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Educational intervention about inhalation techniques in health-care professionals.

Submission date
08/07/2014

Recruitment status
No longer recruiting

Registration date
18/08/2014

Overall study status
Completed

Last Edited
02/11/2023

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
Many patients with asthma or chronic obstructive pulmonary disease (COPD) do not use their inhalers correctly. This is of significant concern as it can lead to poorer control of symptoms and worsening of the condition. Health care professionals also often dont know the correct technique and are therefore unable to teach their patients how to use their inhalers properly. The aim of this study is to see whether showing health care professionals the correct way to use an inhaler (via an educational intervention) results in their patients doing the same.

Who can participate?
Health care professionals from one of the Basic Health Care Units (BHU) taking part in the trial and with at least 30 COPD patients being treated with inhalers.

What does the study involve?
Each health care professional is randomly allocated into one of two groups. Those in group 1 (experimental group) are shown to use an inhaler by a researcher using a training protocol. They then teach their patients the technique they have been taught. Those in group 2 (the control group) are not shown how to use an inhaler by a researcher but instead treat their COPD patients as usual. The inhalation technique of each patient in both groups is then tested. The health care professionals are tested on their knowledge about COPD patients and their treatment, age, sex and their education.

What are the possible benefits and risks of participating?
We are testing an educational and non-invasive intervention that does not pose a risk to the participants. The patients in the experimental group may benefit from learning to use their inhaler properly.

Where is the study run from?
The study is run from a total of 20 BHUs at 8 primary care centres in Málaga (Spain)

When is the study starting and how long is it expected to run for?
January 2014 to December 2016

Who is funding the study?
Ministry of Health and Social Welfare of the Government of Andalusia [Consejeria de Salud, Junta de Andalucia] (Spain)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
PI-0170/13

Study information

Scientific Title
A pragmatic cluster randomized controlled trial: PROF-EPOC Study. Efficacy of an educational intervention about inhalation techniques in health-care professionals.

Acronym
PROF-EPOC

Study objectives
The application of an educational intervention on health-care professionals in Primary Attention will increase in at least 25% the performance of a correct inhalation technique in COPD patients in regards of a control cohort.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committees of Málaga (CEI provincial de Málaga), 12/12/2013.

Primary study design
Interventional

Study design
Pragmatic cluster randomized controlled trial.

Study type(s)
Treatment

Health condition(s) or problem(s) studied
COPD

Interventions
The cluster design (intervention) is based on two levels:
1. The higher or second level is represented by the BHU which have a health-care professional as the chief of the unit (over whom the educational intervention is conducted)
2. The lower or first level represented by the BHU patients which have accepted to participate and are going to receive the educational intervention from their general practitioner (GP). Each block will be form by 4 BHU among which the 2 study cohorts will be uniformly distributed.

Control group:
Cluster that complies with selection criteria but where the intervention is not applied.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Performance of correct inhalation technique by improving the knowledge of the health-care professionals. The correct inhalation technique will be measured by a researcher following the SEPAR guidelines.

Key secondary outcome(s)
1. Functional status (measured by forced spirometry)
2. Dyspnea index (measured by the basal dyspnea index (BDI))
3. Health-related quality of life (measured by the St. George Respiratory Questionnaire)

Timepoints for all outcome measures:
Study data will be recorded at initial visit and 1 year later, with the exception of the educational intervention for the first level intervention group, where the correct inhalation technique and a reminder of this occurs 3 and 6 months after initial intervention

Completion date
31/12/2016

Eligibility

Key inclusion criteria

1. For health-care professionals: having an allocated BHU during the period of the trial, with at least 30 patients included in the COPD Andalusian Health Service Guidelines (COPD PAI) with inhaled therapy and sign the informed consent
2. For patients: COPD diagnosis, being treated in Primary Care Centres included in the trial, having inhaled therapy prescribed and accepting to participate in the trial with a signed informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
286

Key exclusion criteria
1. For health-care professionals: the negativity of health-care professionals chiefs to participate in the trial or that they have to leave the BHU during the trial.
2. For patients: having another respiratory process not included in the COPD definition and cognitive impairments which prevent them from responding in an adequate way the trials questionnaires and the educational intervention assimilation.

Date of first enrolment
01/01/2014

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
Spain

Study participating centre
Calle del Doctor Fernando Vivar 0
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Sponsor information

Organisation
Ministry of Health and Social Welfare of the Government of Andalusia [Consejeria de Salud, Junta de Andalucia] (Spain)

ROR
https://ror.org/01jem9c82

Funder(s)

Funder type
Government

Funder Name
Ministry of Health and Social Welfare of the Government of Andalusia [Consejeria de Salud, Junta de Andalucia] (Spain)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		17/10/2023	02/11/2023	Yes	No
Protocol article	protocol	17/03/2016		Yes	No