RESEARCH IN PHARMACY PRACTICE

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INCREASING QUALITY OF LIFE AND REDUCING PULMONARY EXACERBATIONS IN CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) BY PROVIDING PHARMACIST-DRIVEN IMPROVEMENT IN MEDICATION ADHERENCE: A PRAGMATIC CLUSTER RANDOMIZED CONTROLLED TRIAL

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EFFECTIVENESS OF A PHARMACIST-LED INTERVENTION IN COPD
BACKGROUND

Pharmacist-led interventions have been shown to reduce hospitalizations and exacerbations.

Non-adherence rates are high in COPD, especially related to improper device technique.
The purpose of this study is to evaluate a multifactorial pharmacist intervention to increase patient medication adherence, resulting in improved quality of life, fewer hospitalizations or exacerbations, and more effective use of health care expenditures.
STUDY DESIGN

A pragmatic cluster RCT

- Randomized at the level of the community pharmacy
Each pharmacy will be randomized to either intervention or control group by the research team as they sign on.

Each pharmacy will aim to recruit about 7 patients.

Control group pharmacies deliver “usual care”

Intervention group pharmacies will deliver the enhanced care intervention.
STUDY QUESTION

Population: Patients >40yo with a diagnosis of COPD

Intervention: Multifactorial pharmacist-led intervention

Comparison: Usual care

Outcomes:

• Adherence
• Quality of life
• Inhaler technique
• Healthcare resource utilization
• Medication use
INCLUSION CRITERIA

- Confirmed COPD by physician diagnosis
- Age >40
- Sufficient ability to answer questionnaires in English
EXCLUSION CRITERIA

• Known FEV₁/FVC < 30%
• Diagnosis of dementia
• Prescription for cholinesterase inhibitors
• Known presence of terminal illness
• Patients who do not provide consent
USUAL CARE VS. ENHANCED CARE

Usual care is considered the normal, safe and effective distribution of medications to patients.

The pharmacist should respond to the patient, and whatever clinical information they have about them, as they otherwise would in practice. Because of this, the level of care may be up to intervention-level care.

Enhanced care will consist of medication reviews, targeted teaching, action plans, improving inhaler technique, adherence support strategies, and referral to other healthcare areas.
Primary outcome: Medication adherence

- Measuring proportion with a clinically important improvement

Medication Possession Ratio (MPR) (MCID of 10%)
- Ratio of days of medication supplied over the 6-month follow-up period

Moriskey Medication Adherence Scale (MMAS-8) (MCID of 2 pts)
SECONDARY OUTCOMES

Quality of life
St. George’s Respiratory Questionnaire

Medication inhalation technique
Device-specific checklist

Healthcare resource utilization
frequency of physician visits/hospitalizations, use of pulmonary rehab self-reporting using data collection forms
SECONDARY OUTCOMES

Medication use

Antibiotic and corticosteroid use as an indicator of exacerbation history—patient self-reporting

All outcomes will be scored through questionnaires found in the *Data Collection Form*
SAMPLE SIZE

• Based on proportion of patients with an improvement in adherence
  • Baseline adherence: 50%
  • Minimal detectable difference: 30% relative change
  • Type I error: 5%
  • Type 2 error: 20%
  • Interclass correlation coefficient: 0.05
  • Clusters with inflation factor $1 + p(m-1)$

• Assuming 10-20% drop-out:
  • 20 clusters
  • 140 patients
STUDY FLOW

**Enrolment**
- Patient presents with known COPD or COPD medications
- CONSENT OBTAINED

**Data Collection**
- Data collection forms completed for baseline

**Intervention**
- Enhanced care in Intervention Pharmacies
- Usual care in Control Pharmacies

**Follow Up**
- All data collection forms completed again after 6 months follow-up
ENROLMENT

• Patient presents to pharmacy with COPD medications or known to have COPD

• Consult *Pharmacist Instructions* for a checklist of forms and procedures

• Ask patient if they are interested in participating and introduce patient to *Consent to Take Part in Research* form
CONSENT

• If yes, walk the patient through the consent process
• If no, patient care will resume as normal
• Fill out the Patient Screening and Contact Information form by contacting the patient and/or the patient’s physician
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DATA COLLECTION

If patient meets inclusion criteria, administer baseline questionnaires:

- MMAS-8
- St. Georges Respiratory Questionnaire
- Inhalation Technique Checklist
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**INTERVENTION**

**Control** patients given **usual care**

**Intervention** patients given **systematic pharmacist intervention**

- Medication Review
- Patient Education
- Smoking Cessation Referral
- In conjunction with their primary physician:
  - COPD Action Plan
  - Referral to Pulmonary Rehabilitation
STUDY FLOW

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FOLLOW-UP

At 6 months:

• Repeat baseline questionnaires
• Collect health care resource utilization
• Calculate medication possession ratio
DATA ANALYSIS

- All analyses will be Intention to Treat
- Baseline Characteristics will be compared
  - Cluster level and Patient level
- **Effect of the intervention on Primary and Secondary Outcomes**
  - At 6 months using univariate and multivariable generalized estimating equations
  - The individual will be the unit of analysis
- Multiple imputation will be used for pharmacies or patients lost to follow-up
EPIC TRIAL
STATUS
STATUS

• **Completed**
  - Ethics approval
  - Pharmacist training pilot

• **Ongoing**
  - Protocol registration
  - Protocol manuscript

• **Next Steps**
  - Pharmacist recruitment and training (Jan-Mar)
  - Patient enrolment (Feb-August)
FUNDING

• Currently funded:
  • Health Research Foundation
  • NL arm

• Potential funding:
  • SPOR Network on Chronic Disease
  • Expansion to AB and BC