistent asthma (patients who need inhaled corticosteroids as controller medication)
* at least one asthma control problem (Asthma Therapy Assessment Questionnaire-score *1 or Asthma Control Questionnaire *1.0)
* PC with internet connection available
* able to communicate in the Dutch language
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Exclusion criteria

Patients requiring oral corticosteroids as controller medication and patients with relevant comorbidity

Study design

Design

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

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2006
Enrollment:	320
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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	NL13115.058.06