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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
28/12/2006		☐ Protocol		
Registration date 28/12/2006	Overall study status Completed	Statistical analysis plan		
		[X] Results		
<b>Last Edited</b> 22/05/2013	Condition category Respiratory	[] Individual participant data		
ZZ/UJ/ZU   3	KE2DII GLUI V			

#### Plain English summary of protocol

Not provided at time of registration

#### Study website

http://www.lumc.nl/2050/research/projsmashing.htm

#### Contact information

#### Type(s)

Scientific

#### Contact name

Dr Jacob K. Sont

#### Contact details

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# Additional identifiers

**EudraCT/CTIS** number

#### **IRAS** number

ClinicalTrials.gov number

#### Secondary identifying numbers

N/A

# Study information

#### Scientific Title

#### Acronym

**SMASHING** 

#### **Study objectives**

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.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Approval received from the local ethics committee (Commissie Medische Ethiek) on the 7th August 2006 (reference number: P06.110).

#### Study design

Randomised, controlled, parallel group, multicentre trial

#### Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

Not specified

#### Study type(s)

Treatment

#### Participant information sheet

#### Health condition(s) or problem(s) studied

Asthma

#### Interventions

Please note that as of 06/02/2008 the anticipated end date of this trial was extended to 30/05/2009. The previous end date of this trial was 30/06/2008.

Information and Communication Technology (ICT)-supported care:

- 1. Asthma self-management education in small groups (two sessions per group) by trained asthma specialist nurse:
- a. Discussion of ACQ and ATAQ data in order to assess present situation and electronic asthma action plan
- b. Review medication devices technique and adherence
- c. Plan next doctor visits as needed
- 2. Monitoring asthma control by lung

function and ACQ (input via website or SMS [text messaging]) with electronic data processing and feedback through computer via webpages with graphical presentation of data for patient and nurse

- 3. Virtual consulting room with asthma nurse via email and private messaging
- 4. Social support within a private chatbox and/or internet support group
- 5. Automated sending of reminders via email and/or SMS

#### Control group: usual care:

According to the Dutch General Practitioner (GP) guidelines, patients are invited to visit their general practitioner every three months in order to titrate medication to the lowest level that is needed to maintain control. This frequency can be lowered to one to two 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 pediatrician /pediatric pulmonologist if sufficient control is not achieved within three months. Exacerbations of asthma are treated by either pediatrician and general practitioner:

- 1. Advise to visit to general practitioner or pediatrician to assess present situation
- 2. Review medication devices technique and adherence
- 3. Issue and explain paper asthma action plan, monitoring of lung function with Piko-1 spirometer
- 4. Plan next doctor visits as needed

#### Intervention Type

Other

#### Phase

Not Applicable

#### Primary outcome measure

Health related quality of life as measured by the Pediatric Asthma Quality of Life Questionnaire (PAQLQ).

#### Secondary outcome measures

- 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. Self-reported asthma management behaviour
- 10. Side effects

#### Overall study start date

15/12/2006

#### Completion date

30/05/2009

# **Eligibility**

#### Key inclusion criteria

- 1. Age 12 to 17 years
- 2. Doctors diagnosis of asthma
- 3. Mild to severe persistent asthma (patients who need inhaled corticosteroids as controller medication)
- 4. At least one asthma control problem (Asthma Therapy Assessment Questionnaire [ATAQ] score more than or equal to one or Asthma Control Questionnaire [ACQ] more than or equal to one)
- 5. Able to communicate in the Dutch language

#### Participant type(s)

**Patient** 

#### Age group

Child

#### Lower age limit

12 Years

#### Upper age limit

17 Years

#### Sex

**Not Specified** 

#### Target number of participants

124

#### Key exclusion criteria

Patients requiring oral corticosteroids as controller medication and patients with relevant comorbidity will be excluded.

#### Date of first enrolment

15/12/2006

#### Date of final enrolment

30/05/2009

#### Locations

#### Countries of recruitment

Netherlands

# Study participating centre Department of Medical Decision Making, J10-86 Leiden Netherlands 2300 RC

# Sponsor information

#### Organisation

Leiden University Medical Center (LUMC) (Netherlands)

#### Sponsor details

P.O. Box 9600 Leiden Netherlands 2300 RC

#### Sponsor type

Hospital/treatment centre

#### Website

http://www.lumc.nl/english/start\_english.html#http://www.lumc.nl/english/start\_english.html

#### **ROR**

https://ror.org/05xvt9f17

# Funder(s)

#### Funder type

Research organisation

#### **Funder Name**

Astmafonds (Netherlands)

### **Results and Publications**

#### Publication and dissemination plan

Not provided at time of registration

# Intention to publish date

# Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2012		Yes	No