

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/04/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 13/02/2015	Condition category Respiratory	<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 Clínico 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

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 intervention (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 measure

Treatment adherence evaluated using dose or pill recount, measured at the three visits of the trial.

Secondary outcome measures

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

Overall study start date

01/09/2008

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

140

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)

Sponsor details

Health Research Fund

Ministry of Science and Innovation

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Sponsor type

Government

Website

<http://www.isciii.es/htdocs/index.jsp>

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**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