

Study of inhaler use in asthma and COPD

Submission date 18/04/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/05/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/06/2021	Condition category Respiratory	<input type="checkbox"/> 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

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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 life (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

Secondary study design

Cluster randomised trial

Study setting(s)

Community

Study type(s)

Other

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

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 measure

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

Secondary outcome measures

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.

Overall study start date

10/07/2017

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

An Intra-Cluster Correlation Coefficient (ICC) of 0.3 was assumed. Each pharmacy is expected to recruit three patients of each condition. This yields a design effect of 1.6, a total of 222 subjects for each condition, 444 for both conditions and a total number of 74 pharmacies to be recruited (37 per group, recruiting 3 COPD + 3 asthma patients each).

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)

Sponsor details

Rua Brito Capelo nº 807
Matosinhos
Portugal
4450-068
+351 (0)229 370 969
geral@fundacaoportuguesadopulmao.org

Sponsor type

Other

Website

<https://www.fundacaoportuguesadopulmao.org/>

Organisation

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

Sponsor details

Rua Marechal Saldanha 1
Lisboa
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1249-069
+351 (0)213400600
anf@anf.pt

Sponsor type

Other

Website

<http://www.anf.pt>

Funder(s)

Funder type

Other

Funder Name

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

Results and Publications

Publication and dissemination plan

The Study Protocol and Statistical Analysis Plan will not be published. The research team will prepare and submit two to three manuscripts to high-level international peer-reviewed journals

during 2020–2021, with a preference for leading open-access journals. The preliminary results will be reported at international congress in 2019. Moreover, the project will communicate the final results via several national and international congress during 2020.

Intention to publish date

30/04/2021

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