ISRCTN38734433 https://doi.org/10.1186/ISRCTN38734433

Better Outcomes for Everybody: a study to evaluate whether a new service delivered by community pharmacists in collaboration with physicians to asthma and COPD patients, improves disease control and is value for money, compared with usual care, during and after COVID-19

Submission date
14/06/2021

Recruitment status
No longer recruiting

Registration date
15/06/2021

Overall study status
Completed

Last Edited
09/06/2023

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
Asthma and chronic obstructive pulmonary disease (COPD) are two long-term lung conditions affecting many people globally, and their costs have a relevant impact on the health care system and society. The COVID-19 pandemic has created a backlog of appointments and treatments, and in many cases, these conditions have worsened. This study aims to assess whether a new service provided by community pharmacist in collaboration with physicians improves asthma and COPD control leading to better patient quality of life and reducing the costs for the national health service and the society in Italy, compared with usual care. This study will introduce and test a new care model for managing asthma and COPD, which could be adapted for managing other long-term conditions.

Who can participate?
Community pharmacists and patients aged 18 years and over with asthma or COPD

What does the study involve?
Participants are randomly divided into two groups. The intervention group will receive the new service at the beginning of the study and 6 months later. The control group will receive usual care. The new service consists of a face-to-face or remote consultation with a patient (due to COVID-19), covering asthma/COPD symptoms, health and social care received, medicines used, attitude towards medicines, adherence to medication, and recording pharmacist-identified problems related to the use of medicines.

What are the possible benefits and risks of participating?
Patients may improve their disease control, quality of life, productivity, knowledge and use of their medications, reducing problems related to their medicines. Pharmacists may improve their knowledge and skills while delivering the new service, working closely with physicians and other health care practitioners. Physicians may reduce their work pressure and waiting lists and free up their time to treat patients with more complex conditions. The new service may reduce costs to the NHS and society. There are no expected risks.

Where is the study run from?
Università degli Studi di Catania (Italy)

When is the study starting and how long is it expected to run for?
April 2020 to November 2023

Who is funding the study?
SOFAD srl (Italy)

Who is the main contact?
1. Prof. Andrea Manfrin, amanfrin@uclan.ac.uk
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
11130092020

Study information

Scientific Title
Better Outcomes For Everybody (BOFE) evaluates the effectiveness and cost-effectiveness of a pharmacist-led intervention, delivered by community pharmacists in collaboration with physicians, in improving disease control, compared with usual care, in asthma and COPD patients during and after COVID-19: study protocol for a pragmatic, parallel randomised controlled trial

Acronym
BOFE

Study objectives
Research questions:
Is the pharmacist-led intervention called chronic respiratory conditions medicines use review (CRC-MUR) provided by community pharmacists in collaboration with physicians:

Effective at:
1. Improving asthma or COPD control as assessed by the Asthma Control Test (ACT) and the Clinical COPD Questionnaire (CCQ) scores?
2. Reducing the risk of having asthma and COPD uncontrolled?
3. Optimising the number of active ingredients used by asthma and COPD patients?
4. Identifying and resolving pharmaceutical care issues?
5. Improving patients' adherence to asthma or COPD medications?
6. Achieving the minimal clinical important difference (MCID) in asthma and COPD control?

Cost-effective for:
1. The healthcare system (NHS) and the society (compared to usual care) in terms of cost per quality-adjusted life-year gained (QALY) using the EuroQol five dimension (EQ-5D-5L)

Comparator:
Pharmacists' usual care is the safe supply of medicines and medication-taking advice to the patient.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 22/02/2021, Azienda Ospedaliero-Universitaria Policlinico "G. Rodolico - San Marco" Catania (via Santa Sofia 78 - 95123 Catania, Italy; +39 (0)95 3781855; comitatoeticoct1segr@policlinico.unict.it), ref. 47/2021/PO
2. Approved 29/03/2021, University of Central Lancashire (Preston Fylde Road, PR1 2HE, UK; +44 (0)1772 895583; ethicsinfo@uclan.ac.uk), ref: HEALTH 0163

Study design
Single-centre pragmatic parallel randomized controlled trial

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 a participant information sheet

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

Interventions
The duration of the trial is 24 months with a 12-month follow-up. Pharmacists will encounter their patients five times, at baseline and every 3 months.

Power calculation
The power calculation was conducted using the z-test family, calculating the proportion of the difference between two independent groups with two-tails (48) using the dichotomised scores of ACT and CCQ: controlled (ACT ≥20; CCQ <2) versus non-controlled (ACT <20; CCQ ≥2). A 2:1 randomisation and sample size of 887 patients (591 in the IG and 296 in the CG) will be enough to detect a difference of 15% between the intervention and control group using a dichotomised score (controlled versus non-controlled) of the ACT/CCQ with a 99% power and 5% significant level. The 15% difference represents the difference between the percentage of controlled (65%) versus non-controlled (50%) patients at the end of the study. The power calculation was conducted using G*Power version 3.1.9.4; the results were assessed and confirmed by a senior statistician working at UCLan's Clinical Trial Unit (CTU).

Pharmacist patient ratio
The researchers decided to round up the number for simplicity; therefore, they aim to recruit 100 pharmacists and 900 consecutive patients (asthma = 450; COPD = 450), with a pharmacist-patient ratio of 1:9, meaning that each pharmacist will recruit and follow-up nine patients.

Randomisation, allocation and sequence generation
The patient is the unit of randomisation and intervention.

Block size
The blocks equal to nine were adopted since large blocks reduce predictability but will not restrict the randomisation as closely as small blocks.

Randomisation
An academic from UCLan expert in the use of statistics has overseen the randomisation process. It was decided to simplify the randomisation procedure; therefore, the 2:1 allocation was rounded up to 600 in the intervention group (instead of 591) and 300 in the control group (instead of 296).

Sequence generation
The sequence generation will be conducted using block permutation without stratification, followed by randomisation, due to the expected large sample size (n=900), as suggested by the senior statistician of the LCTU.

Allocation concealment
The allocation concealment will be performed with the sealed envelope online system, which will generate an allocation schedule. In our study, two lists will be produced. The first list will be given to the pharmacist before patient recruitment, where a unique three-digit code (e.g. RR3, TS7, VS5) will be assigned to each participant. A second list will be released at the end of the recruitment process and allocate each three-digit code (participant) to either the interventions group or the control group. This approach will be adopted because it will not be possible to produce 900 sealed envelopes and circulate them on the starting date (before baseline) while keeping the cost within the allocated budget.

Blinding (masking)
In our study, blinding will not be possible either at the pharmacist or patient level because of nature of the intervention requires their full knowledge. However, the CI, as assessor of the main outcome measures, asthma and COPD control, will remain blind throughout. As group allocation will be intrinsic to the data gathered for each patient, to maintain blindness, the CI will access the data only after all patients have been followed up at three months. Friedman et al. (2015) suggested that an unblinded trial might not be simple, but it more accurately reflects clinical practice.

Overall delivery: by community pharmacists in primary care. Delivery format: verbal (face-to-face or remotely using phone or video facilities). Development: it was driven by its affordability (cost associated with the design and delivery), practicability (pharmacists/patients), effectiveness /cost-effectiveness, acceptability (patients/pharmacists/GPs), side effects/safety (patients), consistency, replicability.

CRC-MUR is a pharmacist-led intervention theoretically informed. It consists of a bespoke, systematic, structured face-to-face or remote consultation (due to COVID-19) with a patient, covering asthma/COPD symptoms, health and social care received, medicines used, attitude towards medicines, adherence to medication, recording pharmacist-identified pharmaceutical care issues (PCIs). If required, pharmacists will advise patients, including healthy living advice; they will advise physicians on patients' conditions using a standard template.

Intervention Type
Behavioural

Primary outcome measure
Asthma and COPD control assessed using the Asthma Control Test (ACT score) and the Clinical COPD Questionnaire (CCQ) score at baseline and 12 months (according to the patients' disease) at 3-month intervals

Secondary outcome measures
1. Reduction of the risk of having asthma and COPD uncontrolled, assessed using the ACT and CCQ scores assessed at baseline and 3-month intervals, as reported by patients
2. The number of active ingredients used by patients, as reported by patients at baseline and 12 months at each 3-month interval
3. Patients' self-reported adherence to asthma/COPD medications measured using the

questions used in the I-MUR study at baseline and 12 months assessed at 3-month intervals
4. Pharmaceutical care issues measured using the questions used in the I-MUR study at baseline and 12 months assessed at 3-month intervals
5. The minimal clinical important difference (MCID) in ACT score and CCQ, as reported by patients at baseline and 12 months assessed at 3-month intervals
6. Cost-effectiveness of CRC-MUR asthma/COPD service compared with usual care, measured in terms of cost per quality-adjusted life-year (QALY) as a measure of disease burden, including both the quality and the quantity of life gained, at 12-month follow-up

Overall study start date
02/04/2020

Completion date
30/11/2023

Eligibility

Key inclusion criteria
Pharmacies must have:
1. A private area for private consultation with patients
2. And/or telephone, smartphone, tablet or other devices allowing remote consultation with their patients if required due to COVID-19 restrictions
3. An internet connection

Pharmacists must:
1. Be qualified and registered with the Italian Pharmacy Board practising in Italy
2. Have experiences in providing advice to patients
3. Have already provided one or more services, such as blood pressure monitoring, smoking cessation, cholesterol monitoring, signposting, food intolerance testing (this will be verified during the recruitment process asking for a self-declaration)
4. Be able to attend the full training session(s)

Patients must:
1. Be at least 18 years of age
2. Have been diagnosed with either asthma or COPD, for at least 6 months before enrolment to the study
3. Have a prescription(s) for asthma/COPD medications with R03 as ATC code (Anatomical, Therapeutic Chemical Classification), or drugs for obstructive airways disease

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1000

Total final enrolment
835

Key exclusion criteria
Pharmacies must be excluded if they:
1. Have no internet access
2. No consultation room or no telephone, smartphone, tablet or other devices allowing remote consultation with their patients if required due to COVID-19 restrictions
3. Are currently involved in any other clinical pharmacy research project

Patients must be excluded if they:
1. Have a terminal illness (defined as an advanced stage of a disease with an unfavourable prognosis and no known cure) as identified by the pharmacists through the prescription coding
2. Are currently enrolled in another clinical trial
3. Do not self-administer their medications (e.g. inhaler)
4. Are not able to communicate well in Italian, both written and spoken

Date of first enrolment
07/04/2022

Date of final enrolment
31/07/2022

Locations

Countries of recruitment
Italy

Study participating centre
Università degli Studi di Catania
Piazza Università, 2
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Sponsor information

Organisation
SOFAD srl

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Sponsor type
Industry

Website
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Funder(s)

Funder type
Industry

Funder Name
SOFAD srl

Results and Publications

Publication and dissemination plan
The researchers are going to publish the study protocol, which includes the statistical analysis plan, in an open-access journal. The protocol was drafted according to the SPIRIT guidelines.

The dissemination of the study will start immediately after publishing the protocol. Then, it will continue throughout the study using social media posts, patient events, third sector and public engagement events. Results of the trial will be presented at national and international conferences. They will be submitted as scientific manuscripts to peer-reviewed journals, and afterwards, published in non-peer-review publications in Italian and maybe other languages. The trial results aim to inform the policymakers, the Italian Ministry of Health, the Italian National Health Services, and all the other stakeholders that might benefit from the results. Results will be disseminated to service users and their families via media, healthcare professionals via professional training and meetings, and researchers via conferences and publications.

Intention to publish date
30/06/2024

Individual participant data (IPD) sharing plan
All anonymised data will be stored in the repository UCLanData and clok. Process for requesting the data: http://clok.uclan.ac.uk/34599/1/Policies.pdf. Access to the data will be available only after the publication of all the trial results.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	Peer-reviewed protocol article	30/09/2021	12/07/2022	Yes	No