Reviewer's report

Title: Bodily distress syndrome: A new diagnosis for functional disorders in primary care?

Version: 3  Date: 1 September 2015

Reviewer: Michael Pentzek

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- Major Compulsory Revisions

1. Comments reg. the following lines:
   a) „symptom counts have been shown to be unreliable in clinical practice because of the poor sensitivity and specificity of this approach [21].“
   b) „Box 1: # 3 symptoms from at least one of the following groups: […]
      Single-organ BDS (mild-moderate): involves one or two the symptom groups […]
      Multi-organ BDS (severe): involves three or four of the symptom groups“
   c) „The diagnostic category of BDS is based on the symptom clusters pertaining to bodily distress and introduces symptom pattern recognition as a core element of the diagnostic criteria."
   d) „it is the symptom pattern and not each individual symptom which should be assessed as ‘functional’ or not. This differs from the classification of the current somatoform disorders in the ICD-10;“ It is not clear what the difference is between „symptom count“ and pattern recognition with regard to the BDS concept. Box 1 suggests that symptoms are counted, but within different categories. Is this different to existing criteria? What would be helpful in this context:
      A table in which BDS criteria are compared with existing criteria of various functional disorders.
      A description of the current diagnostic practice of GPs when diagnosing functional disorders. This should be contrasted with the expected diagnostic practice when BDS is applied (i.e. pattern recognition). What change is expected for the GP’s work after implementing BDS?
      A theoretical background paragraph on diagnostic approaches and criteria like symptom count, pattern recognition and more GP-specific diagnostic approaches (e.g. gut feeling, trigger events in low-prevalence settings, watchful waiting, avoidable serious outcomes etc.) and its implications for the BDS syndrome.

2. Comments reg. the following lines:
   “it is not clear to which degree the BDS diagnosis may solve the clinical problems faced by the GP when diagnosing patients with functional disorders.”
   “We discuss […] whether this diagnostic category may be useful and valid in
primary care.”
As a reader I look for answers to these questions and cannot find them in the text. What are the problems of GPs? And which hypothesis exist with regard to any changes in GPs’ clinical practice?

3. Comments reg. the following lines:
“evidence points strongly towards an underlying phenomenon of bodily distress. A diagnostic category based on this concept may improve the clinical diagnostics…”
Please explain why the diagnosis of an underlying concept is expected to improve clinical diagnostics compared with the diagnosis of various phenotypes of a concept?

“In favour of the validity of BDS is the fact that the clinical description of the BDS symptom profiles originates from cluster analysis based on data from a large study of 978 patients from internal medical and neurological departments and from primary care.”
I think a method per se cannot serve as an indicator for validity.
To understand your point, more details on this central study on the 978 patients have to be reported, e.g. which diagnoses were included, was BDS developed with a sample of diagnosed functional disorder patients, which type of functional disorders were included, what are the numbers of patients from the diverse settings etc.

4. Comment on line 218/219: “the BDS construct has been confirmed in a primary-care population”
Important point, please report more details on this. How was this done?

5. Comment on the following lines 220-227 “…whether patients with six specific functional somatic syndromes (chronic fatigue syndrome, fibromyalgia, irritable bowel syndrome, non-cardiac chest pain, hyperventilation syndrome and pain syndrome) and the DSM-IV somatoform disorders characterised by physical symptoms also met the criteria for BDS. The overall [missing word; e.g. concordance?] between BDS and the investigated diagnoses was 95% (95% CI: 93.1-96.0, kappa 0.86, p<0.0001) [40]. These findings indicate that BDS may capture the different diagnoses that appear across the different chapters of the ICD-10 and the somatoform disorders classified according to the (now outdated) DSM-IV.”
This high concordance is not surprising assuming that BDS and its symptom clusters were derived from a sample with exactly these diagnoses in reference 2. (As said before, more details on this central study are necessary to report.)
Readers may not understand why this concordance justifies a new diagnostic concept.

6. There is some confusion about the statistical methods used:
Line 168: “cluster analysis”
A cluster analysis reveals clusters (mostly done on patient level), a PCA reveals factors/components (mostly done on item/symptom level). It is not clear, what was done in this study and on what output (clusters or factors/factor loadings) the symptoms in Box 1 are based.

Furthermore, it is not clear why these „clusters“ are an indicator of validity for the new BDS and not only a confirmation of the several kinds of existing functional disorder diagnoses? If several clusters can be derived from a heterogeneous simple, I would intuitively conclude that there are different illness entities and not an underlying concept.

It would be helpful to describe the difference between the diagnostic entity BDS described in box 1 and the already existing various diagnostic entities associated with the four symptom clusters from box 1 (e.g. irritable bowel syndrome). It seems like BDS is a new umbrella term which subordinates all functional disorders and renames them as multi-organ or single-organ BDS, but by counting the same symptoms as before.

7. Ideas for future research should be outlined in more detail. In particular, it would be instructive to present a design idea for a trial which compares clinical patient outcomes when GPs apply BDS criteria vs. the existing ICD or DSM criteria for functional disorders. Furthermore, a research design would be interesting, which examines how the BDS concept (vs. traditional concepts) fits to the specific decision making process in general practice.

- Minor Essential Revisions
Page 9, lines 161-164: References are not correct or not in concordance with the reference list.

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**
I declare that I have no competing interests.