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Study of inhaler use in asthma and COPD

Submission date
18/04/2019

Recruitment status
No longer recruiting

Registration date
03/05/2019

Overall study status
Completed

Last Edited
17/06/2021

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Asthma and chronic obstructive pulmonary disease (COPD) are two of the most common diseases that cause problems with breathing and are treated mainly at home with the support of family doctors and pharmacies. It is very important to take the right medication for these diseases and to take it the right way to stay as healthy as possible. Other researchers have found that pharmacists can help patients taking their medication better. For instance, medication for asthma and COPD often comes as a spray that has to be inhaled. The researchers found that when pharmacists teach patients how to correctly inhale the medication, the patients take it more regularly, have fewer crises related to their disease, and sometimes even end up having to take less of their medication. In this study, ANF, a Portuguese organisation of pharmacies, and FPP, a Portuguese organisation that deals with lung diseases, together want to see whether this training also works when giving it as part of the day-to-day work in Portuguese pharmacies.

Who can participate?
Asthma or COPD patients who are at least 18 years old

What does the study involve?
Pharmacies are randomly allocated to either deliver an improved form of care on asthma and COPD management (group 1), or to provide the usual care they normally offer (group 2). In group 1, in addition to what the pharmacist normally does when a COPD or asthma patient comes to the pharmacy, and the advice that they normally give, the pharmacist takes some extra time to explain very well how the inhaling of the medication works. A manual for that is provided to the pharmacist, and the pharmacist gives the patient the chance to try the inhaler with the pharmacist watching so that the pharmacist can help and correct possible mistakes. Group 2 pharmacies provide the usual care and both groups collect data from the patients at the start of the study and at 3- and 6-month follow-up visits.

What are the possible benefits and risks of participating?
It is hoped that after the study, patients make fewer mistakes when inhaling their medication and that therefore they will have fewer crises related to their disease. It is not thought that there are any risks related to giving the patients some extra training in taking their medication.

Where is the study run from?
This study will take place in community pharmacies located in three different regions of Portugal – the district (distritos) of Faro, Lisboa and Setúbal.

When is the study starting and how long is it expected to run for?
July 2017 to October 2019.

Who is funding the study?
Portuguese National Association of Pharmacies (ANF)

Who is the main contact?
Ms Sónia Romano
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
INspira/01

Study information

Scientific Title
Cluster randomized controlled trial of the effectiveness and the cost-effectiveness of a pharmacist-led educational inhaler technique intervention on asthma and chronic obstructive pulmonary disease (COPD) patients (INspira)

Acronym
INspira

Study objectives
Educational interventions delivered by community pharmacists on inhaler technique, medication adherence, disease control, health-related quality of live (HrQol), health care resource utilization, can help improve HrQol and overall outcomes in patients with COPD and asthma.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/12/2018, Ethics Committee Institute of Bioethics of Universidade Católica Portuguesa (Instituto de Bioética, Universidade Católica Portuguesa, Porto, Rua de Diogo Botelho, 1327, 4169-005 Porto, Portugal; Tel: +351 (0)226196216;
Email: jaraujo@porto.ucp.pt), Ethical Screening Report 12/2018

Study design
Cluster randomized controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Asthma and chronic obstructive pulmonary disease

Interventions
Pharmacies will be randomly allocated to either deliver an improved form of care on asthma and COPD management (group 1), or to provide the usual care they normally offer (group 2).

The intervention will consist of a complex pharmacist-led educational program to improve inhalation technique. The pharmacist will give the participant written information - iSauda leaflet and training about inhalation technique at baseline, 1, 3 and 6-month follow-up visits. Additional information and counseling about disease management, adherence reinforcement, healthy lifestyles, smoking cessation and vaccine promotion will also be part of the pharmacist intervention. Data will be collected at baseline and all follow-up visits.

Group 2 pharmacies will provide the usual care and collect data from patients at baseline, 3 and 6-months follow-up visits.

Patient data from both groups will be compared. Each patient will be followed for a period of 6 months.

Intervention Type
Behavioural

Primary outcome(s)

Proportion of asthma, COPD and all patients (irrespective of their diagnosis asthma or COPD) who achieve 100% in the assessment of inhaler technique score at 6 months

Key secondary outcome(s))
Assessed at baseline and 6 months:
1. Difference between baseline and 6-month follow-up inhaler technique score
2. COPD disease-specific HRQoL measured by COPD Assessment Test™ (CAT)
3. Disease control status measured by the Asthma Control Test™ (ACT) for Asthma patients and the Modified Medical Research Council Dyspnea Questionnaire (mMRC) for COPD patients
4. Number of Adverse Drug Events (ADEs) collected by patient questionnaire
5. Number of disease exacerbations collected by patient questionnaire
6. Health care resource utilization and costs collected by patient questionnaire

Additional analysis will be conducted to explore and potentially identify factors affecting the control of the diseases.

Completion date
25/10/2019

Eligibility

Key inclusion criteria
1. Aged ≥ 18 years old at trial enrolment
2. Self-reported asthma or COPD diagnosis
3. Chronic or first user of any of the following inhaler devices : Breezhaler; Ellipta; Spiromax; Turbohaler; pMDI; Respimat

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
201

Key exclusion criteria
1. Pregnant women
2. Individuals with any cognitive impairment

3. Motor limitations that jeopardize the performance of the technique or any other condition that not allow them to understand the study objectives or the completion of the questionnaires
4. Patients who do not give their informed consent

Date of first enrolment
25/01/2019

Date of final enrolment
20/04/2019

Locations

Countries of recruitment
Portugal

Study participating centre
Centre for Health Evaluation & Research (CEFAR) of Associação Nacional das Farmácias (ANF)
Rua Marechal Saldanha 1
Lisboa
Portugal
1249-069

Sponsor information

Organisation
Fundação Portuguesa do Pulmão (FPP, Portuguese Lung Foundation)

Organisation
Associação Nacional das Farmácias (ANF, Portuguese National Association of Pharmacies)

Funder(s)

Funder type
Other

Funder Name
Associação Nacional das Farmácias (ANF, Portuguese National Association of Pharmacies)

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Centre for Health Evaluation & Research (CEFAR), Rua Marechal Saldanha 1, 1249-069 Lisboa, Portugal, cefar@anf.pt
Type of data: All of the individual participant data collected during the trial, after deidentification.
When will data be available (start and end dates): Beginning 9 months and ending 5 years following article publication
With whom: Researchers who provide a methodologically sound proposal
For what types of analyses: To achieve aims in the approved proposal and meta-analysis
By what mechanism will data be made available: Proposals should be directed to cefar@anf.pt. To gain access, data requestors will need to sign a data access agreement.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/08/2021	17/06/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes