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A pilot study of clinical pharmacist home visits and consultant respiratory physician collaborative intervention to improve outcomes in people with chronic obstructive pulmonary disease and other health problems

Submission date	**Recruitment status**	[X] Prospectively registered
28/10/2019	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/01/2020	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
31/07/2025	Respiratory	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

People with moderate-to-severe chronic obstructive pulmonary disease (COPD) are so breathless that they need to stop for breath when walking at their own pace. At home, when breathing gets worse e.g. due to infection, hospitalisation often results. Frequent adjustment of medicines for COPD and other medical conditions improves breathing and reduces hospitalisations, but home-based check-ups for breathing and medicines are uncommon. Pharmacist home-visits, undertaken with the support of the patient's GP and chest physician, can help ensure that patients are on the right medication and through so doing reduce the risk of a flare-up of COPD and associated hospital admission. The researchers now want to build on this work to see if pharmacist home-visits are safe and effective for patients and the NHS, but first they need a small-scale pilot study in which some patients get pharmacist home-visits and compare this with patients who do not get home-visits. If the results are promising, the researchers plan to run a trial big enough to test whether pharmacist home-visits improve patient outcomes and reduce hospital admissions for COPD.

Who can participate?

Patients aged over 18 with COPD

What does the study involve?

For all patients, there are no changes to the care they usually receive from the health service. For all participating patients, there are three monthly visits from a researcher to ask some questions and take some measures of respiratory function. None of these measures are invasive – all are routine e.g. blowing into a device that records lung function. Patients who are randomly allocated to the pharmacist intervention group receive pharmacist home visits, on average, every month for 6 months followed by two monthly visits for the following 6 months. However, some patients may receive fewer visits, and some may receive more than this. The decision to

receive more or less visits depends on the patient's preferences and clinical symptoms, through discussion with the pharmacist and consultant respiratory physician and GP. During the visits, the pharmacist assesses the patient's respiratory symptoms, medicines and other conditions, then if agreed with the patient, the pharmacist recommends changes to the patient's medicines, monitoring or referral to other services for further health intervention. For patients allocated to the usual care group, there are no pharmacist visits.

What are the possible benefits and risks of participating?
The benefits of taking part include receiving additional care and attention from a highly qualified pharmacist who is trained to assess and prescribe medicines independently. The pharmacist will be specialist in respiratory care. He or she will be working very closely with the patient's existing respiratory consultant based at the patient's usual hospital, and the patient's GP. This collaboration will ensure that the patient receives more frequent input (from three clinicians: pharmacist, consultant and GP) than they would normally receive if not participating in the trial. The researchers cannot envisage any risks of taking part: in the usual care group (where patients do not receive more frequent input from the pharmacist), it will be care as usual from all existing care providers.

Where is the study run from?
1. NHS Greater Glasgow and Clyde (UK)
2. NHS Lothian (UK)

When is the study starting and how long is it expected to run for?
October 2019 to January 2024

Who is funding the study?
Chief Scientist Office (UK)

Who is the main contact?
Dr Richard Lowrie
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Contact information

Type(s)
Public

Contact name
Dr Richard Lowrie

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
272543

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
GN18RM698; HIPS/19/27

Study information

Scientific Title
Tailored Intervention at home for patients with moderate-to-severe COPD and co-morbidities by Pharmacists and Consultant Physicians (TICC PCP): a pilot randomised controlled trial

Acronym
TICC PCP

Study objectives
This is a pilot randomised controlled trial. It seeks to determine whether we can recruit, retain, collect sufficient information, conduct randomisation as planned, and to assess whether there is enough merit in running a subsequent definitive trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/09/2020, South East Scotland Research Ethics Committee 01 (Waverley Gate, 2-4 Waterloo Place, Edinburgh EH1 3EG, Edinburgh, EH1 3EG, United Kingdom; +44 7971827565; Sandra.Wylie@nhslothian.scot.nhs.uk), ref: 20/SS/0093

Study design
Pilot randomised controlled trial with parallel qualitative and economic evaluations

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)

Treatment

Participant information sheet
Not available in web format. please use contact details to request participant information sheet

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease, and other morbidities

Interventions
Method of randomisation: Interactive Voice Response system operated by the Robertson Centre for Biostatistics, Glasgow University.

Intervention arm: Pharmacist home visits every month for 6 months then every two months for 6 months. Pharmacist will assess respiratory and other health problems, then, based on patient's presenting condition, recommend any changes to medicines or monitoring or onward referral that are likely to lead to improved respiratory health, and improved outcomes from other conditions. Recommendations will be discussed with consultant physician, GP and others. The pharmacist will implement the changes, as an autonomous Independent prescriber.

Usual care arm: No pharmacist visits.

Both arms: researcher home visits every three months to collect objective measures and health-related quality of life and patient experience of treatment, resource use.

The intervention will be tailored to patients' needs, meaning some patients may not require visits every month for 6 months and then 2 monthly for the following 6 months: some will require more, others less. Follow-up 24-30 months.

Intervention Type
Other

Primary outcome measure
Current primary outcome measure as of 07/08/2024:

The primary outcome for this pilot study, was whether to progress to a definitive RCT based on achievement of four progression criteria:
1. Recruitment of at least 70% invited participants within four months;
2. At least 70% of intervention arm participants receiving TICC PCP as planned (at least monthly for 6 months then every two months) from the date of allocation to intervention arm;
3. At least 80% of participants (excluding those who died or developed incapacity before the end of the study) remaining in the study until 21-month data collection;
4. At least 90% of in-person data collected at each study time point (baseline and every three months for up to 21 months). Researchers did not take blood samples during assessments and so the availability of blood results, depended on whether the participant had bloods collected recently as part of their routine care. Therefore, blood results were excluded from the calculation of missing data. A modified version of the Patient Experience with Treatment and Self-management (PETS: a patient-reported measure of treatment burden) was used, which had not been validated, therefore PETS responses were not included in data collection calculations. The percentage of missing data was calculated as the: number of missing data points divided by the total number of possible data points.

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Previous primary outcome measure:

Whether the researchers should proceed to a definitive trial, based on:
1. Eligibility
2. Recruitment
3. Retention
4. Implementation of study procedures (extent of collection of information every three months and time taken; randomisation, intervention delivery (completeness and fidelity between sites))
5. Range of outcomes and optimal duration of follow up
6. Sample size
7. Completeness of efficacy outcome measures and estimates of variability collected from patients, clinical records, and through ISD Scotland record linkage

≥70% of invited patients agreeing to participate
≥70% of patients in the intervention group receiving the intervention as planned
≥80% of patients remaining in the study until the end (excluding those who die between consenting and follow up)
≥90% of data collected as planned
Agreement of the independent TSC on the merits of progressing to a randomised controlled trial

Qualitative - semi-structured interviews with 15-20 patients, and 7-10 health professionals

Secondary outcome measures

Current secondary outcome measures as of 07/08/2024:

The following secondary outcomes and resource use will be measured by independent researchers extracting data from primary and secondary care health records at 3, 6, 9, 12, 15, 18, and 21 months whilst the participant remains in the study:
1. the number of, and the number of people with: Primary care contacts (GP, nurse, healthcare assistant, pharmacist or other), in person or by phone;
2. the number of prescribed medicines for respiratory conditions;
3. the number of prescribed medicines for: bone health; gastrointestinal problems; pain; skin conditions; cardiovascular disorders; depression; anxiety; anaemia; and vitamin or other dietary insufficiency;
4. the total number of prescribed medicines;
5. the total number of, the number of people with, and time to first: ED attendances (without admission) for respiratory reasons;
6. the total number of, the number of people with, and time to first: ED attendances (without admission) for non-respiratory reasons;
7. the total number of, the number of people with, and time to first: hospitalisation for respiratory reasons;
8. the total number of, the number of people with, and time to first: hospitalisation for non-respiratory reasons;
9. the duration of hospitalisation for respiratory reasons;
10. the duration of hospitalisations for non-respiratory reasons;
11. the number of out-patient attendances and out-patient non-attendance for respiratory and other reasons;
12. the total number of, time to, and causes of death.

The following secondary outcomes will be collected from participants during home visits by independent researchers at the same time points noted above whilst the participant remains in the study:
1. the number of COPD exacerbations (confirmed by patient report on use of rescue pack (steroids and/or antibiotics);
2. HRQoL using the EQ-5D-5L instrument score and individual domain scores;
3. modified Medical Research Council Dyspnoea scale (mMRC) score;
4. COPD Assessment Test (CAT) score;
5. the total number of, the number of people with, and time to first fall;
6. the total number of, the number of people with, and time to first fracture;
7. Treatment burden scores (PETS questionnaire) collected at 3, 6, 12, and 21 months); and
8. Patient Health Questionnaire-4 Item (PHQ-4) depression and anxiety score and sub scores (anxiety and depression).

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Previous secondary outcome measures:

Measured at follow up (i.e. 24-30 months or earlier):
1. Number of exacerbations (data linkage showing community pharmacy dispensing dates of short course (5-14 day) antibiotic and/or short course prednisolone at 24 -30 months follow up (this will vary for each patient)
2. Medication changes (prescribed and used) from community pharmacy dispensing records (data linkage)
3. Number of A&E /medical admissions unit visits due to respiratory causes from data linkage
4. Number of emergency admissions due to COPD from ISD data linkage
5. Number of GP emergency visits and GEMS/Lothian Unscheduled Care visits due to COPD /respiratory causes from clinical systems in Glasgow and Lothian, respectively
6. Number and duration of hospitalisations (for respiratory) from ISD data linkage
7. Lung function (FEV1) from researchers' records
8. Patient-reported measures (EQ-5D-5L, PETS both measured by researchers during three monthly visits)
9. Intervention acceptability from analysis of semi-structured interviews

Overall study start date
29/10/2019

Completion date
05/01/2024

Eligibility

Key inclusion criteria
1. Adults (>18 years)
2. With COPD and FEV1< 80% predicted
3. FEV1/FVC ratio<0.7; mMRC ≥215
4. Living at home
5. On a hospital respiratory outpatient clinic list

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Total final enrolment
110

Key exclusion criteria
Lung or suspected other malignancy

Date of first enrolment
07/07/2021

Date of final enrolment
04/01/2022

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
NHS Greater Glasgow and Clyde (South sector)
Clarkston Court
56 Busby Road
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G76 7AT

Study participating centre
NHS Lothian
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EH4 2XU

Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office

Alternative Name(s)
CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Publication and dissemination plan

The protocol, including the statistical analysis plan, will be available. Results to be published in November 2022.

Intention to publish date
01/11/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Richard Lowrie (Richard.Lowrie@ggc.scot.nhs.uk). Type of data: summary data tables of quantitative data including economic evaluation, and qualitative data. Available after completion of the trial in November 2022 for one year. Data will be shared by asking through email for any analyses.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	Baseline data collection form		08/08/2024	No	No
Other files	Distribution of Healthcare Costs		08/08/2024	No	No
Other files	Healthcare resource use unit costs		08/08/2024	No	No
Other files	Participant flow		08/08/2024	No	No
Other files	Reference list		08/08/2024	No	No
Other files	Supplementary Appendix 1 Systematic literature search		08/08/2024	No	No
Other files	description of intervention using the TiDier Framework		08/08/2024	No	No
Protocol article		30/07/2025	31/07/2025	Yes	No