

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

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

## 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

### Protocol serial number

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

## Study type(s)

Quality of life

## 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(s)

Validation of the Spanish version of CRQ

**Key secondary outcome(s)**

1. Improved quality of life after a complete program of rehabilitation
2. Improve the results in CRQ after rehabilitation

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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)

**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

**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?
<a href="#">Results article</a>	results	01/07/2011	11/01/2021	Yes	No