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Effectiveness of a pharmacist intervention in patients with lung disease

Submission date
16/05/2017

Recruitment status
No longer recruiting

Registration date
17/05/2017

Overall study status
Completed

Last Edited
14/10/2022

Condition category
Respiratory

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

Plain English summary of protocol
Background and study aims
Chronic obstructive pulmonary disease (COPD) is a group of lung conditions that cause breathing difficulties. Patients with lung disease often do not take their medications as prescribed (non-adherent) and can have poor inhaler technique. Community pharmacists may be able to improve patient medication adherence thus raising quality of life, reducing complications and reducing healthcare resource use and cost. The aim of this study is to measure the effect of pharmacist intervention on patients with COPD.

Who can participate?
Patients aged 40 and over with COPD

What does the study involve?
Participants are randomly allocated to either a group that receives the intervention or a group that does not receive the intervention (control group). The intervention group receive enhanced care that emphasizes lung disease management through the Medication Therapy Services (MTS) clinic. This involves medication review, patient education, a written COPD action plan, smoking cessation counselling, and referral to a community-based chronic disease self-management program. The control group receive usual care and an educational pamphlet that has information about COPD. Participants are followed up for 6 months to measure medication adherence, quality of life, inhaler technique, and healthcare resource and medication usage. After 6 months participants in the control group are offered the option to be referred to the MTS clinic to receive the detailed care intervention.

What are the possible benefits and risks of participating?
The methods and results from this study could be used to improve the care provided by community pharmacists in the real world. This would improve the health and quality of life of patients with COPD. The risks to participants should be minimal given the educational nature of the intervention. There may be negative emotional reactions or the feeling of being overwhelmed. Should participants suffer any effects from the study questionnaires or the educational session, pharmacists are instructed to allow rest and direct patients to counselling services where necessary.

Where is the study run from?
Respirology ambulatory care clinics at the Health Sciences Centre, and the MTS clinic at School of Pharmacy, Memorial University (Canada)

When is the study starting and how long is it expected to run for?
March 2017 to May 2019

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

Who is the main contact?
1. Dr John Hawboldt
2. Dr Erin Davis

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 COPD (EPIC2): a randomized controlled trial

Acronym
EPIC2

Study objectives
The pharmacist intervention will lead to improved adherence and more effective use of medication such as: better inhalation technique, and being prescribed more appropriate therapy for disease severity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Newfoundland and Labrador Health Research Ethics Board, 01/06/2017, ref: 20180113

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Other

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
Chronic Obstructive Pulmonary Disease (COPD)

Interventions
A random number list will be generated using Excel 2013 (Microsoft Corporation) and patients will be assigned to either intervention or control in a 1:1 ratio by the research assistant as they are recruited. Allocation concealment will be achieved using sequentially numbered, sealed,

opaque envelopes containing the group assignments, opened sequentially when patients have consented to participating in the study.

The intervention group will receive an enhanced form of care that emphasizes COPD management through the Medication Therapy Services (MTS) clinic. The intervention involves 6 main strategies in addition to the COPD education pamphlet:
1. Medication review
2. Patient education
3. A written COPD action plan provided in collaboration with the respirologist if required
4. Provision of, or referral to, smoking cessation counseling (where applicable)
5. Referral to a community-based chronic disease self-management program

The control group will receive usual care and a COPD education pamphlet.

Patients will be followed up for 6 months. At the 6-month point, patients in the control group will be offered the option to be referred to the MTS clinic to receive the detailed care intervention.

Intervention Type
Other

Primary outcome measure
Medication adherence, measured as the proportion of days covered (PDC) at baseline and 6 months

Secondary outcome measures
Measured at baseline and 6 months:
1. Quality of life, assessed by the St. George's Respiratory Questionnaire (shorter version)
2. Medication inhalation technique, measured using a pharmacist-scored scale
3. Healthcare resource utilization (frequency of physician visits, hospitalizations, emergency department visits and pharmacy visits), reported by the patient at 6 months
4. Antibiotic and oral corticosteroid use for acute exacerbations of COPD (AECOPD), reported by the patient at 6 months

Overall study start date
01/03/2017

Completion date
30/05/2019

Eligibility

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

Participant type(s)
Patient

Age group

Adult

Sex
Both

Target number of participants
100 patients in each group

Key exclusion criteria
1. Severe disease defined as 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. Participation in another clinical trial
5. Do not provide consent

Date of first enrolment
01/06/2017

Date of final enrolment
31/12/2018

Locations

Countries of recruitment
Canada

Study participating centre
Respirology ambulatory care clinics at the Health Sciences Centre, and the MTS clinic at School of Pharmacy
Memorial University
St John's
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Sponsor information

Organisation
The Health Research Foundation

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Sponsor type
Research organisation

Website
http://www.hrf-frs.com/home

ROR
https://ror.org/00hg4tf86

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
Planned publication in a high-impact peer reviewed journal

Intention to publish date
01/12/2022

Individual participant data (IPD) sharing plan
Directly identifiable information (e.g., name, personal health number) and indirectly identifying information (e.g., date of birth and place of residence) will be removed from information and replaced with a code. Only the principal investigator and research assistant will retain a list that links the participants' code names with their actual name so data can be re-linked if necessary.

This information is needed to be retained if for someone reason the trialists need to re-link the data. One of these situations could be the debriefing of participants. It will be necessary to retain this information so the trialists can contact them after the study is over. Another situation that perhaps requires retention of data is to assist internal and external audits that may be required of the research team by local research boards. This information will be stored securely in a locked cabinet in the principal investigators office and when stored electronically will be stored on an encrypted device. Consent from participants will be obtained in the respirology clinics.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		06/12/2017	14/10/2022	No	No