

Validation study of the Chronic Respiratory disease self-administered standardized Questionnaire and the feeling thermometer in Spanish language

Submission date 28/11/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/04/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 11/01/2021	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

N/A

Study information

Scientific Title

Validation study of the Chronic Respiratory disease self-administered standardized Questionnaire and the feeling thermometer in Spanish language

Acronym

CRQ

Study objectives

The aim of this project is to study in-patients with chronic respiratory disease undergoing pulmonary rehabilitation:

1. The validity and responsiveness of two different administration modes of the feeling thermometer (FT) as a measure of health-related quality of life (HRQL) in Spanish language
2. The validity and responsiveness of the chronic respiratory disease (CRQ) self-administered, standardized version in Spanish language

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval not yet received as of 19/04/06

Study design

Prospective, randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

Chronic obstructive pulmonary disease (COPD)

Interventions

The methods centre will construct a central randomisation schedule. Patients will be stratified and randomised in blocks. Patients will be randomised to one of two conditions:

1. Self-administered FT, in the form of a visual analogue scale, preceded by ratings of three patient scenarios

2. Self-administered FT, in the form of a visual analogue scale, without prior ratings of three patient scenarios

In a 2x2 factorial design, patients will also randomised to receive:

1. Self administered CRQ standardised version

2. Original version of CRQ (with interviewer) and dyspnoea domain on standardised version

Both groups will receive the SF-36 Spanish version.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Validation of the Spanish version of CRQ

Secondary outcome measures

1. Improved quality of life after a complete program of rehabilitation

2. Improve the results in CRQ after rehabilitation

Overall study start date

01/10/2004

Completion date

01/10/2006

Eligibility

Key inclusion criteria

1. Patients with chronic obstructive pulmonary disease (COPD)

2. At least three months of clinical stability since the admission in hospital

3. Age below 75 years

4. Forced expiratory volume (FEV1) or forced expiratory vital capacity (FVC) <70% and FEV1 <70% of the reference value, with any significant changes after the bronchodilator (<15% or 200 ml)

5. Dyspnoea measured by the Medical Research Council (MRC) >2

6. Distance on the six-minute walking test <300 m

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

40 patients

Total final enrolment

40

Key exclusion criteria

1. Having an osteomuscular pathology that limits exercise capacity
2. Having a cardiac disease that limits exercise capacity
3. Having a respiratory disease other than COPD that limits exercise capacity

Date of first enrolment

01/10/2004

Date of final enrolment

01/10/2006

Locations**Countries of recruitment**

Spain

Study participating centre

C/Sant Antoni Maria Claret 167

Barcelona

Spain

08025

Sponsor information**Organisation**

Hospital de la Santa Creu i Sant Pau (Spain)

Sponsor details

Department of Pneumology

C/Sant Antoni Maria Claret 167

Barcelona

Spain

08025

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/059n1d175>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Hospital de la Santa Creu i Sant Pau (Department of Pneumology)

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	01/07/2011	11/01/2021	Yes	No