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Effectiveness of a pharmacist-driven intervention in chronic obstructive pulmonary disease

Submission date 02/03/2016	**Recruitment status** Stopped	[X] Prospectively registered [X] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 04/03/2016	**Overall study status** Stopped	
Last Edited 29/04/2019	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims
Chronic obstructive pulmonary disease (COPD) is the name for a collection of lung diseases which cause breathing difficulties. Patients with COPD often don't take their medications exactly as prescribed and have difficulty using their inhalers properly. Community pharmacists can help improve quality of life and overall health in these patients. We will study the effect that pharmacists can have on the health of patients with COPD. We hope to show that pharmacists can help improve the use of medications, inhaler technique and quality of life, and decrease health care costs and how many times COPD makes the patients sick.

Who can participate?
COPD patients, at least 40 years old

What does the study involve?
Participating pharmacies are randomly allocated to either provide the care they would normally offer on a daily basis, or to deliver an improved form of care that focuses on COPD management.

What are the possible benefits and risks of participating?
We hope to see an improvement in how well and how often people are remembering to take their medications, compared to before the study started. The only identified risks are the potential for the patient to feel overwhelmed during the data collection process.

Where is the study run from?
This study will take place in pharmacies in Newfoundland and Labrador (NL), Canada.

When is the study starting and how long is it expected to run for?
July 2015 to November 2017

Who is funding the study?
Health Research Foundation (Canada)

Who is the main contact?
1. Dr Erin Davis (emdavis@mun.ca)
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title
Effectiveness of a pharmacist-driven intervention in chronic obstructive pulmonary disease (EPIC): a pragmatic cluster randomized controlled trial

Acronym
EPIC

Study objectives
Community pharmacists can help improve health-related quality of life and overall outcomes in patients with chronic obstructive pulmonary disease (COPD) through a pharmacist-driven intervention on: medication adherence, inhaler technique, health-related quality of life, health care resource utilization, COPD exacerbations, and use of medications.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Newfoundland and Labrador Health Research Ethics Board, 14/05/2015, approval number: 15 091

Study design
Pragmatic cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Other

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

Interventions
We will compare pharmacies delivering an improved form of care that focuses on COPD management with pharmacies providing the care they would normally offer on a daily basis.

Multifactorial pharmacist-led intervention on medication adherence, inhaler technique, health-related quality of life, health care resource utilization, COPD exacerbations, and use of medications. The intervention involves 6 main strategies:
1. Medication review
2. Patient education
3. A written COPD action plan provided in collaboration with their family physician
4. Patient referral to pulmonary rehabilitation in collaboration with their family physician
5. Provision of, or referral to, smoking cessation counseling (where applicable)
6. Referral to a community-based chronic disease self-management program

Intervention Type
Other

Primary outcome measure
Change from baseline to 6 months in medication adherence using the medication possession ratio (MPR) and the Morisky Medication Adherence Scale (MMAS-8)

Secondary outcome measures
1. Proportion of patients with a clinically significant change in adherence
2. Proportion of patients defined as having ‘good adherence’
3. Mean MPR between groups
4. Quality of life as measured by the St. George’s Respiratory Questionnaire
5. Medication inhalation technique using a pharmacist-scored checklist
6. Healthcare resource utilization
7. Antibiotic and oral corticosteroid use for COPD exacerbations
Measured at baseline and 6 months.

Overall study start date
01/07/2015

Completion date
01/11/2017

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Physician-diagnosed COPD
2. Age ≥40 years at trial enrollment
3. Sufficient ability to answer questionnaires in English

Participant type(s)
Patient

Age group
Adult

Sex

Both

Target number of participants
We will maintain a cluster size of 20 pharmacies (10 intervention and 10 control) we will aim to enroll 7 patients per pharmacy, or 140 patients total

Key exclusion criteria
1. A known Forced Expiratory Volume in 1 second (FEV1)/ Forced Vital Capacity (FVC) of <30%
2. A diagnosis of dementia or a prescription for cholinesterase inhibitors
3. A terminal illness
4. Physician-diagnosed asthma
5. Participation in another clinical trial
6. If they do not provide consent

Date of first enrolment
01/05/2016

Date of final enrolment
01/05/2017

Locations

Countries of recruitment
Canada

Study participating centre
Memorial University of Newfoundland
School of Pharmacy
Memorial University of Newfoundland
Health Sciences Centre
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Sponsor information

Organisation
Memorial University of Newfoundland (Canada)

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Sponsor type
University/education

ROR
https://ror.org/04haebc03

Funder(s)

Funder type
Research organisation

Funder Name
Health Research Foundation

Alternative Name(s)
Fondation pour la Recherche en Santé, HRF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Canada

Results and Publications

Publication and dissemination plan
There will be no publication restrictions, and publication of both the protocol and full project will be sought in peer-reviewed journals, the timeline for publication will be confirmed at a later date. The authors plan to hold stakeholder meetings to disseminate study results, as well as present the results at local and national conferences after completion of the study.

Intention to publish date
01/11/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	13/10/2016		Yes	No