Author's response to reviews

Title: Psychometric properties of the Confidence and Trust in Delivery Questionnaire (CTDQ): A pilot study

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Author's response to reviews: see over
Dear editors of BMC Women’s Health

Due to changes in our departments and an unforeseen illness we had to extend the timeline of the resubmission. We are sorry for this delay but we hope that this completely revised version of the manuscript covers all aspects of the reviewers and the editor. We therefore would be happy if our article is accepted in your journal and are looking forward to hearing from you. Please find the point-to-point reply to the comments below.

Kind regards

Thomas

Reviewer: Heather Rowe

1. Introduction: There is no doubt that confidence in caregivers and feelings of being involved in decision making during labour are important components of a woman’s appraisal of her experience of labour. However the authors do not provide a sufficiently coherent argument about the value of assessing these constructs prior to the birth. Who would use such a measure? How would the score be used? What is the proposed mechanism for the link between use of the questionnaire and improved childbirth outcome for women who complete the CTDQ?

Indeed, as this is a pilot study, we are not sure about the usage of the CTDQ. We however provided some information about the assessment prior to birth and gave some explanations on the mechanisms for the link between use of the questionnaire and improved childbirth outcome (p.3).

2. The authors list four existing validated measures that assess similar constructs. However they do not provide sufficient information to describe the specific limitations of these measures, why the proposed new measure is needed or what it will add. Why is confidence and trust in delivery an important construct in pregnancy? What is the value of assessing these constructs prior to birth? Are women’s levels of confidence and trust modifiable? How might this be achieved? Why might it be worthwhile? What is the evidence that changes in these constructs will improve childbirth experience?
Generally there are no special limitations of the existing measures. We wanted to develop a short but reliable instrument that focuses more on the fundamental aspects of confidence and trust (p.4). Some studies like Corbin (1987) suggest a correlation between a perceived sense of control and confidence and trust in their own and the health team’s management efforts. We added this information in the manuscript (p.3).

3. Materials and Methods: Please describe the “methodologists” in more detail and what they contributed to the expert panel.

We added a respective sentence (p.4)

4. Was approval from a properly constituted ethics committee obtained? Please state the name of the committee and the date of approval.

As this was a non invasive epidemiological study there was no necessity to obtain a vote from a local research ethics committee. However the rules for good epidemiological practice were fully applied. This was added to the manuscript (p.5).

5. More details about recruitment are required: Who invited women to participate? How were women invited? Was recruitment consecutive? Or according to convenience? Were signed consent forms completed? Who performed the “comprehensive counselling session? Some of the questions elicit sensitive information. Where were the questionnaires completed? In private, public, at home? How were the questionnaires returned to researchers? By post? In person?

We modified the methods section and provided the required information (p. 5-6).

6. Data collection: Questionnaire #3 needs more explanation. Please spell out SOC acronym and provide a rationale for the use of this scale for the purpose of validation of the CTDQ. How are the psychological constructs measured in the two scales related? Why is the SOQ a suitable external validation standard for the CTDQ?

Questionnaire #3 is now explained in more detail. The reason and rationale to use the SOC was transferred from the discussion part into the method section (p. 6).

7. Similarly Questionnaire #4. The VAS rates “pain level”. It is not clear whether this is current pain, expected pain, or pain in a previous delivery. The authors need to justify why this is a suitable measure for external validation of the CTDQ.

With respect to the comments of the other reviewer, the VAS on pain was now deleted as external validation instrument.

8. Results: Please state recruitment fraction (221/318 ~70%). Provision of comparison sociodemographic data in Table 1 would assist the reader to assess representativeness of the sample. Please provide where possible. A comment about lack of representativeness is made by the authors in the Limitations
section, but data on which this assertion is based should be provided.

**Recruitment fraction is now reported. Unfortunately we only can assume about representativeness. The only information we found on age is given on p. 12.**

9. Dimensions and internal reliability of CTDQ: The authors assert that the factors have clinical as well as statistical relevance. Please state what this is here (eg The factors are interpretable? Meaningful? Are consistent with women’s own descriptions of what is relevant to them?) and elaborate further in the Discussion.

**We rephrased to respective sentences to a more preliminary character.**

10. 3rd para of this section: Please provide a reference for the statement that …., item-total correlations are in the optimal range….”

**Reference is now provided on p. 9**

11. External validity: This section requires further elaboration. For example a description of the specific psychological constructs that are (and are not) correlated, and the distinction between positive and negatively correlated scale scores. Please provide an overall statement of the strength of evidence for the external validity of the CTDQ questionnaire provided by these data.

**Done in the discussion section (p.11)**

12. Discussion: Para 2: It is not clear that the authors’ conclusions are supported by the data. Rather than "clearly indicat(ing) that the core aspects of trust and confidence in labour are captured….", the four-factor solution result might suggest that “confidence and trust in delivery” is not a unitary construct, but rather a set of items, each of which has its own independent meaning. Similarly it is not clear whether the evidence for the independence of the CTDQ from the SOC and “pain perception” measures suggests that the CTDQ is measuring something meaningful or not. The results provide evidence for what the scale is NOT measuring rather than for what it IS measuring. Some acknowledgement of these matters is required n the discussion.

**Indeed the wording “clearly indicating…” is to strong for this pilot study. We therefore rephrased the paragraph and added the points into the limitation section of the discussion (p.12).**

13. Para 3 is unclear. Please re-phrase to make the meaning clear.

**We have rephrased it to make it clearer.**

14. Para 5: The authors appear to be making a case for the use of the CTDQ as a “screening instrument” for women who will go on to have a traumatic delivery. However, the practical implications of its use for this purpose require further elaboration.
We indeed stated that it “might be useful as a screening instrument” as one example of usage. We are quite aware of the practical implications but would like to leave the example as it is.

15. Final para: The points that the authors are making about the lack of association of the CTDQ and the SOC and pain intensity measures are unclear. This paragraph would benefit from re-phrasing to improve clarity.

We have tried to improve clarity in this chapter.

16. Limitations: The authors acknowledge that the sample includes women of mixed parity. It could be argued that prior experience of labour would have an impact on a women’s expectations of childbirth and therefore on the results of the study. Please provide some elaboration on the nature and magnitude of effect that this might have exerted on the results of the study.

We did this analysis and added a chapter in the results and discussion section.

17. Conclusion: The authors state that the CTDQ is “well accepted”. Whilst this is likely to be the case no data are presented to confirm that women or clinicians found it acceptable or easily completed. Again, the authors state that the CTDQ is useful, but do not explain how or when the CTDQ might be used, what clinical or research utility it might have, what might clinicians do when women score high or low, what dimensions could be modified, how this might be achieved, why this might be beneficial, or what risks might be associated with its use.

Well accepted is too strong and thus it was removed.

18. The writing is acceptable with the exception of some instances where re-phrasing would improve clarity (see above). Minor issues not for publication
• Background para 2 line 9: extend should read extent
• Questionnaire Item 8/Table 2: Please consider whether obstetrician be a better English translation than gynaecologist?
• Data collection: Questionnaire #2 please spell out EA
• Table 1: ;meaning of MW should be spelt out. It is not a universally understood abbreviation for mean.
• Table 3 Partners support should read Partner’s support; Add ** p=.05(?)
• Discussion line 1 aims should read aimed

We corrected all the aspects mentioned above.
Reviewer: Albrecht Jahn

1. the authors rightly classify there study as a pilot study; as such I cannot validate the instrument; the conclusions should be adjusted to this situation

We rephrased the title accordingly (p.1)

2. Methodology - Selection bias and representativeness of study population: The authors acknowledge the observation, that their study population is not representative because of the high proportion of women with higher education.

Beyond that women were recruited in the maternity ward in a hospital, while antenatal care in Germany is generally not provided by hospitals. Thus, these women had a special reason, to attend a hospital in pregnancy, most probably because of a complication.

To our knowledge antenatal classes are quite frequently provided at community hospitals like the one in Havelhoehe, but also at other hospitals with a department of obstetrics. Thus our sample is not biased by a high amout of complications. We did not comment on this issue in the manuscript.

In addition, the hospital's focus on integrative medicine may have attracted a very selected clientele.

Yes, but keep in mind that Havelhoehe hospital serves as a normal community hospital. We commented on in the limitations (p.12-13)

There is an issue whether a question like “When I think of labor and its pain I tend to eagerly anticipate it” (what was the wording in German?) would work with all groups of pregnant women. It is advised to attach the original questions as an accompanying file.

We have added the questions in German.

3. Methodology – the rationale for using the Visual analogue scale for external validation is not obvious and needs justification or omission.

As both reviewers were quite critical with this issue, we removed the respective sections.

4. Results – data from SOC

these data figure only in table one (under a misleading heading) with an overall mean of 151.5.

We added a special table 2 with a lot more of information regarding the SOC but also the CDTQ.
Not all readers will be familiar with the SOC and the way it is analysed. It is recommended that the data are presented in more detail and that the process of calculating correlation coefficients per subcategory is explained.

Which values were compared?

**We rephrased and explained accordingly (p.9)**

5. Results – table 1
The heading talks of demographic and socio-medical information. The table should stick to this heading and provide background variables, including major risk factors and hospitalisation in pregnancy. The results of the SOC (and VAS if deemed important) should be presented in a separate table, comparable to table 2

**We added a special table 2 with a lot more of information regarding the SOC but also the CDTQ.**

6. Results - table 3
Firstly there are some inconsistencies: How can the total with trust in medical competence by + 0.308 while all subcategories are negative? It is also surprising to see a negative correlation between CTDQ Trust in medical competence and SOC manageability. The direction of the correlation is impossible to judge, because it is not shown if the direction in the seven level scale (from 1 to seven) of the respective questions was the same or opposite. The figures have * or ** without an explanation of the meaning.

**We regret this mistake and corrected the correlation values which now are consistent.**

Minor Essentiel Revisions:

The issue of epidural anaesthesia (EA) is mentioned in the methodology but not taken up later.

**We deleted the sentence and rephrased.**

There use of acronyms need to be restricted in order to improve readability.

**We tried to be restrictive and added a list of acronyms used.**
Editorial requests:

1) Please revise the title of your manuscript so that it is more informative and reflective of your study.

We changed the title

2) Please include a title page in your manuscript. Manuscript sections should include (in the following order): Abstract; Background; Methods; Results; Discussion; Conclusions; Abbreviations (if any); Competing interests; Authors' contributions; Acknowledgements; References; Figure legends (if any); Tables (if any); Description of Additional files (if any).

We reformatted the manuscript according to the BMC-style

3) Ethical approval. Experimental research that is reported in the manuscript must have been performed with the approval of an appropriate ethics committee. Research carried out on humans must be in compliance with the Helsinki Declaration (http://www.wma.net/e/policy/b3.htm), and any experimental research on animals must follow internationally recognized guidelines. A statement to this effect must appear in the Methods section of the manuscript, including the name of the body which gave approval, with a reference number where appropriate.

As this was a non invasive epidemiological study there was no necessity to obtain a vote from a local research ethics committee. However the rules for good epidemiological practice were fully applied. We added this in a separate chapter.

4) Please revise the background section of your abstract so that it contains some information about the context of the study.

We revised the abstract.