

# Study of inhaler use in asthma and COPD

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

Ms Sónia Romano

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## Additional identifiers

### 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 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

### **Primary study design**

Interventional

### **Study design**

Cluster randomized controlled trial

### **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  $\geq 18$  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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> |         | 01/08/2021   | 17/06/2021 | Yes            | No              |