

# 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

---

### Study ID

1588

---

### DARWIN EU® study

No

---

### Study countries

Spain

---

### 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.

---

## **Study status**

Finalised

## **Research institutions and networks**

## Institutions

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

Spain

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

**Last updated:** 01/02/2024

**Institution**

Educational Institution

Hospital/Clinic/Other health care facility

## Contact details

### Study institution contact

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

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

---

### Study start date

Actual: 02/12/2002

---

### **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

---

**Study type:**

Non-interventional study

---

**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

---

**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

---

### **Age groups**

- Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
- 

### **Special population of interest**

Other

---

### **Special population of interest, other**

Ulcerative colitis and Crohn's disease patients

---

### **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...

---

## Data management

### ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

### Data sources (types)

[Disease registry](#)

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

### Check conformance

Unknown

---

**Check completeness**

Unknown

---

**Check stability**

Unknown

---

**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No