# SMASHING in adults Self-Management of Asthma Supported by Hospitals, Information and communication technology, Nurses and General practitioners.

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Pending |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON20415

**Source**
NTR

**Brief title**
SMASHING in adults

### Sponsors and support

**Primary sponsor:** - Leiden University Medical Center
- ZonMW, The Hague
**Source(s) of monetary or material Support:** none

### Intervention

### Outcome measures

**Primary outcome**

1. Asthma related quality of life;

2. Measurement instrument: AQLQ (asthma quality of life questionnaire);

3. Evaluation at baseline, after 3 months and after 12 months.

**Secondary outcome**

1. Asthma control;

2. Symptom free days;

3. Exacerbations;

4. Health care utilisation;

5. Absence of work/school;

6. Lung function;

7. Exhaled nitric oxide;

8. Medication use;

9. Side effects.

# Study description

**Background summary**

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.

Research Question

A. What is the cost-effectiveness of a self-management programme in adult patients with mild to moderated asthma facilitated by information and communication technology and supported by health care professionals in order to improve quality of life?

B. Does this self-management programme lead to improved asthma related quality of life?

Design

A randomised parallel trial with 2 arms and 1 year follow-up in 2 phases in order to compare ICT-supported care with usual care.
The first 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 second phase includes the intervention and evaluation period.

Study Population

Patients with mild to moderate persistent asthma, aged between 18 and 50, will be identified via the LUMC general practice network (N=175) and hospital information systems (N=75). Patients have access to a computer with an internet-connection and are able to communicate in the Dutch language.

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.

Outcome measures

The primary and secondary outcome are health related quality of life (AQLQ) and asthma control (ACQ), respectively.

Sample size calculation

Using 100 patients per arm and based on a SD of changes in AQLQ-score of 0.75 we are able to detect a difference of 0.3 points between AQLQ-changes of the two arms (" = 0.05 two-sided, ß = 0.20 one-sided).

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.

**Study objective**

A self-management programme guided by doctors and a specialist asthma nurse through information and communication technology will improve asthma related quality of life in a cost-effective way.

**Intervention**

A 12-month intervention period where the patients receive either ‘usual care’ or ‘ICT-supported care’ guided by a specialised asthma nurse and doctor.

Care strategies

(1) Usual care

According to the Dutch GP guidelines, patients are invited to visit their general practitioner every 3 months in order to titrate medication to the lowest level that is needed to maintain control. This frequency can be lowered to 1-2 visits per year once control of asthma has been achieved.
Thirty percent of general practices have nurse practitioners providing self-management education. Patients are referred to a chest physician if sufficient control is not achieved within 3 months. Exacerbations of asthma are treated by either chest physician and general practitioner.

· advise to visit to general practitioner or specialist to assess present situation

· review medication devices technique and adherence

· issue and explain paper asthma action plan, monitoring of lung function with Piko-1 spirometer

· plan next doctor visits as needed

(2) ICT-supported care

· weekly monitoring of asthma control questionnaire (ACQ) and lungfunction through webpages and/or SMS with feedback.

· at least 6 weeks daily monitoring of lung function and symptoms with electronic feedback through webpages and/or SMS

· asthma self-management education in small groups (2x) by trained asthma specialist nurse (see below) :

o discussion of ACQ data in order to assess present situation and electronic asthma action plan

o review medication devices technique and adherence

o plan next doctor visits as needed

· virtual consulting room with asthma nurse via and private messaging

· social support within a private chatbox and/or internet support group

· automated sending of reminders via email and/or SMS

· monitoring asthma control by lung function and ACQ with electronic data processing and feedback through computer via webpages with graphical presentation of data for patient and nurse.

## Contacts

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## Eligibility criteria

### Inclusion criteria

1. 250 patients with mild persistent to moderate asthma (prevalent cases);

2. Age 18-50 yr;

3. Doctors diagnosis of asthma;

4. Asthma severity step 2-3, patients who need inhaled corticosteroids as controller medication (at least 3 months in the past year);

5. PC with internet connection available;

6. Able to communicate in the Dutch language.

### Exclusion criteria

1. Patients with intermittent asthma;

2. Patients with severe asthma;

3. Use of oral glucocorticosteroids as controller medication;

4. Serious co-morbidity interfering with asthma or treatment of asthma;

5. No PC or no internet connection;

6. Not able to communicate in the Dutch language.

## Study design

### Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Masking: | Open (masking not used) |
| Control: | Active |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-01-2006 |
| Enrollment: | 250 |
| Type: | Anticipated |

## Ethics review

Positive opinion

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|---|---|
| Date: | 15-11-2005 |
| Application type: | First submission |

## 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 |
|---|---|
| NTR-new | NL464 |
| NTR-old | NTR505 |
| Other | : N/A |
| ISRCTN | ISRCTN79864465 |

## Study results

**Summary results**

N/A