Evaluating the impact of computer-based decision support for the management of asthma in primary care

| Submission date | Recruitment status | [X] Prospectively registered |
|----------------------------------|--------------------------------|--------------------------------|
| 19/07/2004 | No longer recruiting | Protocol |
| Registration date | Overall study status | Statistical analysis plan |
| 22/07/2004 | Completed | [X] Results |
| Last Edited 11/04/2019 | Condition category Respiratory | [] Individual participant data |
| 11/04/2012 | respiratory | |

Plain English summary of protocol

Background and study aims

Asthma is a chronic condition that is responsible for substantial morbidity (illness). Direct costs for physicians, hospital care and medications in Canada are conservatively estimated at \$306 million per year for people with asthma. Existing evidence suggests that considerable reductions in morbidity could be achieved by early prevention and timely treatment. Much of the costs of asthma care are related to poor disease control due to under-use of effective prophylactic therapies, inadequate monitoring of disease severity, and insufficient patient education. Computerized decision-support systems have provided a new set of tools for enabling integrated evidence-based care, by providing physicians with patient-specific reminders and alerts for needed preventive care and management, and timely feedback from patients. However, there has been limited use of computer-enabled decision-support in primary care, and only one reported study in chronic disease management. A key barrier to success has been the challenge of providing primary care physicians with a computerized solution that will produce value-added benefits and can be integrated easily into their routine workflow. Our prior research has shown that an integrated electronic prescribing and drug management system can provide value-added benefits for physicians because it is linked to information on dispensed medications, and alerts for prescribing problems. Early uptake and utilization of this computerized drug management system by primary care physicians provides an opportunity to develop and evaluate the effectiveness of an integrated asthma management decision-support system to enhance the use of prophylactic therapies and timely monitoring of asthma severity in primary care. Our aim was to determine if computerized decision-support and home-monitoring systems for asthma that is integrated into an electronic prescription and drug management system can increase quality of disease management and improve treatment outcomes for patients with asthma.

Who can participate?

This study will be conducted in a population of about 100 primary care physicians in full-time private fee-for-service practice in about 40 clinics in Quebec, and an estimated 2880-4500 participating asthma patients within their practices. Physicians are eligible for inclusion if they are primary care practitioners who work full-time in practices in Quebec City or Montreal.

Patients will be eligible for inclusion in the study if they are 5 years of age or older, make one or more visits to an enrolled study physician during follow-up, and do not have a diagnosis of chronic obstructive pulmonary disease (COPD).

What does the study involve?

Enrolled physicians will receive the MOXXI electronic prescription and drug management software, equipped with wireless modem to access the central databases and application server, and wireless printer. This system allows physicians to write and send prescriptions electronically, provides alerts for potential prescribing errors, a profile of current and past medications through automated links with the provincial drug insurance plan and community-based pharmacies, a medication compliance calculator based on dispensed prescriptions, and automated problem list creation based on treatment indication and verification of diagnostic codes on medical services claims files. Clinics will be randomly allocated to receive a) computerized decision-support and home-monitoring for asthma integrated with the MOXXI system or b) the MOXXI system alone. The asthma management decision support system uses data from the patient problem and medication lists to provide patient-specific management recommendations based on Canadian Consensus guidelines for asthma management. Webenabled technology for asthma education nurses is used to collect home-monitoring information from patients between visits and feedback to primary care physicians in accordance with options selected by the physician for each patient.

What are the possible benefits and risks of participating? A possible benefit to the patients would be a lower out-of-pocket cost for their medication. This study involves minimal to no risk.

Where is the study run from? The study is run from Quebec City and Montreal, Quebec, Canada.

When is the study starting and how long is it expected to run for? The study started in October 2006 and was completed in June 2009.

Who is funding the study? Canadian Institutes of Health Research (CIHR).

Who is the main contact? Dr Robyn Tamblyn robyn.tamblyn@mcgill.ca

Study website

http://www.moxxi.mcgill.ca/moxxihome.html

Contact information

Type(s)Scientific

Contact name

Dr Robyn Tamblyn

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number NCT00170248

Secondary identifying numbers MCT-67814

Study information

Scientific Title

Evaluating the impact of computer-based decision support for the management of asthma in primary care

Acronym

MOXXI

Study objectives

Current hypothesis as of 17/04/2014:

Computer-based decision support for asthma management will reduce the proportion of asthma patients using greater than 250 doses of FABA or visiting the Emergency Room (ER) for asthma.

Previous hypothesis:

Computer-based decision support for asthma management will reduce the proportion of asthma patients using greater than 500 doses of FABA or visiting the Emergency Room (ER) for asthma.

On 31/01/2014 the following changes were made to the trial record:

- 1. The study design was changed from 'Single centre, two arm, randomised cluster trial with therapeutic management educational type of intervention.' to 'Treatment, parallel assignment, single blind (subject), randomized trial'
- 2. The anticipated start date was changed from 01/06/2002 to 01/10/2006
- 3. The anticipated end date was changed from 01/12/2009 to 30/06/2009
- 4. The target number of participants was changed from 35,000 to 4500

Ethics approval required

Old ethics approval format

Ethics approval(s)

McGill University Institutional Review Board, Montreal, Quebec City (Canada), 06/04/2004, ref: # M-1458

Study design

Treatment, parallel assignment, single blind (subject), randomized trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Asthma

Interventions

Computer-based decision support for asthma management integrated within electronic prescription and drug management. We will evaluate the effectiveness of the computer-based decision-support system by determining whether asthma patients of physicians who receive computer-assisted management tools have better disease control after 18 months of implementation compared to asthma patients of physicians who have the electronic prescription and drug management system alone.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Poor asthma control

Secondary outcome measures

Added 31/01/2014: Quality of care indicators (inhaled corticosteroid to beta2-agonist ratio)

Overall study start date

01/10/2006

Completion date

30/06/2009

Eligibility

Key inclusion criteria

Current inclusion criteria as of 31/01/2014:

81 primary care physicians, 4500 asthma patients of either sex, 5 years of age and older

Previous inclusion criteria:

52 primary care physicians, 43 pharmacies, and 35,0000 asthma patients of either sex, 5 to 45 years of age

Participant type(s)

Patient

Age group

Other

Sex

Both

Target number of participants

4500 patients

Key exclusion criteria

Diagnosis of Chronic Obstructive Pulmonary Disease (COPD)

Date of first enrolment

01/10/2006

Date of final enrolment

30/06/2009

Locations

Countries of recruitment

Canada

Study participating centre Clinical and Health Informatic Research Group Montreal, ON Canada H3A 1A3

Sponsor information

Organisation

Canadian Institutes of Health Research (CIHR) (Canada)

Sponsor details

Room 97, 160 Elgin Street Address locator: 4809A Ottawa, Ontario Canada K1A OW9 +1 888 603 4178 info@cihr-irsc.gc.ca

Sponsor type

Research organisation

Website

http://www.cihr-irsc.gc.ca/

ROR

https://ror.org/01gavpb45

Funder(s)

Funder type

Research organisation

Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-67814)

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 | 01/07/2015 | 26/02/2019 | Yes | No |