ISRCTN77785397 https://doi.org/10.1186/ISRCTN77785397

Using the internet to help individuals stay healthy and prevent further reductions in health from existing chronic diseases

Submission date
08/09/2011

Recruitment status
No longer recruiting

Registration date
08/11/2011

Overall study status
Completed

Last Edited
16/04/2015

Condition category
Respiratory

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
One of the greatest healthcare challenges is the increasing costs and social burden of chronic disease - a challenge which the healthcare system is poorly equipped to address. Self-management refers to learning and practicing skills necessary to carry on an active and emotionally satisfying life in the face of a chronic condition. This requires providing patients with tools and strategies to manage their health and to develop the confidence needed to take up healthy behaviors and stop unhealthy ones. Unfortunately, the support provided by the healthcare system to help individuals manage their health has mainly involved a combination of infrequent brief discussions during physician visits and educational pamphlets, but has not provided the patient with ongoing information and monitoring in response to changes in their health. Self-management support for patients by the care team is recognized as an integral element needed for improving health outcomes by guiding individuals to care for their own health and to make positive health choices. To provide this type of support a direct line of communication is required between the patient and care team, extending the care experience outside of the physician’s office or clinic. Health information technology (HIT) offers a unique opportunity to provide regular monitoring by supplying a means for two-way communication and exchange of information between the patient and care team. Chronic obstructive pulmonary disease (COPD) is the fourth leading cause of death in Canada and is one condition where self-management has been shown to be effective for improving health outcomes. This study will evaluate the acceptability and test the effects of using a COPD web-based self-management tool on selected health behaviors and outcomes.

Who can participate?
Patients aged 40 and over with stable COPD .

What does the study involve?
Participants will be randomly allocated to either the intervention group or the control group. Both groups will receive usual care, which includes being managed by their respective specialists or general practitioners and receiving the Living Well with COPD program. In addition to usual care, the intervention group will also get access to the COPD web-based self-management tool.

What are the possible benefits and risks of participating?
If the tool is found to be effective, it will be deployed and further tested on a larger scale and adapted for other chronic diseases. Other than the time required for this study, there is no direct disadvantage or risk to health by participating in this study.

Where is the study run from?
Montreal Chest Institute, Sacre Coeur Hospital, Montreal, Canada.

When is the study starting and how long is it expected to run for?
From January 2012 to December 2013.

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

Who is the main contact?
Dr Sara Ahmed
sara.ahmed@mcgill.ca

Contact information

Type(s)
Scientific

Contact name
Dr Sara Ahmed

Contact details
McGill University
3655 Promenade Sir William Osler
Montreal
Canada
H3G 1Y5
-
sara.ahmed@mcgill.ca

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
246788

Study information

Scientific Title

Maximizing the effects of self-management interventions on chronic disease outcomes: the development of a Chronic Obstructive Pulmonary Disease (COPD) web-based patient portal

Study objectives
Higher rates of usage of the web-based tool will be associated with:
1. Greater improvements in COPD action plan adherence in the event of an exacerbation
2. Reduced nurse case manager work load

Ethics approval required
Old ethics approval format

Ethics approval(s)
McGill Faculty of Medicine Institutional Review Board (IRB), Canada 1 December 2010, ref: A08-M73-10B

Study design
Multicentre two-armed randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Chronic Obstructive Pulmonary Disease (COPD)

Interventions
Intervention group:
In addition to usual care, access to the COPD web-based self-management system including educational COPD content, personal medical information such demographic, drug and medical visit information.

Control group:
Usual care

Duration: 12 months

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Improvement in patients' adherence to action plan in the event of exacerbation
2. Action plan adherence defined as the patient taking antibiotic or prednisolone within three days of starting an acute exacerbation

Secondary outcome measures
1. Medication adherence
2. COPD self-efficacy
3. COPD specific health-related quality of life (chronic respiratory questionnaire, St George's respiratory questionnaire)
4. Adverse events (number of respiratory emergency deparment visits and hospitalisations)

Overall study start date
01/01/2012

Completion date
31/12/2013

Eligibility

Key inclusion criteria
1. Males and females patients with stable COPD aged 40 years and older
2. Patients who started the "Living Well with COPD" program
3. Have access to a computer and internet
4. Current or previous smoker (at least 10 packs per year)
5. Forced expiratory volume in 1 second (FEV1) after the use of a bronchodilator between 25% and 70% of the predicted normal value and FEV1 - forced vital capacity ratio less than 70%
6. Two COPD exacerbations in the previous year

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
80

Key exclusion criteria
1. Previous diagnosis of asthma
2. Left congestive heart failure
3. Terminal disease
4. Dementia

5. Uncontrolled psychiatric illness
6. Long term care-facility stays

Date of first enrolment
01/01/2012

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
Canada

Study participating centre
Montreal Chest Institute
Montreal
Canada

Sponsor information

Organisation
McGill University (Canada)

Sponsor details
Faculty of Medicine
McIntyre Medical Building
3655 Promenade Sir William Osler
Montreal
Canada
H3G 1Y6
-
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, ref: MOP - 115082 (Canada)

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