IMPlementation strategies of internet-based Asthma Self-management Support in usual carE (IMPASSE) Trial

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The objective of this project is to investigate the (cost-) effectiveness of these tailored implementation strategies in comparison to a common used implementation strategy, in a three arm randomized trial.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON35913

Source
ToetsingOnline

Brief title
IMPASSE

Condition

- Other condition

Synonym
asthma

Health condition

Luchtwegaandoening: astma

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: ZonMw (Projectnr: 80-82315-97-10004); Astmafonds (Projectnr: 3.4.09.011)

Intervention

Keyword: Asthma control, implementation, personal health record, self-management

Outcome measures

Primary outcome

1. the proportion of practices that participate in IBSM, 2. the proportion of referred patients that participate in IBSM and 3. asthma related quality of life in participating patients.

Secondary outcome

Patient level: clinical outcomes (asthma control, lung function, usage of airway treatment and presence of exacerbations); self-management related outcomes (health education impact, medication adherence and illness perceptions); asthma related quality of life and patient utilities.

Professional and organizational level: adherence of professionals to implementation strategies, experience with IBSM and feasibility of IBSM in daily practice. Cost-effectiveness: medical costs and health care consumption.

Study description

Background summary

Internet-Based Self-Management (IBSM) support cost-effectively improves asthma control, asthma related quality of life, number of symptom-free days and lung function in patients with mild to moderate persistent asthma. The current challenge is to implement IBSM in clinical practice.

Based on previously detected barriers and facilitators for implementation we developed implementation strategies for IBSM that address these barriers and facilitators.

Study objective

The objective of this project is to investigate the (cost-) effectiveness of these tailored implementation strategies in comparison to a common used implementation strategy, in a three arm randomized trial.

Study design

Study design: a three-arm cluster randomised trial with a cluster pre-randomisation design and 12 months follow-up per practice comparing the following three IBSM implementation strategies:
1. Basic Implementation Strategy (BIS): dissemination of the IBSM programme (*PatientCoach*)
2. Start-up Support Implementation Strategy (SSIS): BIS + start-up support for professionals (i.e. support in selection of the appropriate population and training of professionals)
3. Practice Coach Implementation Strategy (PCIS): SSIS + additional training and ongoing support for professionals

Study burden and risks

Internet based self-management support consists of an internet-based self-management programme (PatientCoach) and professional support (patient's own general practitioner and/or practice nurse). Professional support is hich is concordant with usual care.

Patients will be asked to monitor their asthma by using the the internet-based self-management programme (PatientCoach). Furthermore, for the purpose of research patients will be asked to fill in questionnaires at baseline, 3 and 6 months.

Patients using PatientCoach,combined with support of a health care professional (general practitioner and/or practice nurse) will have the possibility to improve self-management skills of their asthma. This means that the patient will be able to recognize and cope with asthma symptoms. For example, the patient will learn which type of medication is the most suitable for specific complaints. Internet-based self-management empowers the patient in controlling his/her asthma.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

(All of the following criteria)
• age 18-50 yr
• doctors diagnosis of asthma
• patients who need inhaled corticosteroids as controller medication (step 2-4 GINA guideline) and / or montelukast inhaled corticosteroids >= 3 months in the previous year
• access to the internet
• written informed consent

Exclusion criteria

• inability to understand written and oral Dutch instructions

• active diseases likely to interfere with the purpose of the study, such as a terminal illness or a severe psychiatric disease
• daily or alternate day oral corticosteroid therapy for at least 1 month before entering the study
• patients who are primarily under treatment by a pulmonologist

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-02-2012
Enrollment:	420
Type:	Actual

Ethics review

Approved WMO

Date:	23-05-2011
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	NL36445.058.11