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

Submission date	Recruitment status	[_] Prospectively registered
28/11/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/04/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/01/2021	Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Guell Rous M Rosa

Contact details
C/Sant Antoni Maria Claret 167
Barcelona
Spain
08025
+34 (0)93 556 57 10
mguellr@santpau.es

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