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

Submission date 28/12/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/12/2006	**Overall study status** Completed	
Last Edited 22/05/2013	**Condition category** Respiratory	

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
Department of Medical Decision Making, J10-86
Leiden University Medical Center
P.O. Box 9600
Leiden
Netherlands
2300 RC
+31 (0)71 526 4578
j.k.sont@lumc.nl

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