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### Paper:

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Journal of Crohn's and Colitis

**Systematic review of disease specific HRQoL measures in  
inflammatory bowel disease**

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Classifications:	Quality of Life, socio-economical and psychological end points, Clinical trials

SCHOLARONE™  
Manuscripts



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3 26 **ABSTRACT:**  
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5 27 **Background and aim:** Several measures have been developed to assess the  
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7 28 health related quality of life (HRQoL) of patients with inflammatory bowel  
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9 29 disease (IBD). Our aim is to systematically review the HRQoL measures  
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11 30 specific for patients with IBD and to appraise their measurement properties  
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14 31 and methodological quality.  
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17 32 **Methods:** We searched the PubMed, Embase and PsycINFO databases for  
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19 33 original articles describing the development and/or evaluation of one or more  
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21 34 of the measurement properties (e.g., internal consistency, reliability, validity,  
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23 35 responsiveness) of HRQoL measures specific for IBD. We assessed the  
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25 36 measurement properties and examined the methodological quality of the  
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27 37 measurement properties of each instrument using a standardized checklist.  
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30  
31 38 **Results:** We examined the full text of 75 articles that we deemed potentially  
32  
33 39 eligible and identified 10 disease specific HRQoL measures in IBD that  
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35 40 covered different aspects of patients' lives. Internal consistency, construct  
36  
37 41 validity and content validity were the commonly evaluated measurement  
38  
39 42 properties. Seven HRQoL measures scored positive for at least four of eight  
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41 43 measurement properties. The majority of studies were rated as "fair" to "poor"  
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43 44 when assessing their methodology quality. The most established HRQoL in  
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45 45 the literature was the Inflammatory Bowel Disease Questionnaire (IBDQ).  
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48  
49 46 **Conclusions:** Most of the included HRQoL measures did not include all the  
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51 47 required measurement properties or had a problem with their methodological  
52  
53 48 quality. The most widely used and validated measure was the IBDQ. Further  
54  
55 49 validation studies are required to support the use of other HRQoL measures.  
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## 50 INTRODUCTION

51 Inflammatory bowel disease (IBD) is known to impair quality of life (1-4) and  
52 cause a substantial burden to patients, their families and the society (4-7). It  
53 affects patients' lives mentally, emotionally, socially and physically (7, 8).

54 Health related Quality of life (HRQoL) is a multidimensional concept that  
55 measures physical, emotional, mental and social impact of the disease on  
56 patients lives (9). Measuring HRQoL provides an important insight into  
57 patients' perception of their health and the effect of treatments. Instruments  
58 used to measure HRQOL may be generic or disease-specific. Disease-  
59 specific instruments assess domains specific to a given disease and are  
60 therefore considered more sensitive to changes in the patient's health state  
61 (10). Generic instruments, by contrast, are aimed at measuring the overall  
62 HRQoL of patients and therefore, are useful to compare HRQoL across  
63 different disease states as well as for the evaluation of health economics  
64 outcomes (11, 12).

65 In the last two decades measurement of health related quality of life (HRQoL)  
66 has been increasingly used in inflammatory bowel disease (IBD) to support  
67 both research and clinical care (1, 13-19). This has led to a better evaluation  
68 of the patients' health and subsequently to improvements in their quality of  
69 care (15, 16). In scientific research, these measures are important to evaluate  
70 the effectiveness of new therapies in clinical trials. An up-to-date systematic  
71 review will provide a useful resource for research professionals and IBD  
72 specialists to ensure they can select an appropriate HRQoL measure for  
73 patients in their practice.

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3 74 The aim of this article is to systematically review the current health related  
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5 75 quality of life (HRQoL) measures specific for patients with IBD and to appraise  
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7 76 their measurement properties using a robust evaluation methodology  
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9 77 checklist.  
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Accepted Manuscript

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3 99 **METHODS**

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5 100 Search strategy

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7 101 This systematic review was undertaken in line with search strategies checklist  
8  
9 102 of the Cochrane review group (20) and followed the PRISMA (Preferred  
10  
11 103 Reporting Items for Systematic Reviews and Meta Analysis) statement (21)  
12  
13 104 (Appendix 1).

14  
15 105 We searched the following electronic databases via Ovid SP up to 1<sup>st</sup> of  
16  
17 106 October 2013: MEDLINE, EMBASE, and PsychoINFO. Key search terms and  
18  
19 107 add synonyms were searched separately in three main filters that were  
20  
21 108 merged together. Targeted hand searches using the names of measures  
22  
23 109 identified in the initial searches were carried out. The detailed search strategy  
24  
25 110 can be found in Appendix 2.

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28  
29 111 1. Target population: Inflammatory bowel disease, Crohn's disease,  
30  
31 112 ulcerative colitis, terminal ileitis, regional ileitis, granulomatous enteritis,  
32  
33 113 proctitis, proctocolitis, and colitis.

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35  
36 114 2. Construct: quality of life, health related outcome measure, patient-  
37  
38 115 reported outcome measure, disability, health status, health related  
39  
40 116 quality of life, health status measures, patient outcome assessment,  
41  
42 117 and questionnaire.

43  
44  
45 118 3. Psychometric properties of HRQoL measures: psychometrics,  
46  
47 119 reproducibility, reliability, validation studies, validation, face validity,  
48  
49 120 content validity, construct validity, concurrent validity, convergent  
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51 121 validity, and discriminant validity.

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56 123 Selection criteria  
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3 124 We included all original articles in English describing the development and/or  
4  
5 125 evaluation of one or more of the measurement properties (e.g., internal  
6  
7 126 consistency, reliability, validity, responsiveness) of the HRQoL measures  
8  
9  
10 127 specific for patients with IBD. Articles were included if they sought to assess  
11  
12 128 at least one domain of quality of life in IBD.

13  
14 129 Two reviewers (LA and IR) independently screened titles, abstracts and the  
15  
16 130 references of these articles to obtain any additional articles of relevance. Full  
17  
18 131 texts of eligible articles were obtained. If any disagreement existed regarding  
19  
20 132 the inclusion or exclusion of articles, a third independent reviewer was  
21  
22 133 consulted.

23  
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25 134

#### 26 27 135 Data Extraction

28  
29 136 Data from eligible articles were extracted independently using a pre-prepared  
30  
31 137 data extraction proforma. The following data were extracted:

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33  
34 138 1. Different disease specific HRQoL measures. For each questionnaire  
35  
36 139 we identified the dimensions of HRQoL that were assessed (e.g. social,  
37  
38 140 work, disease burden ...etc.).
- 39  
40  
41 141 2. Measurement properties: we assessed the measurement properties of  
42  
43 142 each HRQoL measure using the quality properties checklist proposed  
44  
45 143 by Terwee et al (22) (Table 1) which were: (1) reliability (including  
46  
47 144 internal consistency, reliability, and measurement error), (2) validity  
48  
49 145 (including content validity, structural validity and hypothesis testing  
50  
51 146 (construct validity)), and (3) responsiveness.
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53  
54 147 3. Methodology quality assessment: we reported on the methodological  
55  
56 148 quality of the original development studies for the included HRQoL  
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3 149 measures using the COSMIN (COnsensus-based Standards for the  
4 selection of health Measurement Instruments) checklist (23, 24). The  
5 150  
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7 151 COSMIN checklist assesses the methodology quality of the internal  
8 consistency, reliability, measurement error, responsiveness, content  
9 152  
10 consistency, reliability, measurement error, responsiveness, content  
11 153 validity, construct validity, and factor analysis (structural validity). Each  
12 measurement property methodology was assessed against certain  
13 154  
14 quality standards and rated on a 4-point scale (1=poor, 2=fair, 3=good  
15 155  
16 or 4=excellent). The overall score for the methodological quality of a  
17 156  
18 certain property is determined by taking the lowest rating. Depending  
19 157  
20 on the number of measurement properties assessed in a study, some  
21 158  
22 studies received one quality evaluation whereas other studies received  
23 159  
24 several. The measurement property of a study was rated as having  
25 160  
26 'excellent' quality if all relevant COSMIN items were scored adequate.  
27 161

31 162 4. Levels of the HRQoL measure establishment or use in literature: we  
32 used Cohen's criteria (25) (table 2) to determine the level of  
33 163  
34 establishment of each specific HRQoL measure. The Cohen criteria  
35 164  
36 classify the measures into three levels of establishment depending on  
37 165  
38 the number of publications, the extent to which the measures are  
39 166  
40 described in literature and their psychometric properties.  
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3 174 **RESULTS**

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5 175 Results of the database search and included studies:

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7 176 The database search resulted in 437 articles (Figure 1). References were  
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9 177 uploaded into EndNote and duplicates were removed leaving 389 articles.  
10  
11 178 After screening the titles and abstracts, 196 articles were excluded because  
12  
13 179 they did not include validation of the HRQoL and 10 articles were excluded  
14  
15 180 because they were published as abstracts in conferences and not as full  
16  
17 181 papers. The full texts of 183 articles were obtained and reviewed. We  
18  
19 182 excluded 108 articles that did not include the validation or evaluation of the  
20  
21 183 psychometric properties of the HRQoL measures. Seventy-five articles were  
22  
23 184 deemed eligible. After linking multiple reports of the same HRQoL measure,  
24  
25 185 we identified 10 disease specific HRQoL measures in IBD (Table 3):  
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- 30 186 1. Inflammatory bowel disease questionnaire (IBDQ) (26, 27)  
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32 187 2. Shortened inflammatory bowel disease questionnaire (SIBDQ) (28)  
33  
34 188 3. IBDQ was further shortened to 9 items, the IBDQ-9 (29).  
35  
36 189 4. Rating form of IBD patient concerns (RFIPC): (30).  
37  
38 190 5. Edinburgh IBD quality of life questionnaire (EIBDQ): (31).  
39  
40 191 6. The IBD disability score: (32),  
41  
42 192 7. The IBD disability index: (33)  
43  
44 193 8. Social Impact of Chronic Conditions–Inflammatory Bowel Disease  
45  
46 194 (SICC-IBD) questionnaire (34).  
47  
48 195 9. Crohn's disease perceived work disability questionnaire (CPWDQ) (35)  
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50 196 10. Crohn's disease burden questionnaire: (36).  
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3 199 Assessing the psychometric properties of the HRQoL measures:  
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5 200 A narrative summary of the included measures and their properties  
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7 201 assessment is described in table 4. The IBDQ was the most widely used  
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9 202 HRQoL in IBD. Although the original papers (26, 27) did not report all the  
10  
11 203 psychometric properties, subsequent studies validated the IBDQ into different  
12  
13 204 languages and have further proved its validity, internal consistency and  
14  
15 205 reliability (37-51). The 32-item IBDQ questionnaire was shortened to 10 items  
16  
17 206 (short IBDQ) (28) and 9 items (IBDQ-9) (29). When evaluating the  
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19 207 measurement properties for the rest of the HRQoL measures using the  
20  
21 208 Terwee's criteria, none has met all the criteria. Flooring and ceiling effects  
22  
23 209 were not clearly reported when validating most of the HRQoL measures.  
24  
25 210 When appraising the internal consistency of each measure, 8 measures  
26  
27 211 achieved the recommended Cronbach's value of 0.7 -0.9 (22) (Table 1). Two  
28  
29 212 measures did not have their internal consistency assessment reported in the  
30  
31 213 literature. Ratings of the content validity were good for most of the measures  
32  
33 214 as they used appropriate methods in generating items that covered various  
34  
35 215 quality of life aspects of IBD (e.g. focus group, patient involvement, item  
36  
37 216 generation and selection, measure reduction etc.). CD burden measure did  
38  
39 217 not use an appropriate method to generate the items. Construct validity was  
40  
41 218 appropriately assessed in almost all measures except IBD disability index,  
42  
43 219 which was not fully validated. The HRQoL measures were compared with  
44  
45 220 other measures of disease severity or quality of life. Six HRQoL measures  
46  
47 221 correctly assessed the test-retest reliability and achieved the required values  
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49 222 of the intraclass correlation coefficient, Kappa coefficients or confidence  
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51 223 intervals. Most of the measures did not assess the inter-rater reliability as part  
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3 224 of the reliability testing. Three HRQoL measures had their responsiveness  
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5 225 assessed in the original study report using the required statistics such as  
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7 226 responsiveness ratio or paired t-tests. Seven measures did not have their  
8  
9 227 responsiveness reported in literature. Measurement error evaluation and  
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11 228 factor analysis was not assessed for most of the HRQoL measures.  
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16 230 Assessing the methodology qualities of the HRQoL measures  
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18 231 None of the HRQoL measures development studies showed adequate  
19  
20 232 methodological quality in all COSMIN sections. Most of the publications  
21  
22 233 scored excellent for content validity having captured the domains that are  
23  
24 234 relevant to IBD patients through consultation with patients, and/or or literature  
25  
26 235 review or other methods as described by Steiner and Norman (52). Although  
27  
28 236 all HRQoL measures assessed the construct validity using other measures of  
29  
30 237 HRQoL or disease activity, more than half of the measures scored “fair” either  
31  
32 238 because they did not provide information on the missing items, a hypotheses  
33  
34 239 regarding the direction and magnitude of correlations, sample size or  
35  
36 240 achieved the required statistics. Most HRQoL measures were assessed for  
37  
38 241 reliability, internal consistency and responsiveness. However, for most of  
39  
40 242 them, this was not described in enough details to meet the COSMIN criteria.  
41  
42 243 Most of the publications did not report how missing items were handled and  
43  
44 244 how repeated measurements were conducted (mode of administration,  
45  
46 245 sample size, statistical analyses and time interval for test-retest). Most of the  
47  
48 246 studies did not include the assessment of measurement error or factor  
49  
50 247 analysis in the measure development and were rated “poor” for these criteria.  
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52 248 Table 5 shows the COMSIN ratings for the IBD specific HRQoL measures.  
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3 249 Assessing the level of credibility of the HRQoL measures:  
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5 250 We used Cohen's criteria (25) to appraise the degree establishment of the  
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7 251 different HRQoL measures in IBD. According to Cohen's criteria, only the  
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9 252 IBDQ and SIBDQ were considered to be well-established measures, while the  
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11 253 RFIC is approaching the level of well-established assessments. The rest were  
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13 254 rated as promising assessments (Table 6).  
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3 274 **Discussion:**  
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5 275 Assessing the HRQoL in patients with IBD is an important outcome measure  
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7 276 in assessing the efficacy of new treatments or intervention. Typically, HRQoL  
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9 277 measures have been developed and used to describe mean scores (or mean  
10  
11 278 response) for a group of patients (e.g. those in each arm of a trial). The last  
12  
13 279 decade has seen a rapid increase in the number of measures to assess the  
14  
15 280 HRQoL in patients with IBD (32-36, 53-57).  
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18 281 In this systematic review we identified 10 different HRQoL specific measures  
19  
20 282 used for patients with IBD. We assessed the internal consistency, reliability,  
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22 283 measurement error, content validity, factor analysis, construct validity,  
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24 284 responsiveness, ceiling and flooring effects depending on the information  
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26 285 obtained from the literature. Some of the HRQoL measures had some aspects  
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28 286 of psychometric strength especially construct validity. However, they varied  
29  
30 287 greatly in terms of their characteristics and most of them did not fulfill all the  
31  
32 288 required properties proposed by Terwee et al (22). Notably, the IBDQ(26, 27),  
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34 289 which is the most commonly used HRQoL measure in the literature, was not  
35  
36 290 fully validated in the original study. However it was further validated in  
37  
38 291 subsequent studies that used it or translated it to other languages. The IBDQ  
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40 292 has the advantage of having shorter versions (SIBDQ(28) and IBDQ-9(29))  
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42 293 and has been translated into different languages, which facilitate its use  
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44 294 worldwide.  
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49 295 We used the COSMIN checklist (23, 24) to appraise the methodological  
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51 296 quality of the original HRQoL measures development studies. This included  
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53 297 evaluation of the methodological quality of different properties such as the  
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55 298 reliability, internal consistency, content validity, structural validity (factor  
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3 299 analysis), responsiveness, measurement error and construct validity. Using  
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5 300 the COSMIN criteria of the methodology quality, the majority of studies were  
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7 301 rated as “fair” to “poor” either because they did not reach the required  
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10 302 standards or because of insufficient information. These studies are not  
11  
12 303 necessarily of poor quality, but our results suggest that high quality studies  
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14 304 are required to properly evaluate their measurement properties.

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17 305 We also assessed the level of establishment of the HRQoL measures using  
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19 306 the Crohn's criteria (25). We found that the IBDQ and SIBDQ were considered  
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21 307 to be well-established measures, and the RFIC is approaching the level of  
22  
23 308 well establishment. The rest were rated as promising assessments.

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27 309 We used a robust quality criteria (22) to systematically evaluate the  
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29 310 psychometric properties of the identified HRQoL measures . We also used  
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31 311 COSMIN checklist (23) to assess the methodological quality of the properties  
32  
33 312 of the HRQoL measures in IBD. These criteria are increasingly used in  
34  
35 313 systematic reviews of outcome measures (58-63). The content validity,  
36  
37 314 reliability, and validity of the COSMIN standards checklist were showed to be  
38  
39 315 valid and reliable (64). However, a limitation of the COSMIN checklist and the  
40  
41 316 quality properties of outcome measures (22-24) is that they were recently  
42  
43 317 developed and might not be applicable to measures developed before its  
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45 318 introduction. The inconsistency in the measurement properties may be  
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47 319 explained by the fact that there was no agreement on a definition of the  
48  
49 320 required measurement properties until recently. However, questionnaires still  
50  
51 321 need to meet validity and reliability criteria and be described in a  
52  
53 322 comprehensive manner. Studies included in the systematic review were  
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3 323 judged to be of poor methodological quality when evaluated by the COSMIN  
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5 324 checklist if they were not descriptive enough to reach the COSMIN pre-  
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7 325 defined standards. Especially when it comes to missing items, if not clearly  
8  
9 326 described, then most properties will be rated fair even if they were undertaken  
10  
11 327 properly in the study. Most of the HRQoL have been recently developed and  
12  
13 328 their validation is still ongoing. Hence, future studies are likely to provide  
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15 329 additional evidence to support their validity and reliability.  
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19 330 Although the COSMIN checklist and the quality criteria for the measurement  
20  
21 331 properties were designed to be as objective as possible, reviewers' judgments  
22  
23 332 can be different. Therefore, two reviewers evaluated the included studies and  
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25 333 a third reviewer was consulted in case of disagreement.  
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29 334 We limited our search to English language studies due to the limited  
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31 335 translation facilities available to us. Therefore, we might have missed HRQoL  
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33 336 measures that were developed in other languages. However, our extensive  
34  
35 337 and systematic search included studies that were carried out in non-English  
36  
37 338 speaking countries but written in English. We did not find any mention of non  
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39 339 English HRQoL measure specifically developed for IBD.  
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43 340 Previous reviews of HRQoL measures in patients with IBD have limited their  
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45 341 search to only a single concept of multi-dimensional HRQoL and included a  
46  
47 342 limited number of measures (1, 65-68). There is no review in the literature that  
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49 343 has evaluated the methodological quality of the measurement properties of  
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51 344 the included HRQoL measures. One of the strengths of this systematic review  
52  
53 345 is that it did not only focus on the single concept of multi-dimensional HRQoL,  
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55 346 but took into account related concepts such as disease burden, work  
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3 347 productivity, fatigue, and social impact. We performed the literature search in  
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5 348 a systematic way to identify all HRQoL measures used in IBD.  
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7 349 To our knowledge, this is the first systematic review of HRQoL measures in  
8  
9 350 IBD that systematically appraised the measurement properties and the  
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11 351 methodological quality of the HRQoL measures using a robust and  
12  
13 352 standardized approach. This facilitates good comparison between the HRQoL  
14  
15 353 measures on their quality of their measurement properties. This review will  
16  
17 354 better guide the use of HRQoL in various clinical and research settings. It will  
18  
19 355 also help clinicians, researchers and the general public to better assess the  
20  
21 356 scientific literature on HRQoL in IBD. Several new HRQoL measures are  
22  
23 357 emerging and our study showed that most of the HRQoL are supported by  
24  
25 358 evidence of at least one type of reliability or validity and further validation  
26  
27 359 studies might support their use. The choice of HRQoL measure in future will  
28  
29 360 depend on the context for which it will be used (for example. social, disease  
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31 361 burden, disability ...etc). Until then, the IBDQ(26, 27) has the strongest  
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33 362 published evidence of reliability and validity and it is well established in  
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35 363 literature.  
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5 373 **Authors' contributions:** LA was responsible for developing initial drafts of  
6  
7 374 the manuscript, designing the study, obtaining funding, data collection and  
8  
9 375 analysis and final approval of the study. IR contributed to the collection and  
10  
11 376 assembly of data and final approval of the article. PD contributed to data  
12  
13 377 collection and all drafts of the manuscript. HAH and JGW contributed to  
14  
15 378 designing the study, critical revision of all drafts of the manuscript and data  
16  
17 379 analysis.  
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22  
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26  
27 383 University, Wales deanery and the Welsh Government.  
28

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32 385 **Competing interests:** None.  
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35  
36 387 **Figure legends:**

37  
38 388 Figure 1: Flow chart of the systematic search results  
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40  
41 389 **Appendices:**

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43 390 Appendix 1: PRISMA checklist for systematic search  
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45 391 Appendix 2: Electronic databases search strategy  
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398 **TABLES:**399 **Table 1: Quality criteria for rating the results of measurement properties**

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Properties	Ratings	Quality criteria
Reliability		
Internal consistency	+	Cronbach's alpha(s) between 0.70 – 0.90
	?	No information available
	-	Cronbach's alpha(s) <0.70 or >0.90 or not done
Reproducibility (test-retest reliability)	+	ICC or weighted kappa $\geq 0.70$ OR Pearson's $r \geq 0.80$
	?	No information available
	-	ICC/weighted kappa <0.70 OR Pearson's $r < 0.80$
Measurement error	+	Measurement error, smallest detectable change (SDC) are measured. SDC is less than MIC
	?	No information available
	-	The study did not report a convincing evidence that the measurement error was assessed or/and it was more than the MIC
Validity		
Content validity	+	Appropriate assessment of content validity was performed.
	?	No information available
	-	Content validity was not assessed properly
Factor analysis	+	Important factors/domains should explain at least 50% of the variance
	?	No information available
	-	Important factors/ domains explain <50% of the variance

Construct validity hypothesis testing	+	Correlation coefficient for the validity should be in the middle i.e. 0.4 -0.8
	?	No information available
	-	Correlation coefficient for the validity is not between 0.4 -0.8
Responsiveness	+	Responsiveness was assessed using an appropriate method.
	?	No information available
	-	Responsiveness was not assessed using an appropriate method.
Ceiling and floor effects		
	+	≤15% of the respondents achieved the highest or lowest possible scores;
	?	No information available
	-	>15% of the respondents achieved the highest or lowest possible scores, despite adequate design and methods;
Interpretability	+	Mean and SD scores presented of at least four relevant subgroups of patients and MIC defined;
	?	No information available
	-	Mean and SD scores were not presented of at least four relevant subgroups of patients or MIC was not defined
+, Positive rating; ?, no information available or indeterminate rating; -, negative rating		

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406 **Table 2: Cohen criteria for the level of credibility of the outcome**  
 407 **measures (25)**

Category	Criteria
Well-established assessment	I. The measure must have been presented ( <u>validated</u> ) in at least two peer-reviewed articles by different investigators or investigatory teams.
	II. Sufficient detail about the measure to allow critical evaluation and replication (e.g., measure and manual provided or available upon request).
	III. Detailed (e.g., statistics presented) information indicating good validity and reliability in at least one peer-reviewed article.
Approaching well established assessment	I. The measure must have been presented in at least two peer-reviewed articles, which might be by the same investigator or investigatory team.
	II. Sufficient detail about the measure to allow critical evaluation and replication (e.g., measure and manual provided or available upon request).
	III. Validity and reliability information either presented in vague terms (e.g., no statistics presented) or only moderate values presented.
Promising assessment	I. The measure must have been presented in at least one peer-reviewed article.
	II. Sufficient detail about the measure to allow critical evaluation and replication (e.g., measure and manual provided or available upon request).
	III. Validity and reliability information either presented in

	vague terms (e.g., no statistics presented) or moderate values presented.
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**Table 3: Summary of the specific HRQoL measures in IBD**

HRQoL measures	Ref:	Year	Domains covered	Items numbers
IBDQ	(26, 27)	1989	Disease specific HRQoL measure. It includes gastrointestinal symptoms, systemic symptoms, emotional dysfunction and social dysfunction domains.	32
SIBDQ	(28)	1996	A short version of IBDQ. It includes feeling tiredness, social aspects, sport activities, pain, depressed, winds, weight, feeling relaxed, going to toilet even if bowel are empty, and feeling angry	10
IBDQ-9	(29).	2004	A shorter version of IBDQ-36. Includes Nausea, delay social engagement, passing winds, bowel movements, abdominal cramps, unwell, fatigue, feeling happy, energy level	9
RFIPC	(30).	1991	Four components are: a) impact of disease (e.g., being a burden, loss of energy, loss of bowel control); b) sexual intimacy; c) complications of disease (e.g., developing cancer, having surgery, dying early); and d) body stigma (e.g., feeling dirty or smelly)	25
EIBDQ	(31)	2002	Three underlying dimensions: a disease specific factor, a bowel specific factor and an information factor	15
IBD disability score	(32)	2013	Assess the disability of patients with IBD The questionnaire comprised the following domains; demographics, mobility, gastrointestinal-related problems, self-care, major life activities, mental health and interaction with the environment	49

IBD disability index	(33)	2012	Based on the ICF coding system for IBD. General health, body functions, body structures and activities and participation, environmental factors.	28
SICC-IBD	(34)	2012	Assess social dysfunction of IBD patients. It covers education, work, earnings and relationships	8
CPWDQ	(35)	2011	Assess the impact of Crohn's disease on the patients at work. Asks about the impact of weight loss, fistula, surgery, symptoms, stoma, pain, using toilet facilities, medications, feelings, work relationship, work capacity, work stability, incontinence	16
CD burden	(36)	2010	It measures the burden of Crohn's disease (CD) and its treatment on HRQoL	2



**Table 4: The measurement properties of the specific HRQoL measures used in IBD**

	HRQoL measure	Internal consistency	Test-retest reliability	Measurement error	Content validity	Factor analysis	Construct validity	Responsiveness	Ceiling and flooring effect
1.	IBDQ	+	+	+	+	+	+	+	+
2.	SIBDQ	+	+	-	+	-	+	+	-
3.	IBDQ-9	+	+	-	+	-	+	+	-
4.	RFIPC	+	+	-	+	+	-	-	-
5.	EIBDQ	+	-	-	+	+	+	-	-
6.	IBD disability score	+	+	+	+	-	+	-	
7.	IBD disability index	-	-	-	+	-	-	-	-
8.	SICC-IBD	+	-	-	+	-	+	-	-
9.	CPWDQ	+	+	-	+	+	+	-	-
10.	CD burden	-	-	-	-	-	+	-	-

**Table 5: The methodological quality of HRQoL measurement properties as described in the original development articles.**

	HRQoL measures	Ref:	Internal consistency	Reliability	Measurement error	Content validity	Factor analysis	Construct validity	Responsiveness
1.	IBDQ	(26, 27)	Poor/fair	Fair	Poor	Excellent	Poor	Fair	Fair
2.	SIBDQ	(28)	Poor/fair	Fair	Poor	Excellent	Poor	Fair	Poor
3.	IBDQ-9	(29).	Fair	Fair	Poor	Excellent	Poor	Fair	Poor
4.	RFIPC	(30).	Excellent	Good	Poor	Excellent	Excellent	Excellent	Poor
5.	EIBDQ	(31)	Fair	Poor	Poor	Excellent	Fair	Fair	Poor
6.	Allen et al	(32)	Poor	Poor	Fair	Excellent	Poor	Good	Poor
7.	IBD disability index	(33)	?	?	?	Excellent	?	?	?
8.	SICC- IBD	(34)	Poor	Poor	Poor	Excellent	Poor	Good	Poor
9.	CPWD Q	(35)	Fair	Fair	Poor	Excellent	Fair	Fair	Poor
10.	CD burden	(36)	Poor	Poor	Poor	Poor	Poor	Fair	Poor

**Table 6: Assessing the level of establishment of the HRQoL measures**

Category	Outcome measures
Well-established assessment	IBDQ (26) (27) (69) (38, 41, 70, 71), SIBDQ (28, 72-75)
Approaching well-established assessment	RFIC (30, 76-78)
Promising assessment	UK-IBDQ(51), IBDQ-9(29), SICC-IBD(34), CPWDQ(35), Allen et al(32), EIBDQ(31) , CD burden(36), IBD disability index(33)

Accepted Manuscript

**APPENDICES:****Appendix 1: PRISMA checklist for systematic search**

<i>Section/topic</i>	<i>#</i>	<i>Checklist item</i>	<i>Reported on page #</i>
<b>TITLE</b>			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	Title of the section
<b>ABSTRACT</b>			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
<b>INTRODUCTION</b>			
Rationale	3	Describe the rationale for the review in the context of what is already known.	4-5
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	4-5
<b>METHODS</b>			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	N/A
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	7
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	6
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	32
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	7
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	7
Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	6-7
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	N/A
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	Tables 3-6
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of	N/A

		consistency (e.g., $I^2$ ) for each meta-analysis.	
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	N/A
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A
<b>RESULTS</b>			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	Figure 1
Study characteristics	18	For each study, present characteristics for which data were extracted and provide the citations.	Tables 3-6
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome-level assessment (see Item 12).	N/A
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group and (b) effect estimates and confidence intervals, ideally with a forest plot.	N/A
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	N/A
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	N/A
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A
<b>DISCUSSION</b>			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., health care providers, users, and policy makers).	13
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review level (e.g., incomplete retrieval of identified research, reporting bias).	13-15
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	16
<b>FUNDING</b>			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	17

**Appendix 2: Electronic database search strategy**

Database: Ovid EMBASE 1900 - 2013

	Search terms	No. of references
1.	inflammatory bowel disease.mp. or *enteritis/ or exp inflammatory bowel disease/ or exp ulcerative colitis/ or exp Crohn disease/ or exp colitis/	156123
2.	limit 1 to (human and english language and yr="1900 - 2013")	92702
3.	exp ulcerative colitis/ or Colitis Gravis.mp.	50344
4.	limit 3 to (human and english language and yr="1900 - 2013")	31100
5.	Granulomatous Enteritis.mp. or *enteritis/	25798
6.	limit 5 to (human and english language and yr="1900 - 2013")	15054
7.	Regional Enteritis.mp. or exp Crohn disease/	57543
8.	limit 7 to (human and english language and yr="1900 - 2013")	39551
9.	ileitis/ or exp Crohn disease/ or Regional Ileitis.mp.	60090
10.	limit 9 to (human and english language and yr="1900 - 2013")	40854
11.	exp Crohn disease/ or Terminal Ileitis.mp.	57655
12.	limit 11 to (human and english language and yr="1900 - 2013")	39576
13.	exp proctitis/ or exp proctocolitis/ or Idiopathic Proctocolitis.mp.	5336
14.	limit 13 to (human and english language and yr="1900 - 2013")	2972
15.	2 or 4 or 6 or 8 or 10 or 12 or 14	93155
16.	quality of life.mp. or **"quality of life"/	299007
17.	limit 16 to (human and english language and yr="1900 - 2013")	230656
18.	*questionnaire/ or **"quality of life"/ or *outcomes research/ or patient reported outcomes.mp.	82767
19.	limit 18 to (human and english language and yr="1900 - 2013")	63415
20.	health related outcome measure.mp.	2
21.	limit 20 to (human and english language and yr="1900 - 2013")	2
22.	health status.mp. or *health status/	102973

23.	limit 22 to (human and english language and yr="1900 - 2013")	78926
24.	patient outcome assessment.mp. or *outcome assessment/	10674
25.	limit 24 to (human and english language and yr="1900 - 2013")	9037
26.	17 or 19 or 21 or 23 or 25	319296
27.	15 and 26	4060
28.	validation.mp. or *instrument validation/ or *validation study/ or *validation process/	208947
29.	limit 28 to (human and english language and yr="1900 - 2013")	121475
30.	*qualitative validity/ or *discriminant validity/ or *external validity/ or *validity/ or *consensual validity/ or *criterion related validity/ or validity.mp. or *concurrent validity/ or *content validity/ or *face validity/ or *construct validity/ or *convergent validity/ or *internal validity/ or *predictive validity/	143520
31.	limit 30 to (human and english language and yr="1900 - 2013")	96200
32.	*reliability/ or *questionnaire/ or Reliability of Results.mp. or *reproducibility/	28158
33.	limit 32 to (human and english language and yr="1900 - 2013")	19560
34.	29 or 31 or 33	201034
35.	27 and 34	217

Database: Ovid MEDLINE(R) 1860 to 2013, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations 1860-2013

	Search terms	No. of references
1.	exp Inflammatory Bowel Diseases/	59020
2.	limit 1 to (english language and yr="1860 - 2013")	47115
3.	Colitis, Ulcerative/	26947
4.	limit 3 to (english language and yr="1860 - 2013")	20565
5.	Crohn Disease/	30001
6.	limit 5 to (english language and yr="1860 - 2013")	23767
7.	Crohn Disease/	30001
8.	limit 7 to (english language and yr="1860 - 2013")	23767



9.	Colitis, Ulcerative/	26947
10.	limit 9 to (english language and yr="1860 - 2013")	20565
11.	Idiopathic Proctocolitis.mp.	32
12.	limit 11 to (english language and yr="1860 - 2013")	13
13.	Colitis Gravis.mp.	7
14.	limit 13 to (english language and yr="1860 - 2013")	1
15.	Regional Enteritis.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	809
16.	limit 15 to yr="1860 - 2013"	808
17.	Granulomatous Enteritis.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	123
18.	limit 17 to (english language and yr="1860 - 2013")	113
19.	Regional Ileitis.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	226
20.	limit 19 to (english language and yr="1860 - 2013")	161
21.	Granulomatous Colitis.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	322
22.	limit 21 to (english language and yr="1860 - 2013")	261
23.	Terminal Ileitis.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	347
24.	limit 23 to (english language and yr="1860 - 2013")	159
25.	2 or 4 or 6 or 8 or 10 or 12 or 14 or 16 or 18 or 20 or 22 or 24	47643
26.	**"Quality of Life"/ or **Outcome Assessment (Health Care)"/ or *Patient Satisfaction/ or patient reported outcomes.mp. or *Treatment Outcome/	93494
27.	limit 26 to (english language and humans and yr="1860 - 2013")	82097
28.	health status.mp. or *Health Status/	103700
29.	limit 28 to (english language and humans and yr="1860 - 2013")	87567
30.	Life Qualities.mp. or **Quality of Life"/	51005



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4	31.	limit 30 to (english language and humans and yr="1860 - 2013")
5		44084
6	32.	Life Quality.mp. or **Quality of Life"/
7		53401
8	33.	limit 32 to (english language and humans and yr="1860 - 2013")
9		45260
10	34.	27 or 29 or 31 or 33
11		157376
12	35.	25 and 34
13		689
14	36.	*Validation Studies/ or validation.mp. or *Validation Studies as Topic/
15		146196
16	37.	limit 36 to (english language and humans and yr="1860 - 2013")
17		94702
18	38.	Reliability of Results.mp. or exp "Reproducibility of Results"/
19		268135
20	39.	limit 38 to (english language and humans and yr="1860 - 2013")
21		193504
22	40.	validity.mp. or **Reproducibility of Results"/ or *Questionnaires/
23		125565
24	41.	limit 40 to (english language and humans and yr="1860 - 2013")
25		91596
26	42.	(Reliability and Validity).mp. [mp=title, abstract, original title, name of
27		substance word, subject heading word, keyword heading word, protocol
28		supplementary concept word, rare disease supplementary concept word,
29		unique identifier]
30		29168
31	43.	limit 42 to (english language and humans and yr="1860 - 2013")
32		23742
33	44.	**"Reproducibility of Results"/ or Reproducibility.mp.
34		296317
35	45.	limit 44 to (english language and humans and yr="1860 - 2013")
36		206824
37	46.	**"Reproducibility of Results"/ or Face validity.mp. or *Questionnaires/
38		31078
39	47.	limit 46 to (english language and humans and yr="1860 - 2013")
40		26488
41	48.	**"Outcome Assessment (Health Care)"/ or Content validity.mp.
42		23114
43	49.	limit 48 to (english language and humans and yr="1860 - 2013")
44		20841
45	50.	*Psychometrics/ or Construct validity.mp.
46		16807
47	51.	limit 50 to (english language and humans and yr="1860 - 2013")
48		14153
49	52.	concurrent validity.mp.
50		3787
51	53.	limit 52 to (english language and humans and yr="1860 - 2013")
52		3242
53	54.	*Psychological Tests/ or Convergent validity.mp. or *Psychiatric Status
54		22810
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	Rating Scales/	
55.	limit 54 to (english language and humans and yr="1860 - 2013")	15939
56.	Checklist.mp.	18282
57.	limit 56 to (english language and humans and yr="1860 - 2013")	14783
58.	instrument.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	76392
59.	limit 58 to (english language and humans and yr="1860 - 2013")	48347
60.	*Quality Indicators, Health Care/ or **Quality of Health Care"/ or Performance measures.mp.	36940
61.	limit 60 to (english language and humans and yr="1860 - 2013")	27367
62.	37 or 39 or 41 or 43 or 45 or 47 or 49 or 51 or 53 or 55 or 57 or 59 or 61	406612
63.	35 and 62	165

Database: Ovid PsycINFO 1860 - 2013

	Search terms	No. of references
1.	exp Ulcerative Colitis/ or inflammatory bowel disease.mp.	669
2.	limit 1 to yr="1860 - 2013"	664
3.	Crohn's disease.mp.	382
4.	limit 3 to yr="1860 - 2013"	381
5.	Crohn disease.mp.	22
6.	limit 5 to (english language and yr="1860 - 2013")	15
7.	Idiopathic Proctocolitis.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]	0
8.	limit 7 to (english language and yr="2013")	0
9.	Proctocolitis.mp.	1
10.	limit 9 to (english language and yr="1860 - 2013")	1
11.	exp Ulcerative Colitis/ or exp Colitis/ or Colitis.mp.	771
12.	limit 11 to (english language and yr="1860 - 2013")	619

13.	Granulomatous Enteritis.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]	0
14.	limit 13 to (english language and yr="1860 - 2013")	0
15.	Terminal Ileitis.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]	0
16.	limit 15 to (english language and yr="1860 - 2013")	0
17.	2 or 4 or 6 or 8 or 10 or 12 or 14 or 16	1234
18.	quality of life.mp. or exp "Quality of Life"/	45441
19.	limit 18 to (english language and yr="1860 - 2013")	41844
20.	**Quality of Life"/ or *Treatment Outcomes/ or *Measurement/ or patient reported outcomes.mp.	68202
21.	limit 20 to (english language and yr="1860 - 2013")	63212
22.	health related outcome measure.mp.	0
23.	limit 22 to (english language and yr="1860 - 2013")	0
24.	*Performance Tests/ or **Quality of Services"/ or Performance measures.mp.	8019
25.	limit 24 to (english language and yr="1860 - 2013")	7716
26.	questionnaire.mp. or *Questionnaires/	219432
27.	limit 26 to (english language and yr="1860 - 2013")	196473
28.	19 or 21 or 23 or 25 or 27	272418
29.	17 and 28	191
30.	*Statistical Validity/ or *Test Reliability/ or *Measurement/ or *Test Construction/ or validation.mp. or *Questionnaires/ or *Psychometrics/ or *Test Validity/ or *Foreign Language Translation/	131989
31.	limit 30 to (english language and yr="1860 - 2013")	117809
32.	*Test Validity/ or *Statistical Validity/ or validity.mp.	121770
33.	limit 32 to (english language and yr="1860 - 2013")	109074
34.	Face validity.mp.	1307
35.	limit 34 to (english language and yr="1860 - 2013")	1255
36.	*Statistical Reliability/ or Reliability.mp. or *Interrater Reliability/ or *Test Reliability/	75133

37.	limit 36 to (english language and yr="1860 - 2013")	66708
38.	*Statistical Analysis/ or *Rating Scales/ or *Test Reliability/ or Reproducibility.mp. or *Test Validity/	70936
39.	limit 38 to (english language and yr="1860 - 2013")	62751
40.	Construct validity.mp. or *Test Validity/	48892
41.	limit 40 to yr="1860 - 2013"	48706
42.	Content validity.mp.	2741
43.	limit 42 to (english language and yr="1860 - 2013")	2529
44.	Convergent validity.mp.	4478
45.	limit 44 to (english language and yr="1860 - 2013")	3963
46.	31 or 33 or 35 or 37 or 39 or 41 or 43 or 45	201286
47.	29 and 46	35

## Abbreviations:

1. ".mp" stands for multi-purpose. MP search which searches several fields at once. The fields searched by a .MP includes the Title, Original Title, Abstract, Subject Heading, Name of Substance, and Registry Word fields.
2. "Exp" means Explode. This is a function of Ovid to retrieve citations using the selected term and all of its more specific terms.
3. " \* "means focus the search on the search terms in the subject heading. Articles are considered when the major point or focus of the article is the search term.
4. " or " combines search results that include any of the search terms
5. "and" combines search results that included both / all search terms

**REFERENCES:**

1. Irvine EJ. Quality of life of patients with ulcerative colitis: past, present, and future. *Inflamm Bowel Dis*. 2008;14(4):554-65.
2. Moradkhani A, Beckman LJ, Tabibian JH. Health-related quality of life in inflammatory bowel disease: Psychosocial, clinical, socioeconomic, and demographic predictors. *Journal of Crohns & Colitis*. 2013;7(6):467-73.
3. Robertson DA, Ray J, Diamond I, Edwards JG. Personality profile and affective state of patients with inflammatory bowel disease. *Gut*. 1989;30(5):623-6.
4. Maunder RG, Cohen Z, McLeod RS, Greenberg GR. Effect of intervention in inflammatory bowel disease on health-related quality of life: a critical review. *Dis Colon Rectum*. 1995;38(11):1147-61.
5. Casellas F, Arenas JI, Baudet JS, Fabregas S, Garcia N, Gelabert J, et al. Impairment of health-related quality of life in patients with inflammatory bowel disease: a Spanish multicenter study. *Inflamm Bowel Dis*. 2005;11(5):488-96.
6. Hussain FN, Ajjan RA, Kapur K, Moustafa M, Riley SA. Once versus divided daily dosing with delayed-release mesalazine: a study of tissue drug concentrations and standard pharmacokinetic parameters. *Aliment Pharmacol Ther*. 2001;15(1):53-62.
7. Kornbluth A, Sachar DB. Ulcerative colitis practice guidelines in adults: American College Of Gastroenterology, Practice Parameters Committee. *Am J Gastroenterol*. 2010;105(3):501-23; quiz 24.
8. Rubin GP, Hungin AP, Chinn DJ, Dwarakanath D. Quality of life in patients with established inflammatory bowel disease: a UK general practice survey. *Aliment Pharmacol Ther*. 2004;19(5):529-35.
9. Bowling A. Measuring disease. Buckingham: Open University Press; 1995.
10. Patrick DL, Deyo RA. Generic and disease-specific measures in assessing health status and quality of life. *Medical care*. 1989;27(3 Suppl):S217-32.
11. Ware J, Jr., Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. *Medical care*. 1996;34(3):220-33.
12. EuroQol--a new facility for the measurement of health-related quality of life. The EuroQol Group. *Health Policy*. 1990;16(3):199-208.
13. Nurmi E, Haapamaki J, Paavilainen E, Rantanen A, Hillila M, Arkkila P. The burden of inflammatory bowel disease on health care utilization and quality of life. *Scand J Gastroenterol*. 2013;48(1):51-7.
14. Casellas F, Robles V, Borrueal N, Torrejon A, Castells I, Navarro E, et al. Restoration of quality of life of patients with inflammatory bowel disease after one year with antiTNFalpha treatment. *Journal of Crohn's & colitis*. 2012;6(9):881-6.
15. Magasi S, Ryan G, Revicki D, Lenderking W, Hays RD, Brod M, et al. Content validity of patient-reported outcome measures: perspectives from a PROMIS meeting. *Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation*. 2012;21(5):739-46.
16. Marshall S, Haywood K, Fitzpatrick R. Impact of patient-reported outcome measures on routine practice: a structured review. *J Eval Clin Pract*. 2006;12(5):559-68.



17. Guo Z, Wu R, Zhu W, Gong J, Zhang W, Li Y, et al. Effect of exclusive enteral nutrition on health-related quality of life for adults with active Crohn's disease. *Nutr Clin Pract*. 2013;28(4):499-505.
18. Pallis AG, Mouzas IA. Instruments for quality of life assessment in patients with inflammatory bowel disease. *Dig Liver Dis*. 2000;32(8):682-8.
19. Hickey A, Barker M, McGee H, O'Boyle C. Measuring health-related quality of life in older patient populations: a review of current approaches. *Pharmacoeconomics*. 2005;23(10):971-93.
20. JPT H, S G. *Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]*. Available from [www.cochrane-handbook.org](http://www.cochrane-handbook.org). Accessed 1st of September 2013: The Cochrane Collaboration; 2011. Available from: [www.cochrane-handbook.org](http://www.cochrane-handbook.org).
21. Moher D, Liberati A, Tetzlaff J, Altman DG. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *Journal of clinical epidemiology*. 2009;62(10):1006-12.
22. Terwee CB, Bot SD, de Boer MR, van der Windt DA, Knol DL, Dekker J, et al. Quality criteria were proposed for measurement properties of health status questionnaires. *Journal of clinical epidemiology*. 2007;60(1):34-42.
23. Mokkink LB, Terwee CB, Patrick DL, Alonso J, Stratford PW, Knol DL, et al. The COSMIN checklist for assessing the methodological quality of studies on measurement properties of health status measurement instruments: an international Delphi study. *Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation*. 2010;19(4):539-49.
24. Terwee CB, Mokkink LB, Knol DL, Ostelo RW, Bouter LM, de Vet HC. Rating the methodological quality in systematic reviews of studies on measurement properties: a scoring system for the COSMIN checklist. *Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation*. 2012;21(4):651-7.
25. Cohen LL, La Greca AM, Blount RL, Kazak AE, Holmbeck GN, Lemanek KL. Introduction to special issue: Evidence-based assessment in pediatric psychology. *J Pediatr Psychol*. 2008;33(9):911-5.
26. Guyatt G, Mitchell A, Irvine EJ, Singer J, Williams N, Goodacre R, et al. A new measure of health status for clinical trials in inflammatory bowel disease. *Gastroenterology*. 1989;96(3):804-10.
27. Irvine EJ. Development and subsequent refinement of the inflammatory bowel disease questionnaire: a quality-of-life instrument for adult patients with inflammatory bowel disease. *J Pediatr Gastroenterol Nutr*. 1999;28(4):S23-7.
28. Irvine EJ, Zhou Q, Thompson AK. The Short Inflammatory Bowel Disease Questionnaire: a quality of life instrument for community physicians managing inflammatory bowel disease. CCRPT Investigators. *Canadian Crohn's Relapse Prevention Trial*. *Am J Gastroenterol*. 1996;91(8):1571-8.
29. Alcalá MJ, Casellas F, Fontanet G, Prieto L, Malagelada JR. Shortened questionnaire on quality of life for inflammatory bowel disease. *Inflamm Bowel Dis*. 2004;10(4):383-91.
30. Drossman DA, Leserman J, Li ZM, Mitchell CM, Zagami EA, Patrick DL. The rating form of IBD patient concerns: a new measure of health status. *Psychosom Med*. 1991;53(6):701-12.

31. Smith GD, Watson R, Palmer KR. Inflammatory bowel disease: developing a short disease specific scale to measure health related quality of life. *Int J Nurs Stud.* 2002;39(6):583-90.
32. Allen PB, Kamm MA, Peyrin-Biroulet L, Studd C, Mc Dowell C, Allen BCM, et al. Development and validation of a patient-reported disability measurement tool for patients with inflammatory bowel disease. *Alimentary Pharmacology & Therapeutics.* 2013;37(4):438-44.
33. Peyrin-Biroulet L, Cieza A, Sandborn WJ, Coenen M, Chowers Y, Hibi T, et al. Development of the first disability index for inflammatory bowel disease based on the international classification of functioning, disability and health. *Gut.* 2012;61(2):241-7.
34. Smith JJ, Netuveli G, Sleight SP, Das P, Tekkis PP, Gabe SM, et al. Development of a social morbidity score in patients with chronic ulcerative colitis as a potential guide to treatment. *Colorectal Disease.* 2012;14(5):e250-e7.
35. Vergara M, Montserrat A, Casellas F, Gallardo O, Suarez D, Motos J, et al. Development and validation of the Crohn's disease perceived work disability questionnaire. *Inflamm Bowel Dis.* 2011;17(11):2350-7.
36. Wilcox AR, Dragnev MC, Darcey CJ, Siegel CA. A new tool to measure the burden of Crohn's disease and its treatment: do patient and physician perceptions match? *Inflamm Bowel Dis.* 2010;16(4):645-50.
37. Muller S, Jan Irvine E, Gathany T. PGI18 LINGUISTIC VALIDATION OF THE INFLAMMATORY BOWEL DISEASE QUESTIONNAIRE (IBDQ) IN 35 LANGUAGES. *Value in health : the journal of the International Society for Pharmacoeconomics and Outcomes Research.* 2008;11(3):A89.
38. Pallis AG, Mouzas IA, Vlachonikolis IG. The inflammatory bowel disease questionnaire: a review of its national validation studies. *Inflamm Bowel Dis.* 2004;10(3):261-9.
39. Verissimo R. Quality of life in inflammatory bowel disease: psychometric evaluation of an IBDQ cross-culturally adapted version. *Journal of gastrointestinal and liver diseases : JGLD.* 2008;17(4):439-44.
40. Hjortswang H, Jarnerot G, Curman B, Sandberg-Gertzen H, Tysk C, Blomberg B, et al. Validation of the inflammatory bowel disease questionnaire in Swedish patients with ulcerative colitis. *Scand J Gastroenterol.* 2001;36(1):77-85.
41. Pallis AG, Vlachonikolis IG, Mouzas IA. Quality of life of Greek patients with inflammatory bowel disease. Validation of the Greek translation of the inflammatory bowel disease questionnaire. *Digestion.* 2001;63(4):240-6.
42. Bernklev T, Moum B, Moum T. Quality of life in patients with inflammatory bowel disease: translation, data quality, scaling assumptions, validity, reliability and sensitivity to change of the Norwegian version of IBDQ. *Scand J Gastroenterol.* 2002;37(10):1164-74.
43. Hashimoto H, Green J, Iwao Y, Sakurai T, Hibi T, Fukuhara S. Reliability, validity, and responsiveness of the Japanese version of the Inflammatory Bowel Disease Questionnaire. *J Gastroenterol.* 2003;38(12):1138-43.
44. Pontes RM, Miszputen SJ, Ferreira-Filho OF, Miranda C, Ferraz MB. [Quality of life in patients with inflammatory bowel diseases: translation to Portuguese language and validation of the "Inflammatory Bowel Disease Questionnaire" (IBDQ)]. *Arq Gastroenterol.* 2004;41(2):137-43.

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  - 49
  - 50
  - 51
  - 52
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  - 54
  - 55
  - 56
  - 57
  - 58
  - 59
  - 60
45. Janke KH, Klump B, Steder-Neukamm U, Hoffmann J, Hauser W. [Validation of the German version of the Inflammatory Bowel Disease Questionnaire (Competence Network IBD, IBDQ-D)]. *Psychother Psychosom Med Psychol.* 2006;56(7):291-8.
46. Masachs M, Casellas F, Malagelada JR. [Spanish translation, adaptation, and validation of the 32-item questionnaire on quality of life for inflammatory bowel disease (IBDQ-32)]. *Rev Esp Enferm Dig.* 2007;99(9):511-9.
47. Ren WH, Lai M, Chen Y, Irvine EJ, Zhou YX. Validation of the mainland Chinese version of the Inflammatory Bowel Disease Questionnaire (IBDQ) for ulcerative colitis and Crohn's disease. *Inflamm Bowel Dis.* 2007;13(7):903-10.
48. Vidal A, Gomez-Gil E, Sans M, Portella MJ, Salamero M, Pique JM, et al. Psychometric properties of the original Inflammatory Bowel Disease Questionnaire, a Spanish version. *Gastroenterol Hepatol.* 2007;30(4):212-8.
49. Ciccocioppo R, Klersy C, Russo ML, Valli M, Boccaccio V, Imbesi V, et al. Validation of the Italian translation of the Inflammatory Bowel Disease Questionnaire. *Dig Liver Dis.* 2011;43(7):535-41.
50. Irvine EJ, Feagan B, Rochon J, Archambault A, Fedorak RN, Groll A, et al. Quality of life: a valid and reliable measure of therapeutic efficacy in the treatment of inflammatory bowel disease. Canadian Crohn's Relapse Prevention Trial Study Group. *Gastroenterology.* 1994;106(2):287-96.
51. Cheung WY, Garratt AM, Russell IT, Williams JG. The UK IBDQ-a British version of the inflammatory bowel disease questionnaire. development and validation. *Journal of clinical epidemiology.* 2000;53(3):297-306.
52. Streiner DL NG. *Health Measurement Scales: A practical guide to their development and use.* Fourth ed. Oxford university press 2008.
53. Casellas F, Ginard D, Vera I, Torrejon A. Development and testing of a new instrument to measure patient satisfaction with health care in inflammatory bowel disease: the CACHE questionnaire. *Inflamm Bowel Dis.* 2013;19(3):559-68.
54. Casellas F, Ginard D, Vera I, Torrejon A, Geteccu. Development and Testing of a New Instrument to Measure Patient Satisfaction With Health Care in Inflammatory Bowel Disease: The CACHE Questionnaire. *Inflammatory Bowel Diseases.* 2013;19(3):559-68.
55. Janke KH, Raible A, Bauer M, Clemens P, Meisner C, Hauser W, et al. Questions on life satisfaction (FLZM) in inflammatory bowel disease. *Int J Colorectal Dis.* 2004;19(4):343-53.
56. Lehmann M, Walther M, Ulitzsch S, Thomas A, Haeuser W, Stallmach A. Validation and First Results of the German QUOTE-IBD to Measure Quality of Care from the Perspective of Patients with Inflammatory Bowel Disease. *Zeitschrift Fur Gastroenterologie.* 2013;51(2):196-+.
57. Ormerod C, Shackcloth D, Harrison M, Brown E, Bodger K. The IBD-Control Questionnaire: Development and Psychometric Validation of a Tool for Capturing Disease Control From the Patient Perspective for use in Routine Care *Gastroenterology.* 2012;142(5 supplement 1):S658-S.
58. Mutsaers JH, Peters R, Pool-Goudzwaard AL, Koes BW, Verhagen AP. Psychometric properties of the Pain Attitudes and Beliefs Scale for Physiotherapists: a systematic review. *Manual therapy.* 2012;17(3):213-8.
59. Mokkink LB, Terwee CB, Stratford PW, Alonso J, Patrick DL, Riphagen I, et al. Evaluation of the methodological quality of systematic reviews of health



1  
2  
3 status measurement instruments. *Quality of life research : an international*  
4 *journal of quality of life aspects of treatment, care and rehabilitation.*  
5 2009;18(3):313-33.

6 60. Beattie M, Lauder W, Atherton I, Murphy DJ. Instruments to measure  
7 patient experience of health care quality in hospitals: a systematic review  
8 protocol. *Systematic reviews.* 2014;3:4.

9 61. Calder AM, Mulligan HF. Measurement properties of instruments that  
10 assess inclusive access to fitness and recreational sports centers: a systematic  
11 review. *Disability and health journal.* 2014;7(1):26-35.

12 62. Haywood KL, Collin SM, Crawley E. Assessing severity of illness and  
13 outcomes of treatment in children with Chronic Fatigue Syndrome/Myalgic  
14 Encephalomyelitis (CFS/ME): a systematic review of patient-reported outcome  
15 measures (PROMs). *Child: care, health and development.* 2014.

16 63. Kendzerska TB, Smith PM, Brignardello-Petersen R, Leung RS, Tomlinson  
17 GA. Evaluation of the measurement properties of the Epworth sleepiness scale: A  
18 systematic review. *Sleep medicine reviews.* 2013.

19 64. Mokkink LB, Terwee CB, Gibbons E, Stratford PW, Alonso J, Patrick DL, et  
20 al. Inter-rater agreement and reliability of the COSMIN (Consensus-based  
21 Standards for the selection of health status Measurement Instruments) checklist.  
22 *BMC medical research methodology.* 2010;10:82.

23 65. Mouzas IA, Pallis AG. Assessing quality of life in medical trials on patients  
24 with inflammatory bowel disease. *Annals of Gastroenterology.* 2000;13(4):261-  
25 3.

26 66. Mouzas IA. Quality measurement of quality of life in IBD. *Archives of*  
27 *Gastroenterohepatology.* 2001;20(3-4):84-8.

28 67. Irvine EJ. Health-related quality-of-life in Crohn's disease. *Research and*  
29 *Clinical Forums.* 1998;20(3):49-58.

30 68. Irvine EJ. Quality of life issues in patients with inflammatory bowel  
31 disease. *Am J Gastroenterol.* 1997;92(12 Suppl):18S-24S.

32 69. Russel MG, Pastoor CJ, Brandon S, Rijken J, Engels LG, van der Heijde DM,  
33 et al. Validation of the Dutch translation of the Inflammatory Bowel Disease  
34 Questionnaire (IBDQ): a health-related quality of life questionnaire in  
35 inflammatory bowel disease. *Digestion.* 1997;58(3):282-8.

36 70. Kim WH, Cho YS, Yoo HM, Park IS, Park EC, Lim JG. Quality of life in  
37 Korean patients with inflammatory bowel diseases: ulcerative colitis, Crohn's  
38 disease and intestinal Behcet's disease. *Int J Colorectal Dis.* 1999;14(1):52-7.

39 71. Lopez-Vivancos J, Casellas F, Badia X, Vilaseca J, Malagelada JR. Validation  
40 of the spanish version of the inflammatory bowel disease questionnaire on  
41 ulcerative colitis and Crohn's disease. *Digestion.* 1999;60(3):274-80.

42 72. Rose M, Fliege H, Hildebrandt M, Korber J, Arck P, Dignass A, et al.  
43 Validation of a German version of the "Short Inflammatory Bowel Disease  
44 Questionnaire" [SIBDQ]. *Zeitschrift Fur Gastroenterologie.* 2000;38(4):277-86.

45 73. Lam MY, Lee H, Bright R, Korzenik JR, Sands BE. Validation of Interactive  
46 Voice Response System Administration of the Short Inflammatory Bowel Disease  
47 Questionnaire. *Inflammatory Bowel Diseases.* 2009;15(4):599-607.

48 74. Jowett SL, Seal CJ, Barton JR, Welfare MR. The Short Inflammatory Bowel  
49 Disease Questionnaire is reliable and responsive to clinically important change  
50 in ulcerative colitis. *American Journal of Gastroenterology.* 2001;96(10):2921-8.

1  
2  
3 75. Han SW, Gregory W, Nylander D, Tanner A, Trewby P, Barton R, et al. The  
4 SIBDQ: Further validation in ulcerative colitis patients. *American Journal of*  
5 *Gastroenterology*. 2000;95(1):145-51.

6 76. Stjernman H, Granno C, Bodemar G, Jarnerot G, Ockander L, Tysk C, et al.  
7 Evaluation of the Inflammatory Bowel Disease Questionnaire in Swedish patients  
8 with Crohn's disease. *Scandinavian Journal of Gastroenterology*. 2006;41(8):934-  
9 43.

10 77. Hjortswang H, Jarnerot G, Curman B, Sandberg-Gertzen H, Tysk C,  
11 Blomberg B, et al. Validation of the inflammatory bowel disease questionnaire in  
12 Swedish patients with ulcerative colitis. *Scandinavian Journal of*  
13 *Gastroenterology*. 2001;36(1):77-85.

14 78. Andrzejewska J, Talarska D. The quality of life in inflammatory bowel  
15 disease. The analysis and validation of a new research tool. *Przegląd*  
16 *Gastroenterologiczny*. 2009;4(2):88-92.  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
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Figure 1: Flow chart of the systematic search results

