

# DEVELOPMENT AND VALIDATION OF A SHORTENED VERSION OF THE SPANISH QUALITY OF LIFE QUESTIONNAIRE FOR INFLAMMATORY BOWEL DISEASE

**First published:** 25/10/2010

**Last updated:** 25/10/2010

Study

Finalised

## Administrative details

### EU PAS number

EUPAS1587

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### Study ID

1588

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### DARWIN EU® study

No

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### Study countries

☐ Spain

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## Study description

Questionnaires for measuring quality of life in patients with inflammatory bowel disease usually include a large number of items and are time-consuming for both administration and interpretation. Our aim was to elaborate and validate a short quality-of-life questionnaire with the most representative items from the Spanish version of the 36-item Inflammatory Bowel Disease Questionnaire (IBDQ-36) using the Rasch analysis. The responses to 311 IBDQ-36 questionnaires from 167 patients with ulcerative colitis (UC) and 144 with Crohn's disease (CD) were analyzed. IBDQ-36 was shortened with successive Rasch analyses until all the remaining items showed acceptable separation and goodness-of-fit properties. Validation of the short questionnaire was studied in a new group of 125 patients by determining its validity and reliability. A 9-item short questionnaire was obtained (IBDQ-9). Its correlation with IBDQ-36 was excellent ( $r = 0.91$ ). Correlation between IBDQ-9 and clinical indices of activity was statistically significant in UC ( $r = 0.70$ ) and CD ( $r = 0.70$ ). IBDQ-9 score discriminates adequately between patients in clinical remission or relapse ( $P < 0.01$ ). Sensitivity to change was determined in 14 patients who improved clinically, showing significant IBDQ-9 changes between both determinations ( $P < 0.01$ ), with an effect size of -2.67 in UC and -5.29 in CD. IBDQ-9 was also homogeneous, with a Cronbach's alpha of 0.95 in UC and 0.91 in CD. In 35 clinically stable patients, test-retest reliability was good, with a statistically-significant correlation between both questionnaires ( $r = 0.76$  in UC and 0.86 in CD,  $P < 0.01$ ) and an intraclass correlation coefficient of 0.82 in UC and 0.84 in CD. In conclusion, a short and valid questionnaire to measure quality of life in patients with inflammatory bowel disease was obtained using a new measurement model. Its use should facilitate comprehension of the impact of inflammatory bowel disease.

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## Study status

Finalised

## Research institutions and networks

## Institutions

### University Hospital Vall d'Hebron (HUVH)

☐ Spain

**First published:** 01/02/2024

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**Institution**

**Educational Institution**

**Hospital/Clinic/Other health care facility**

## Contact details

### Study institution contact

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**Study contact**

[luis.prieto@ema.europa.eu](mailto:luis.prieto@ema.europa.eu)

### Primary lead investigator

Luis Prieto

**Primary lead investigator**

## Study timelines

### Date when funding contract was signed

Actual: 01/10/2002

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### Study start date

Actual: 02/12/2002

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### **Date of final study report**

Actual: 11/11/2003

## Sources of funding

- Other

## More details on funding

Ministry of Science & Technology, Vall d'Hebron Hospital

## Study protocol

[Tesis Maria Jose Alcala.pdf](#)(398.19 KB)

## Regulatory

### **Was the study required by a regulatory body?**

No

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Other

**If 'other', further details on the scope of the study**

Development of a questionnaire for health related quality of life assessment

**Data collection methods:**

Combined primary data collection and secondary use of data

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**Main study objective:**

To elaborate and validate a short quality-of-life questionnaire with the most representative items from the Spanish version of the 36-item Inflammatory Bowel Disease Questionnaire (IBDQ-36) using the Rasch analysis

## Study Design

**Non-interventional study design**

Cross-sectional

## Study drug and medical condition

**Medical condition to be studied**

Crohn's disease

Inflammatory bowel disease

## Population studied

## Short description of the study population

Patients with ulcerative colitis and Crohn's disease

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### Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

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### Special population of interest

Other

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### Special population of interest, other

Ulcerative colitis and Crohn's disease patients

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### Estimated number of subjects

311

## Study design details

### Data analysis plan

The responses to 311 IBDQ-36 questionnaires from 167 patients with ulcerative colitis (UC) and 144 with Crohn's disease (CD) were analyzed. IBDQ-36 was shortened with successive Rasch analyses until all the remaining items showed acceptable separation and goodness-of-fit properties. Validation of the short questionnaire was studied in a new group of 125 patients by determining its validity and reliability.

## Documents

### Study publications

Alcalá MJ, Casellas F, Fontanet G, Prieto L, Malagelada JR. Shortened  
questionn...

Casellas F, Alcalá MJ, Prieto L, Miró JR, Malagelada JR. Assessment of the infl...

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## Data management

### Data sources

#### Data sources (types)

[Disease registry](#)

### Use of a Common Data Model (CDM)

#### CDM mapping

No

### Data quality specifications

#### Check conformance

Unknown

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#### Check completeness

Unknown

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#### Check stability

Unknown

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## **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No