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Educational intervention to improve the treatment adherence in patients with chronic obstructive pulmonary disease (COPD)

Submission date
23/03/2010

Recruitment status
No longer recruiting

Registration date
28/04/2010

Overall study status
Completed

Last Edited
13/02/2015

Condition category
Respiratory

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
EC07/90654

Study information

Scientific Title

Efficacy and safety of a multifactorial intervention to improve treatment adherence in patients with chronic obstructive pulmonary disease (COPD)

Acronym
ICEPOC

Study objectives
A multifactorial educational intervention (information about chronic obstructive pulmonary disease [COPD], doses reminder, development of inhalation technique skills and audiovisual support) in patients with COPD prescribed fixed daily doses of inhaled treatment, with a follow up period of 1 year and two reinforcement visits (3 and 6 month after intervention) increases at least 25% the treatment adherence in the intervention group versus the control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethical Committee of Distrito Sanitario Málaga approved on the 1st March 2007
2. Ethical Committee of Distrito Sanitario Axarquía approved on the 13th May 2008
3. Committee of Clinical Trials of Hospital Cínico Universitario Virgen de la Victoria approved on the 30th November 2007

The study protocol was reviewed by Spanish Medicine Agency and Sanitary products.

Study design
Multicentre randomised controlled clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease (COPD)

Interventions
Subjects will be divided randomly into two groups, using the block randomisation technique: a control group and an intervention group. All patients will attend the same number of appointments. The intervention group will have an educational intervention.

The intervention consists in three parts that include the most relevant aspects related to the treatment adherence in patients with COPD:

Part 1: Motivational aspects to improve the adherence -
Why the recommended therapeutic regimen is not accomplished, to emphasize on the motivational aspects that could improve the treatment adherence in the next follow up visits. This intervention session will be recorded with a patient formal consent for later analysis.

Part 2: Cognitive aspects related with treatment adherence -
The intervention group received information about the disease so they can be more confident and more conscious about the importance of the daily treatment intake.

Part 3: Skills developing -
Inhaled technique training. The intervention group was trained about how they use their inhalers, why a good technique is important and practice the proper technique with placebo inhalers.

Groups will be formed from 6 to 9 patients, a proper number according to the bibliography for this type of intervention. The session time lasts about 2 hours including the patient's reception, the material distribution, the mentioned contents and the farewell. All interventions will be conducted by two professionals specially trained in motivational techniques and in the use of inhaler devices. Audiovisual and written material will be used in parts 2 and 3 of the intenvention (leaflet with the most relevant disease aspects and scheme about inhalation technique).

The educational intervention has a duration of 1 - 2 hours, depending on the group of patients. The follow-up period is one year with 3 appointments to emphasize on the motivational aspects that could improve treatment adherence. The duration of these appointments depends on the patients adherence and skills. The measurement of duration of visits will be a result of our study.

In the control arm the participants have the same follow-up period and visits without the intervention.

Visit scheme:

Intervention group:
Visit 0 (inclusion): all the study data (primary, secondary and independent variables) will be recorded and the treatment adherence will be measured
pVisit 1 pre-adherence: It will take place one month before visit 1 in order to measure its compliance
Visit 1: It will take place 3 months after the intervention. Primary outcome will be measured and encouraging work about inhalers techniques and motivational aspects related to adherence will be individually applied.
pVisit 2 pre-adherence: It will take place 1 month before visit 2 in order to measure its adherence
Visit 2: It will take place 6 months after the intervention. Primary outcome will be measured and encouraging work about inhalers techniques and motivational aspects related to adherence will be individually applied.
pVisit 3 pre-adherence: It will take place 1 month before visit 3 in order to measure its adherence
Visit 3: It will take place after 1 year follow up. It will involve a whole visit in which all the study data will be measured.

Control group:
Visit 0 (inclusion): all the study data (primary, secondary and independent variables) will be recorded and the treatment adherence will be measured
pVisit 1 pre-adherence: It will take place one month before visit 1 in order to measure its compliance
Visit 1: It will take place 3 months after the intervention. Primary outcome will be measured.
pVisit 2 pre-adherence: It will take place 1 month before visit 2 in order to measure its adherence
Visit 2: It will take place 6 months after the intervention. Primary outcome will be measured.

pVisit 3 pre-adherence: It will take place 1 month before visit 3 in order to measure its adherence
Visit 3: It will take place after 1 year follow up. It will involve a whole visit in which all the study data will be measured.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Treatment adherence evaluated using dose or pill recount, measured at the three visits of the trial.

Key secondary outcome(s))
Measured at start and end of study:
1. Functional status (spirometry)
2. Quality of life, measured using the Spanish version of the St Georges Respiratory Questionnaire and the specifically developed SeguiEPOC Questionnaire

Completion date
30/09/2010

Eligibility

Key inclusion criteria
1. Confirmed COPD diagnose by spirometry (Spanish Society of Pulmonology and Thoracic Surgery [SEPAR] guidelines)
2. Belong to the selected Primary Care Centres in Malaga area
3. Prescription of fixed daily doses of inhaled treatment
4. Accepted to participate in the study and gives informed consent
5. Aged greater than or equal to 18 years, either sex

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria

1. Diagnosis of other respiratory conditions which are not included in the COPD definition
2. Cognitive impairment problems

Date of first enrolment
01/09/2008

Date of final enrolment
30/09/2010

Locations

Countries of recruitment
Spain

Study participating centre
Unidad Docente Medicina Familiar y Comunitaria
Málaga
Spain
29009

Sponsor information

Organisation
Carlos III Institute of Health (Instituto de Salud Carlos III) (Spain)

ROR
https://ror.org/00ca2c886

Funder(s)

Funder type
Government

Funder Name
Carlos III Institute of Health (Instituto de Salud Carlos III) (Spain) - Health Research Fund, Ministry of Science and Innovation (MICINN)

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	results	25/04/2014		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes