Author's response to reviews

Title: Evaluation of the Birmingham IBS Symptom Questionnaire.

Authors:

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Author's response to reviews: see over
Dear Dr Norton

RE: Evaluation of the Birmingham IBS Symptom Score.

Many thanks for your consideration of the above paper and the comments of your reviewers. We are delighted that the reviewers believe the article to be of importance in its field. We thank you for the detailed and considered reviewers’ comments and we have redrafted the paper in the light of these comments. Please find below a summary of the actions taken in the light of reviewers’ comments.

We look forward to hearing from you about this revised paper.

Yours sincerely

Andrea Roalfe on behalf of the authors.

**Response to reviewer 1 (Lloyd Sutherland) comments:**

**Discretionary changes**

1. **Community (population based) sample rather than a referral based sample.**
   We agree that we need to draw attention to the fact that this study differs from many other symptom tools in that it was designed and validated for use in a community sample. We have included a statement in the first paragraph of the discussion to highlight this.

2. **Well written, concise review of the literature**
   Thank you for your positive comments.

3. **The authors might want to consider placing a copyright symbol on the questionnaire...**
   We agree that we need to control the use of the questionnaire and have instead included a footnote directing potential users to the author for permission to use.

**Minor essential revisions**

1. **Questions in the questionnaire use a 4 week passage of time whilst the second questionnaire was sent out within 10 days. Given the fact that the authors state in the**
Background that trials should have a duration of 2-3 months, do the authors think that the difference in time might have altered the acceptability of the questionnaire? The second questionnaire was sent out after 1 week to measure reproducibility and also measure change in symptoms over 7-10 day period. This is an appropriate timescale in which to measure reproducibility but we agree that this is a shorter time span than the duration recommended for trials. We addressed this limitation by referencing results showing an improvement in symptoms over a 3 month period in an RCT of hypnotherapy versus usual care. We have now acknowledged this limitation more clearly in the discussion.

2. In future trials would the authors recommend using both the IBS symptom questionnaire and the IBS-QOL questionnaire? Yes we recommend using both questionnaires since symptoms and QoL measure different aspects of response to treatment. We have added a sentence in the discussion to clarify this.

3. How was the random sample created? Individuals aged 18 and over were randomly selected from each practice, using a computer random number generator, stratified by deprivation quartile. We have reworded the first sentence of the second paragraph of the methods to clarify this.

4. Did the questionnaire perform well in both genders? Similar results for reliability, validity and reproducibility were found for men and women, however gender specific effect sizes could not be reliably estimated due to the small sample of males reporting a change in symptoms. We have included a statement in the discussion to report this.

Response to reviewer 2 (Pali Hungin) comments:

Is it likely to be effective in a clinical setting? A few important points arise: the subjects consisted of both those with Rome II confirmed IBS and those with a previous diagnosis… I am not sure if the same results might have been obtained from each of these groups…

Efficacy of the tool in a clinical setting remains to be established. The primary aim of this study was to establish a valid and reliable tool for use in a research setting. However the representativeness of the cohort to a primary care population would suggest there may some value in determining possible applications for this tool in clinical practice. We believe these aims are clearly stated but would be happy to review these if the reviewer believes they lack clarity.

Also, whereas some of the questions are relatively descriptive (“loose, mushy or water bowel motions”) others rely on entirely on the subjects’ own interpretation (eg “diarrhoea” or “constipation”). There has to be a question mark about the clinical reliability of responses to such questions – a case in point is the differentiation in two different questions between hard bowel motion and constipation…Previous research has shown disconnect between patients’ own interpretations and a Rome based evaluation.

The primary aim of this study was to establish a patient reported symptom score for repeated use in trials. In this setting patient interpretation of symptoms is not an issue and could be seen as beneficial in allowing patients to self-define symptoms within tight parameters. Translation to a clinical setting will require further testing especially in light of known differences in the way patients and doctors define key symptoms such as constipation (MJ Herz et al. Constipation: a different entity for patients and
The paper would be strengthened by including interviews, or by an explanation of how the difficulties above are overcome in commending this questionnaire. The risk is that the instrument itself may have scored well (it has!) but that it does not describe accurately what the patients problems actually are in the real life situation. Also, other factors such as bloating or tiredness did not appear in the symptom evaluation questionnaire even though they are regarded as part of IBS. Does this matter here?

We agree that further research would strengthen this questionnaire and acknowledge that whilst the instrument scores well it may have failed to capture some elements of the disease. There is an argument for excluding symptoms which are widespread in the population and tiredness for example is certainly one such symptom with an estimated community prevalence of 30% (J Heyworth and K McCaul. Prevalence of non-specific health symptoms in South Australia. Int J Environmental Health Research 2001; 11: 291-298). We have highlighted this as an issue in the discussion.

Response to reviewer 3 (Yasuhiro Sagami) comments:

1. **Major compulsory revision**

   *In this manuscript 15% of all samples were unable to work for health reasons. Is this sample appropriate for the diagnosis of IBS? Could not they work for only exacerbation of IBS? I just guess that they had not only IBS but also other severe diseases occurring severe abdominal symptoms. Authors have to present more details of the group unable to work in the manuscript. If not presented, authors must describe the limitation (about samples) of the research in discussion of the manuscript.*

   We cannot give more details on why some persons were unable to work. The possibility of response bias due to 15% not working because of health problems may exist. However we do know that the prevalence in our sample, of a range of conditions such as diabetes (5%), hypertension (31%) and cancer (4%) are similar to the national figures and thus our responders are representative of the general population. It is possible that those persons unable to work for health reasons may be due to the severity of IBS, however, patients with other pre-existing GI conditions such as Crohn’s disease and ulcerative colitis were excluded from the study. We have added a sentence to the discussion to describe the possible response bias.

2. **Minor essential revision**

   *In Rome # criteria, IBS patients have chronic and frequent abdominal pain/discomfort that has a relief by defecation and an onset associated change in frequency or form of stool. Therefore the relation between abdominal pain and status of defection is the key of clinical evaluation in IBS. However, there is no analysis about the relation between pain and defecation. Authors should describe the relation between abdominal pain and defecation.*

   The relationship is complex with both diarrhoea and constipation being associated with abdominal pain and further confounded by individual variability in the time that altered defecation takes to manifest itself in abdominal pain. For these reasons we do not believe this analysis and discussion is appropriate in this questionnaire validation paper.

3. **Discretionary revision**
Different numbers were presented in abstract (534 persons) and manuscript (533 persons) as the total mailed persons in this research.

Thank you for pointing this out. The abstract has been corrected to 533 persons.