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

No registrations found.

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

Summary

ID

NL-OMON20254

Source
NTR

Brief title
IMPASSE

Health condition

Asthma

Sponsors and support

Primary sponsor: Leiden University Medical Center (LUMC)
Source(s) of monetary or material Support: Netherlands Organisation for Health Research and Development (ZON-MW 80-82315-97-10004);
the Netherlands Asthma Foundation (NAF 3.4.09.011)

Intervention

Outcome measures

Primary outcome

1. Patient participation in IBSM;

2. Patients with a clinically relevant improvement in asthma-related quality of life.

Secondary outcome

Patient level:

1. Effect evaluation:

A. Clinical outcome;

B. Self-management related outcome.

Professional and organizational level:

1. General practice participation in IBSM;

2. Process evaluation:

A. Adherence of practice nurses/ GP’s to the implementation strategy;

B. Experience with IBSM;

C. Feasibility of IBSM in daily practice.

3. Economic evaluation:

A. Cost-effectiveness;

B. Cost-utility.

Study description

Background summary

Background:

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.

The aim 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:

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 population:

Patients with mild to moderate persistent asthma from general practices, age 18-50 yr, need for daily treatment with inhaled corticosteroids (more than 3 months usage of inhaled corticosteroids in the previous year), and will be identified via primary care patient registries in the Leiden region. We aim to evaluate 14 practices that participate in IBSM in all three strategies, involving 140 patients per arm to be invited to for evaluation of IBSM.

Primary outcomes are:

1. Patient participation in IBSM;

2. Patietns with a clincially relevant improvement in asthma-related quality of life.

Secondary outcomes are:

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);
Professional and organizational level: adherence of professionals to implementation strategies, experience with IBSM and feasibility of IBSM in daily practice. Cost-effectiveness:

cost effectiveness and cost-utility.

Study objective

To evaluate the impact of three different implementation strategies for implementing IBSM in current clinical practice, we have proposed the following three hypotheses:

1. Hypothesis 1 (Reach): More general practices will participate in IBSM in the practice coach- and the Start-up Support Implementation Strategy - as compared to the Basic Implementation Strategy;

2. Hypothesis 2 (Participate): The proportion of referred patients who participate in the IBSM programme in the practice coach- and the Start-up Support Implementation Strategy will be greater as compared to the Basic Implementation Strategy;

3. Hypothesis 3 (Outcome): The proportion of patients who participate in the IBSM programme and have an important improvement in asthma-related quality of life will be greater among those in the practice coach- and the Start-up Support Implementation Strategy will be greater compared to the Basic Implementation Strategy;

4. Hypotheses 4 (Cost-effectiveness): The practice coach- and the start-up implementation strategy will be more cost-effective as compared to the Basic Implementation Strategy.

Study design

Baseline, 3 and 6 months.

Intervention

The intervention to be implemented, is an Internet Based Selfmanagement (IBSM) application named PatientCoach. It consists of both a generic web-based system (with information on asthma, monitoring, feedback, and a pre defined medication plan) and an instruction visit for patients.

Three implementation strategies for implementating IBSM will be compared:

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.

Follow-up per patient is six months in the SSIS and PCIS strategies. Patients in the BIS strategy will only be approached for an endpoint evaluation at 6 months.

End-points on the practice level (SSIS and PCIS strategies) will be measured at 12 months after the first invitation letter to the general practice to participate in IBSM. Individual patient outcomes will be evaluated in the PCIS and SSIS-strategy at baseline, 3 and 6 months after a patient's start with PatientCoach. Individual patient outcomes in the BIS-strategy will be evaluated at 6 months (end-point evaluation) after a patient's start with PatientCoach.

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Eligibility criteria

Inclusion criteria

(All of the following criteria)

1. Age 18-50 yr;

2. Doctors diagnosis of asthma;

3. Patients who need inhaled corticosteroids as controller medication (step 2-4 GINA guideline) and / or montelukast;

4. Inhaled corticosteroids ≥ 3 months in the previous year;

5. Access to the internet;

6. Written informed consent.

Exclusion criteria

1. Inability to understand written and oral Dutch instructions;

2. Active diseases likely to interfere with the purpose of the study, such as a terminal illness or a severe psychiatric disease;

3. Daily or alternate day oral corticosteroid therapy for at least 1 month before entering the study;

4. Patients who are primarily under treatment by a pulmonologist.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2011
Enrollment:	420
Type:	Anticipated

Ethics review

Positive opinion

Date:	01-07-2011
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	NL2829
NTR-old	NTR2970
Other	METC LUMC : P11.077
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A