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Facilitating patient self-management in chronic disease: integrating electronic personal health records and ongoing communication into a web-based self-management tool

Submission date 23/03/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 07/04/2009	**Overall study status** Completed	
Last Edited 05/12/2016	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Sarah Ahmed

Contact details
3654 Prom Sir-William-Osler
Montreal
Canada
H3G 1Y5
+1 (0)514 398 4400 ext. 00531
sara.ahmed@mcgill.ca

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

179464; MOP-89859

Study information

Scientific Title
Facilitating patient self-management in chronic disease: integrating electronic personal health records and ongoing communication into a web-based self-management tool - a multicentre, two-armed randomised controlled trial

Study objectives
Higher rates of usage of the web-based self-management tool will be associated with greater improvements in asthma-related quality of life and asthma control.

Ethics approval required
Old ethics approval format

Ethics approval(s)
McGill Institutional Review Board (IRB), 18/02/2009, ref: A10-E36-08B

Study design
Multicentre two-armed randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Interventions
Intervention group: access to the web-based self-management tool including personal asthma profile, educational material, communication and feedback with the healthcare team, telephone follow-up by the study nurse
Control group: usual care and follow-up

Duration: 6 months

Intervention Type

Other

Phase
Not Applicable

Primary outcome measure
1. Asthma Specific Health-Related Quality of Life, measures four functional impairments at baseline and at the end of the study
2. Asthma control, defined as the excess use of rescue fast-acting bronchodilators (beta-2-agonists) (FABA) at baseline and at the end of the study

Secondary outcome measures
1. Technology Acceptance Measure (TAM): to evaluate intention to use the system and perceived benefits at the end of the study
2. Usage rates of the system, assessed by examining automated audit trails which will include the frequency of use defined as the number of minutes patients spent logged into the system /week
3. Patterns usage
4. Asthma Self-Efficacy, using a rating scale an overall mean score is calculated that can range from 1 (no confidence) to 5 (very confident), measured at baseline and at the end of the study
5. Medication adherence, evaluated by comparing medications prescribed to medications dispensed based on the prescription claims file
6. Healthcare utilisation: asthma-related emergency room (ER) visits/hospitalisations

Overall study start date
30/03/2009

Completion date
30/12/2011

Eligibility

Key inclusion criteria
1. Male and female patients over the age of 18 years suffering from asthma
2. Have full health insurance coverage from Régie de l'assurance maladie du Québec (RAMQ)
3. Physicians are actively using the asthma decision support system
4. In poor control despite being prescribed appropriate therapy and a written action plan. Specifically, poor control is defined as those patients who have had a respiratory-related emergency room (ER) visit or excessive beta-2-agonist use in the six months before recruitment.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
96 patients

Key exclusion criteria
1. Aged over 60 years
2. Serious medical diagnosis such as lung cancer
3. Severely limited mobility preventing patients from leaving home

Date of first enrolment
30/03/2009

Date of final enrolment
30/12/2011

Locations

Countries of recruitment
Canada

Study participating centre
3654 Prom Sir-William-Osler
Montreal
Canada
H3G 1Y5

Sponsor information

Organisation
McGill University (Canada)

Sponsor details
Faculty of Medicine
McIntyre Medical Building
3655 Promenade Sir William Osler
Montreal, Quebec
Canada
H3G 1Y6
+1 (0)514 398 1768
researchsec.med@mcgill.ca

Sponsor type
University/education

Website
http://www.mcgill.ca/medicine/

ROR
https://ror.org/01pxwe438

Funder(s)

Funder type
Government

Funder Name
Canadian Institutes of Health Research (Canada) (ref: MOP-89859)

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

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?
Protocol article	protocol	14/12/2011		Yes	No
Results article	results	01/12/2016		Yes	No