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Paper:

Alrubaiy, L., Rikaby, I., Dodds, P., Hutchings, H. & Williams, J. Systematic review of the health related quality of life (HRQoL) measures for inflammatory bowel disease. *Journal of Crohn's and Colitis*

<http://dx.doi.org/10.1093/ecco-jcc/jjv002>

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OXFORD
UNIVERSITY PRESS

Journal of Crohn's and Colitis

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

Journal:	<i>Journal of Crohn's and Colitis</i>
Manuscript ID:	ECCO-JCC-2014-0124.R1
Manuscript Type:	Review
Date Submitted by the Author:	10-Dec-2014
Complete List of Authors:	Alrubaiy, Laith; Swansea University, College of Medicine Rikaby, Ibtihal; Cardiff and Vale university health board, Pharmacy Dodds, Phedra; Swansea University, School of Medicine Hutchings, Hayley; Swansea University, School of Medicine Williams, John; Swansea University, School of Medicine
Classifications:	Quality of Life, socio-economical and psychological end points, Clinical trials

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Manuscripts

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5 2 **Systematic review of the health related quality of life (HRQoL) measures**
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7 3 **for inflammatory bowel disease**
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49 22 **Keywords** : Patients reported outcome measures, quality of life, Crohn's
50
51 disease, ulcerative colitis, inflammatory bowel disease
52
53

54 24 **Word count** : Abstract 236 words. Main manuscript 2618 words
55

56 25 **Short title** : Systematic review of HRQoL measures in IBD
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ABSTRACT:

Background and aim: Several measures have been developed to assess the health related quality of life (HRQoL) of patients with inflammatory bowel disease (IBD). Our aim is to systematically review the HRQoL measures specific for patients with IBD and to appraise their measurement properties and methodological quality.

Methods: We searched the PubMed, Embase and PsycINFO databases for original articles describing the development and/or evaluation of one or more of the measurement properties (e.g., internal consistency, reliability, validity, responsiveness) of HRQoL measures specific for IBD. We assessed the measurement properties and examined the methodological quality of the measurement properties of each instrument using a standardized checklist.

Results: We examined the full text of 75 articles that we deemed potentially eligible and identified 10 disease specific HRQoL measures in IBD that covered different aspects of patients' lives. Internal consistency, construct validity and content validity were the commonly evaluated measurement properties. Seven HRQoL measures scored positive for at least four of eight measurement properties. The majority of studies were rated as "fair" to "poor" when assessing their methodology quality. The most established HRQoL in the literature was the Inflammatory Bowel Disease Questionnaire (IBDQ).

Conclusions: Most of the included HRQoL measures did not include all the required measurement properties or had a problem with their methodological quality. The most widely used and validated measure was the IBDQ. Further validation studies are required to support the use of other HRQoL measures.

INTRODUCTION

Inflammatory bowel disease (IBD) is known to impair quality of life (1-4) and cause a substantial burden to patients, their families and the society (4-7). It affects patients' lives mentally, emotionally, socially and physically (7, 8). Health related Quality of life (HRQoL) is a multidimensional concept that measures physical, emotional, mental and social impact of the disease on patients lives (9). Measuring HRQoL provides an important insight into patients' perception of their health and the effect of treatments. Instruments used to measure HRQOL may be generic or disease-specific. Disease-specific instruments assess domains specific to a given disease and are therefore considered more sensitive to changes in the patient's health state (10). Generic instruments, by contrast, are aimed at measuring the overall HRQoL of patients and therefore, are useful to compare HRQoL across different disease states as well as for the evaluation of health economics outcomes (11, 12).

In the last two decades measurement of health related quality of life (HRQoL) has been increasingly used in inflammatory bowel disease (IBD) to support both research and clinical care (1, 13-19). This has led to a better evaluation of the patients' health and subsequently to improvements in their quality of care (15, 16). In scientific research, these measures are important to evaluate the effectiveness of new therapies in clinical trials. An up-to-date systematic review will provide a useful resource for research professionals and IBD specialists to ensure they can select an appropriate HRQoL measure for 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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99 **METHODS**

100 Search strategy

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

105 We searched the following electronic databases via Ovid SP up to 1st of
106 October 2013: MEDLINE, EMBASE, and PsychoINFO. Key search terms and
107 add synonyms were searched separately in three main filters that were
108 merged together. Targeted hand searches using the names of measures
109 identified in the initial searches were carried out. The detailed search strategy
110 can be found in Appendix 2.

- 111 1. Target population: Inflammatory bowel disease, Crohn's disease,
112 ulcerative colitis, terminal ileitis, regional ileitis, granulomatous enteritis,
113 proctitis, proctocolitis, and colitis.
- 114 2. Construct: quality of life, health related outcome measure, patient-
115 reported outcome measure, disability, health status, health related
116 quality of life, health status measures, patient outcome assessment,
117 and questionnaire.
- 118 3. Psychometric properties of HRQoL measures: psychometrics,
119 reproducibility, reliability, validation studies, validation, face validity,
120 content validity, construct validity, concurrent validity, convergent
121 validity, and discriminant validity.

122

123 Selection criteria

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3 124 We included all original articles in English describing the development and/or
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5 125 evaluation of one or more of the measurement properties (e.g., internal
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7 126 consistency, reliability, validity, responsiveness) of the HRQoL measures
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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 24 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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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
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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
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56 148 quality of the original development studies for the included HRQoL
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measures using the COSMIN (COnsensus-based Standards for the selection of health Measurement Instruments) checklist (23, 24). The COSMIN checklist assesses the methodology quality of the internal consistency, reliability, measurement error, responsiveness, content validity, construct validity, and factor analysis (structural validity). Each measurement property methodology was assessed against certain quality standards and rated on a 4-point scale (1=poor, 2=fair, 3=good or 4=excellent). The overall score for the methodological quality of a certain property is determined by taking the lowest rating. Depending on the number of measurement properties assessed in a study, some studies received one quality evaluation whereas other studies received several. The measurement property of a study was rated as having 'excellent' quality if all relevant COSMIN items were scored adequate.

4. Levels of the HRQoL measure establishment or use in literature: we used Cohen's criteria (25) (table 2) to determine the level of establishment of each specific HRQoL measure. The Cohen criteria classify the measures into three levels of establishment depending on the number of publications, the extent to which the measures are described in literature and their psychometric properties.

174 RESULTS

175 Results of the database search and included studies:

176 The database search resulted in 437 articles (Figure 1). References were
177 uploaded into EndNote and duplicates were removed leaving 389 articles.
178 After screening the titles and abstracts, 196 articles were excluded because
179 they did not include validation of the HRQoL and 10 articles were excluded
180 because they were published as abstracts in conferences and not as full
181 papers. The full texts of 183 articles were obtained and reviewed. We
182 excluded 108 articles that did not include the validation or evaluation of the
183 psychometric properties of the HRQoL measures. Seventy-five articles were
184 deemed eligible. After linking multiple reports of the same HRQoL measure,
185 we identified 10 disease specific HRQoL measures in IBD (Table 3):

- 186 1. Inflammatory bowel disease questionnaire (IBDQ) (26, 27)
- 187 2. Shortened inflammatory bowel disease questionnaire (SIBDQ) (28)
- 188 3. IBDQ was further shortened to 9 items, the IBDQ-9 (29).
- 189 4. Rating form of IBD patient concerns (RFIPC): (30).
- 190 5. Edinburgh IBD quality of life questionnaire (EIBDQ): (31).
- 191 6. The IBD disability score: (32),
- 192 7. The IBD disability index: (33)
- 193 8. Social Impact of Chronic Conditions–Inflammatory Bowel Disease
194 (SICC-IBD) questionnaire (34).
- 195 9. Crohn's disease perceived work disability questionnaire (CPWDQ) (35)
- 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
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11 203 psychometric properties, subsequent studies validated the IBDQ into different
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13 204 languages and have further proved its validity, internal consistency and
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15 205 reliability (37-51). The 32-item IBDQ questionnaire was shortened to 10 items
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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.
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25 210 When appraising the internal consistency of each measure, 8 measures
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27 211 achieved the recommended Cronbach's value of 0.7 -0.9 (22) (Table 1). Two
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29 212 measures did not have their internal consistency assessment reported in the
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31 213 literature. Ratings of the content validity were good for most of the measures
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33 214 as they used appropriate methods in generating items that covered various
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35 215 quality of life aspects of IBD (e.g. focus group, patient involvement, item
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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
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41 218 appropriately assessed in almost all measures except IBD disability index,
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43 219 which was not fully validated. The HRQoL measures were compared with
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45 220 other measures of disease severity or quality of life. Six HRQoL measures
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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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of the reliability testing. Three HRQoL measures had their responsiveness assessed in the original study report using the required statistics such as responsiveness ratio or paired t-tests. Seven measures did not have their responsiveness reported in literature. Measurement error evaluation and factor analysis was not assessed for most of the HRQoL measures.

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230 Assessing the methodology qualities of the HRQoL measures

231 None of the HRQoL measures development studies showed adequate
232 methodological quality in all COSMIN sections. Most of the publications
233 scored excellent for content validity having captured the domains that are
234 relevant to IBD patients through consultation with patients, and/or or literature
235 review or other methods as described by Steiner and Norman (52). Although
236 all HRQoL measures assessed the construct validity using other measures of
237 HRQoL or disease activity, more than half of the measures scored “fair” either
238 because they did not provide information on the missing items, a hypotheses
239 regarding the direction and magnitude of correlations, sample size or
240 achieved the required statistics. Most HRQoL measures were assessed for
241 reliability, internal consistency and responsiveness. However, for most of
242 them, this was not described in enough details to meet the COSMIN criteria.
243 Most of the publications did not report how missing items were handled and
244 how repeated measurements were conducted (mode of administration,
245 sample size, statistical analyses and time interval for test-retest). Most of the
246 studies did not include the assessment of measurement error or factor
247 analysis in the measure development and were rated “poor” for these criteria.
248 Table 5 shows the COMSIN ratings for the IBD specific HRQoL measures.

249 Assessing the level of credibility of the HRQoL measures:
250 We used Cohen's criteria (25) to appraise the degree establishment of the
251 different HRQoL measures in IBD. According to Cohen's criteria, only the
252 IBDQ and SIBDQ were considered to be well-established measures, while the
253 RFIC is approaching the level of well-established assessments. The rest were
254 rated as promising assessments (Table 6).

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Discussion:

Assessing the HRQoL in patients with IBD is an important outcome measure in assessing the efficacy of new treatments or intervention. Typically, HRQoL measures have been developed and used to describe mean scores (or mean response) for a group of patients (e.g. those in each arm of a trial). The last decade has seen a rapid increase in the number of measures to assess the HRQoL in patients with IBD (32-36, 53-57).

In this systematic review we identified 10 different HRQoL specific measures used for patients with IBD. We assessed the internal consistency, reliability, measurement error, content validity, factor analysis, construct validity, responsiveness, ceiling and flooring effects depending on the information obtained from the literature. Some of the HRQoL measures had some aspects of psychometric strength especially construct validity. However, they varied greatly in terms of their characteristics and most of them did not fulfill all the required properties proposed by Terwee et al (22). Notably, the IBDQ(26, 27), which is the most commonly used HRQoL measure in the literature, was not fully validated in the original study. However it was further validated in subsequent studies that used it or translated it to other languages. The IBDQ has the advantage of having shorter versions (SIBDQ(28) and IBDQ-9(29)) and has been translated into different languages, which facilitate its use worldwide.

We used the COSMIN checklist (23, 24) to appraise the methodological quality of the original HRQoL measures development studies. This included evaluation of the methodological quality of different properties such as the reliability, internal consistency, content validity, structural validity (factor

analysis), responsiveness, measurement error and construct validity. Using the COSMIN criteria of the methodology quality, the majority of studies were rated as “fair” to “poor” either because they did not reach the required standards or because of insufficient information. These studies are not necessarily of poor quality, but our results suggest that high quality studies are required to properly evaluate their measurement properties.

We also assessed the level of establishment of the HRQoL measures using the Crohn’s criteria (25). We found that the IBDQ and SIBDQ were considered to be well-established measures, and the RFIC is approaching the level of well establishment. The rest were rated as promising assessments.

We used a robust quality criteria (22) to systematically evaluate the psychometric properties of the identified HRQoL measures . We also used COSMIN checklist (23) to assess the methodological quality of the properties of the HRQoL measures in IBD. These criteria are increasingly used in systematic reviews of outcome measures (58-63). The content validity, reliability, and validity of the COSMIN standards checklist were showed to be valid and reliable (64). However, a limitation of the COSMIN checklist and the quality properties of outcome measures (22-24) is that they were recently developed and might not be applicable to measures developed before its introduction. The inconsistency in the measurement properties may be explained by the fact that there was no agreement on a definition of the required measurement properties until recently. However, questionnaires still need to meet validity and reliability criteria and be described in a 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
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9 326 described, then most properties will be rated fair even if they were undertaken
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11 327 properly in the study. Most of the HRQoL have been recently developed and
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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
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21 331 properties were designed to be as objective as possible, reviewers' judgments
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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
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35 337 and systematic search included studies that were carried out in non-English
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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
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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
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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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productivity, fatigue, and social impact. We performed the literature search in a systematic way to identify all HRQoL measures used in IBD. To our knowledge, this is the first systematic review of HRQoL measures in IBD that systematically appraised the measurement properties and the methodological quality of the HRQoL measures using a robust and standardized approach. This facilitates good comparison between the HRQoL measures on their quality of their measurement properties. This review will better guide the use of HRQoL in various clinical and research settings. It will also help clinicians, researchers and the general public to better assess the scientific literature on HRQoL in IBD. Several new HRQoL measures are emerging and our study showed that most of the HRQoL are supported by evidence of at least one type of reliability or validity and further validation studies might support their use. The choice of HRQoL measure in future will depend on the context for which it will be used (for example. social, disease burden, disability ...etc). Until then, the IBDQ(26, 27) has the strongest published evidence of reliability and validity and it is well established in literature.

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373 **Authors' contributions:** LA was responsible for developing initial drafts of
374 the manuscript, designing the study, obtaining funding, data collection and
375 analysis and final approval of the study. IR contributed to the collection and
376 assembly of data and final approval of the article. PD contributed to data
377 collection and all drafts of the manuscript. HAH and JGW contributed to
378 designing the study, critical revision of all drafts of the manuscript and data
379 analysis.

380

381 **Funding statement:** This work was supported by the Welsh Clinical
382 Academic training (WCAT) scheme and is collaboration between Swansea
383 University, Wales deanery and the Welsh Government.

384

385 **Competing interests:** None.

386

387 **Figure legends:**

388 Figure 1: Flow chart of the systematic search results

389 **Appendices:**

390 Appendix 1: PRISMA checklist for systematic search

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**

400 (22)

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 ≥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		

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

Category	Criteria
Well-established assessment	I. The measure must have been presented (validated) 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 measures	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.	CPWDQ	(35)	Fair	Fair	Poor	Excellent	Fair	Fair	Poor
10.	CD burden	(36)	Poor	Poor	Poor	Poor	Poor	Fair	Poor

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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)

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

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	Title of the section
ABSTRACT			
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
INTRODUCTION			
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
METHODS			
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
RESULTS			
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
DISCUSSION			
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
FUNDING			
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

31.	limit 30 to (english language and humans and yr="1860 - 2013")	44084
32.	Life Quality.mp. or **Quality of Life/	53401
33.	limit 32 to (english language and humans and yr="1860 - 2013")	45260
34.	27 or 29 or 31 or 33	157376
35.	25 and 34	689
36.	*Validation Studies/ or validation.mp. or *Validation Studies as Topic/	146196
37.	limit 36 to (english language and humans and yr="1860 - 2013")	94702
38.	Reliability of Results.mp. or exp "Reproducibility of Results"/	268135
39.	limit 38 to (english language and humans and yr="1860 - 2013")	193504
40.	validity.mp. or **Reproducibility of Results"/ or *Questionnaires/	125565
41.	limit 40 to (english language and humans and yr="1860 - 2013")	91596
42.	(Reliability and Validity).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]	29168
43.	limit 42 to (english language and humans and yr="1860 - 2013")	23742
44.	**"Reproducibility of Results"/ or Reproducibility.mp.	296317
45.	limit 44 to (english language and humans and yr="1860 - 2013")	206824
46.	**"Reproducibility of Results"/ or Face validity.mp. or *Questionnaires/	31078
47.	limit 46 to (english language and humans and yr="1860 - 2013")	26488
48.	**Outcome Assessment (Health Care)/ or Content validity.mp.	23114
49.	limit 48 to (english language and humans and yr="1860 - 2013")	20841
50.	*Psychometrics/ or Construct validity.mp.	16807
51.	limit 50 to (english language and humans and yr="1860 - 2013")	14153
52.	concurrent validity.mp.	3787
53.	limit 52 to (english language and humans and yr="1860 - 2013")	3242
54.	*Psychological Tests/ or Convergent validity.mp. or *Psychiatric Status	22810

	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 reference s
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

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Figure 1: Flow chart of the systematic search results

