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Development and validation of scale assessing the knowledge about breast feeding benefits and practices among antenatal and postnatal mothers in South India

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Dear Dr Rushender,

Reviewers have now commented on your paper, which has yielded 2 minor revision and a reject verdict. You will see that they are advising that you revise your manuscript. If you are prepared to undertake the work required, I would be pleased to reconsider my decision.
We kindly ask you to pay particular attention to the comments of reviewer 3 and request that you implement the reviewer's comments to the fullest extent possible or properly rebut the comments where you deem necessary.

For your guidance, reviewers' comments are appended below.

If you decide to revise the work, please submit a list of changes or a rebuttal against each point which is being raised when you submit the revised manuscript. Also, please ensure that the track changes function is switched on when implementing the revisions. This enables the reviewers to rapidly verify all changes made.

Your revision is due by Dec 22, 2021.

To submit a revision, go to https://www.editorialmanager.com/jctres/ and log in as an Author. You will see a menu item call Submission Needing Revision. You will find your submission record there.

Yours sincerely

Michal Heger
Editor-in-Chief
Journal of Clinical and Translational Research

Reviewers' comments:

Reviewer #1: The paper correctly follows the standard procedures for factor analysis in the development of a useable scale.

Reviewer #2: Hi Dr Michal,
Below are my review comments:
Review comments

Manuscript: JCTRes-D-21-00097

The authors reported the development and validation of an instrument for assessing knowledge about benefits of breastfeeding and practices. However, I believe the article could be improved by providing the readers with more information about how the instrument was developed. It currently unclear whether the 377 women were essential in developing and validating the instrument. Please consider the following points / questions;

1. There is limited information about how the items were selected and The composition of the review panel.

2. What literature did you used and how did you come about them?

3. What search terms were used and which databases were searched.

4. How were the themes/questions identified.

5. How many people were in the team of experts that considered face and content validity and what is there background? Are they experts in breastfeeding or paediatrics and what are there qualifications?

6. Why were 11 out 13 questions retained.

7. How many of the 11 questions are to asses knowledge about benefit of breastfeeding and how many to assess practice?

8. Could the instrument be developed and validated without involving the 384 participants?

9. How was the sample size of 384 determined? Could the pilot testing of the instrument be done with less participants?

10. Was the method of analysis the most appropriate ? why was it necessary
to perform exploratory factor analysis, confirmatory factor analysis , RMSEA and Turker-Lewis index.

Reviewer #3: As a woman (with children), I'm actually a bit perplexed by the introduction, and the one-sided exposure of the problem of not being able to breastfeed a child due to a lack of knowledge among women. As an European woman I can't judge the situation in South India at all, so maybe I'm wrong. And it is of course valid to measure women's knowledge on breastfeeding benefits and practices. However, now it is phrased as if it is mainly the responsibility and obligation of women. What about economic aspects for these women: do these women have the money to feed themselves enough to be able to breast feed their child? Do they have the opportunities to breastfeed the child while working (for 2 years for each child)? Are there opportunities to make sure they can expressing mother milk while working? What about women who want to breastfeed their child, but who are for whatever reason not able to do so? What about the responsibility for the society to value this role of women? By focusing only in the introduction about women's knowledge, I think the authors do them wrong, and feed the feeling as if it is their own fault and responsibility to not being able to breast feed their child which can even lead to death.

As a clinimetric expert, I have some more concerns and suggestions for improvement. The construct that the authors want to measure is not clear: in the title it is 'knowledge on breastfeeding benefits and practices', in the paper it is also described as 'good breastfeeding practices', or 'knowledge about breastfeeding'. And what do the authors mean by the construct: benefits for whom? Why not also talk about disadvantages (acting as natural contraception? In the Netherlands we learn that this is not true)? Does the knowledge mainly refers to knowledge on how to physically give breastfeeding, or also on societal and economic aspects of how to be able to give breastfeeding (e.g. which rights do women have for e.g. taking time off, is this paid by the employer etc.)? Without a clear definition, the validity of an instrument cannot be assessed. Should their knowledge also be true?

The first draft was developed by 'we' and a 'team of experts' (page 6 section 2.2). Who were these people, and what made them an expert? Were women involved? Also, in this stage 2 items were
removed (page 6). Which items were that? And for which reasons were they removed?

Nowadays, it is common practice to involve people from the target population to be involved in the development of an instrument. Were women involved? If no, why not?

Content (and face) validity refers to three aspects: relevance, comprehensiveness and comprehensibility. In the development of the draft the authors give attention to relevance and comprehensibility (p 5: appropriateness, relevancy, ambiguity, syntax and difficulty). What is the difference between appropriateness of items and relevancy of items? What do the authors mean by syntax? The final scorings algorithm? Does difficulty of items refers to the content of the items, in the context of IRT-based difficulty of items? or rather the difficulty of the wording of the items, and the difficulty of understanding what the developers intend?

In the next phase, the draft of the questionnaire was tested among women. What was asked in the semi-structured interview (page 6)? Were they asked again about relevance of

comprehensibility of each item, and the comprehensiveness of the items?

A factor analysis should only be conducted on items that are based on a reflective model. Is this a reflective or a formative model? When reading the items, I'm not sure whether it would be a reflective model and would like to read a reasoning about it (see for explanation e.g. Jarvis https://www.jstor.org/stable/10.1086/376806?seq=1#metadata_info_tab_contents) The results of the factor analyses informs us on how to add items into scores; only items within factors should be added, and not a total score across factors should be used, as this is not the fit of the model. Moreover, internal consistency should not be assessed on items that do not together form a unidimendional scale. As the Cronbach alpha likely increases when more items are involved (as is the case when it is calculated for the whole set of items), it is very likely that each of the Cronbach alpha's of the three unidimensional scales are (much) lower. Perhaps even too low, meaning that more items should be added in the subscale. The authors should provide the Cronbach alpha's for the three factors. (I disagree that a Cronbach alpha of 0.8 refers to 'very good' internal consistency - as is stated in the discussion).

The final set of items is provided in the Tables. However, I have some concerns on the phrasing and use of jargon. Is the exact wording used of the items, or are they shortened in the Tables? Many of the questions are not correct, i.e. 'whether the breastfeeding promote child to mother bonding?' is not a proper sentence. What is the stem of the items? is it 'do you know if…'? and if so, I can answer the question with 'yes', but are my ideas about it correct? Some items seem to be suggestive (e.g. items 6 and 7; if you ask, I guess it is probably true?). How is this guessing factor taken into account? Does the target population understands words like 'immunity', 'calorie', 'protein', 'uterine involution', and 'lactation'? what are the response options of each of the questions? Is the first question an open question, and how is this used in the scoring?

Authors' response

Reply to the reviewers' comments

Reviewer Number	Original comments of the reviewer	Reply by the author(s)	Changes done on page number and line number
1	Reviewer #1: The paper correctly follows the standard procedures for factor analysis in the development of a useable scale.	We thank the reviewer for the valuable comments.	No changes required
2	The authors reported the development and validation of an instrument for assessing knowledge about benefits of breastfeeding and practices. However, I believe the article could be improved by providing the readers with more information about how the instrument was developed. It currently unclear whether the 377 women were essential in developing and validating the instrument. Please consider the following points / questions;	We thank the reviewer for the valuable comments. Though, there are no absolute rules for sample size in validating a questionnaire, larger samples are always better than smaller samples, it is recommended that	No changes required

		investigators utilize as large a sample size as possible. Previous studies have also provided the following grading based on the sample size of a validation study: sample sizes of 50 should be considered as very poor, 100 as poor, 200 as fair, 300 as good, 500 as very good, and 1000 or more as excellent. (Reference: Comfrey AL, Lee HB. A First Course in Factor Analysis. Hillsdale, NJ: Lawrence Erlbaum Associates) Since, our study falls in good category, it can be considered as appropriate sample size.	
	1. There is limited information about how the items were selected and The composition of the review panel.	We have developed the items based on literature review and expert opinion for assessing the knowledge and benefits of breastfeeding. The team of review panel consists of a panel of public health experts in the department of community medicine. We have also mentioned the same in the methods section now. We sincerely hope for reviewer's understanding in this regard.	Page 4, line 85

	2. What literature did you used and how did you come about them?	We have conducted a rapid review of literature and identified studies with theme similar to the current study. We have retrieved those studies and identified the questions from the questionnaire used in the respective study. We have added this note in the methods section.	Page 4, line 76-82
	3. What search terms were used and which databases were searched.	We thank the reviewer for the valuable comments. We have added the search terms and databases searched in the methods section.	Page 4, line 76-82
	4. How were the themes/questions identified.	The themes were decided by the authors to assess the knowledge level about the benefits and practices in their own service area and the questions were identified based on the literature review and expert opinion and mentioned extensively in the methods section.	Page 4, line 76-82
	5. How many people were in the team of experts that considered face and content validity and what is there background? Are they experts in breastfeeding or paediatrics and what are there qualifications?	We had a team of public health experts with postgraduate qualification in the field of community medicine as a team of experts. All of them had extensive knowledge about the breast feeding benefits	Page 4, line 76-82

		and practices during their undergraduate, postgraduate training and post MD experience in the field of public health.	
	6. Why were 11 out 13 questions retained.	Two questions were excluded as they were not appropriate for the theme of questionnaire. We have also added that information in the manuscript	Page 4, line 88-89
	7. How many of the 11 questions are to asses knowledge about benefit of breastfeeding and how many to assess practice?	Eight questions on benefits of breastfeeding and three questions on practices of breastfeeding. We have also added that information in the manuscript	Page 4, line 87-89
	8. Could the instrument be developed and validated without involving the 384 participants? 9. How was the sample size of 384 determined? Could the pilot testing of the instrument be done with less participants?	We thank the reviewer for the valuable comments. Though, there are no absolute rules for sample size in validating a questionnaire, larger samples are always better than smaller samples, it is recommended that investigators utilize as large a sample size as possible. Previous studies have also provided the following grading based on the sample size of a validation study: sample sizes of 50 should be considered as very poor, 100 as poor, 200 as	No changes required

		fair, 300 as good, 500 as very good, and 1000 or more as excellent. (Reference: Comfrey AL, Lee HB. A First Course in Factor Analysis. Hillsdale, NJ: Lawrence Erlbaum Associates) Since, our study falls in good category, it can be considered as appropriate sample size.	
	10. Was the method of analysis the most appropriate ? why was it necessary to perform exploratory factor analysis, confirmatory factor analysis , RMSEA and Turker-Lewis index.	Yes, it is appropriate as per the standard guidelines to develop and validate a scale. We are attaching the references on the same: Mimura C, Griffiths P. A Japanese version of the Perceived Stress Scale: cross cultural translation and equivalence assessment. BMC Psychiatry. 2008; 8(1): 85–91. Al-Dubai SA, Aishagga MA, Rampal KG, Sulaiman NA. Factor Structure and Reliability of the Malay Version of the Perceived Stress Scale among Malaysian Medical Students. Malays J Med Sci. 2012; 19(3):43–49. Schermelleh-Engel K, Moosbrugger H, Muller H. Evaluating the	No changes required

		fit of structural equation models: tests of significance and descriptive goodness of fit measures. MPR Online. 2003; 8(2):23–74. We sincerely hope for reviewer's understanding in this regard	
3	As a woman (with children), I'm actually a bit perplexed by the introduction, and the one-sided exposure of the problem of not being able to breastfeed a child due to a lack of knowledge among women. As an European woman I can't judge the situation in South India at all, so maybe I'm wrong. And it is of course valid to measure women's knowledge on breastfeeding benefits and practices. However, now it is phrased as if it is mainly the responsibility and obligation of women. What about economic aspects for these women: do these women have the money to feed themselves enough to be able to breast feed their child? Do they have the opportunities to breastfeed the child while working (for 2 years for each child)? Are there opportunities to make sure they can expressing mother milk while working? What about women who want to breastfeed their child, but who are for whatever reason not able to do so? What about the responsibility for the society to value this role of women? By focusing only in the introduction about women's knowledge, I think the authors do them wrong, and feed the feeling as if it is their own fault and responsibility to not being able to breast feed their child which can even lead to death.	We thank the reviewer for the valuable comments. As suggested, we have rephrased the entire introduction section one-sided exposure of the problem of not being able to breastfeed a child due to a lack of knowledge among women and addressed it as one of the issues and not as a main issue.	Changes done throughout the introduction section. Page 3 line 43-49
	As a clinimetric expert, I have some more concerns and suggestions for improvement. The construct that the authors want to measure is not clear: in the title it is 'knowledge on breastfeeding benefits and practices', in the paper it is also described as 'good breastfeeding practices', or 'knowledge about breastfeeding'. And what do the authors mean by the construct: benefits for whom? Why not also talk about disadvantages (acting as natural contraception? In the Netherlands we learn that this is not true)? Does the knowledge mainly refers to knowledge on how to physically give breastfeeding, or also on societal and economic aspects of how to be able to give breastfeeding (e.g. which rights do women have for e.g. taking time off, is this paid by the employer etc.)? Without a clear definition, the validity of an instrument cannot be assessed. Should their knowledge also be true?	We thank the reviewer for the valuable comments. We have clarified throughout the manuscript that we are assessing the breastfeeding benefits and practices. We have only explored the physical aspect and not the societal and economic aspects of breast feeding. We have added this in the limitation section.	Changes done throughout the manuscript
	The first draft was developed by 'we' and a 'team of experts' (page 6 section 2.2). Who were these people, and what made them an expert? Were women involved? Also, in this stage 2 items were removed (page 6). Which items were that? And for which reasons were they removed?	We thank the reviewer for the valuable comments. It was already	Page 4, line 76-82

		asked by the previous reviewer and we have addressed the same in the methods section and explained the process properly.	
	Nowadays, it is common practice to involve people from the target population to be involved in the development of an instrument. Were women involved? If no, why not?	We have not included the target population in the development of the instrument. We were not aware of such practice and we will definitely follow it in our future studies. We sincerely regret for the mistake done in our study.	No changes required.
	Content (and face) validity refers to three aspects: relevance, comprehensiveness and comprehensibility. In the development of the draft the authors give attention to relevance and comprehensibility (p 5: appropriateness, relevancy, ambiguity, syntax and difficulty). What is the difference between appropriateness of items and relevancy of items? What do the authors mean by syntax? The final scorings algorithm? Does difficulty of items refers to the content of the items, in the context of IRT-based difficulty of items? or rather the difficulty of the wording of the items, and the difficulty of understanding what the developers intend?	The difference between appropriateness and relevancy is that appropriateness means the appropriate placing of the wordings in the questions while the relevance is related to relevance of the question to the particular theme of the questionnaire. Syntax is actually the syntactic ambiguity in which we assessed the presence of two or more possible meanings within a single sentence or sequence of word. Difficulty refers to the difficulty in understanding the wording of the items.	No changes required.

	In the next phase, the draft of the questionnaire was tested among women. What was asked in the semi-structured interview (page 6)? Were they asked again about relevance of comprehensibility of each item, and the comprehensiveness of the items?	Yes, there were asked about the relevance and comprehensibility of the items.	No changes required.
	A factor analysis should only be conducted on items that are based on a reflective model. Is this a reflective or a formative model? When reading the items, I'm not sure whether it would be a reflective model and would like to read a reasoning about it (see for explanation e.g. Jarvis https://www.jstor.org/stable/10.1086/376806?seq=1#metadata_info_tab_contents)	We have performed tetrad test to find out whether it is a reflective or formative model. We found that the comparison of intercorrelations between pairs of errors are zero indicating that the set of non-overlapping tetrads vanishes.	No changes required
	The results of the factor analyses informs us on how to add items into scores; only items within factors should be added, and not a total score across factors should be used, as this is not the fit of the model. Moreover, internal consistency should not be assessed on items that do not together form a unidimendional scale. As the Cronbach alpha likely increases when more items are involved (as is the case when it is calculated for the whole set of items), it is very likely that each of the Cronbach alpha's of the three unidimensional scales are (much) lower. Perhaps even too low, meaning that more items should be added in the subscale. The authors should provide the Cronbach alpha's for the three factors. (I disagree that a Cronbach alpha of 0.8 refers to 'very good' internal consistency - as is stated in the discussion).	As suggested, we have reported separate Cronbach alpha for the three factors and found it to be 0.80 for the factor with items on breastfeeding practices and 0.74 for factors with items on general breastfeeding benefits and 0.52 for specific hormonal breastfeeding benefits. We have also removed the term very good and replaced it with acceptable.	Page 12, line 183-185
	The final set of items is provided in the Tables. However, I have some concerns on the phrasing and use of jargon. Is the exact wording used of the items, or are they shortened in the Tables? Many of the questions are not correct, i.e. 'whether the breastfeeding promote child to mother bonding?' is not a proper sentence. What is the stem of the items? is it 'do you know if…'? and if so, I can answer the question with 'yes', but are my ideas about it correct? Some items seem to be suggestive (e.g. items 6 and 7; if you ask, I guess it is probably true?). How is this guessing factor taken into account? Does the target population understands words like 'immunity', 'calorie', 'protein', 'uterine involution', and 'lactation'? what are the response options of each of the questions? Is the first question an open question, and how is this used in the scoring?	We understand the concern of the reviewer. We have actually shortened the question for the purpose of Table while the exact question had the terms “do you know if”. All the questions had three responses allowable except question	No changes are required.

		1: Yes, No and Don't know. Yes means it is correct answer. For the first question, the options were mother, baby, both mother and baby and don't know. We have actually translated it into the native language in a way that patient understands and we have clarified the same during initial piloting, where we assessed the difficulty of the terms used and we found the results to be satisfactory. We sincerely hope for reviewer understanding in this regard.	

2nd Editorial decision
08-Jan-2022

Ref.: Ms. No. JCTRes-D-21-00097R1
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Dear authors,

I am pleased to inform you that your manuscript has been accepted for publication in the Journal of Clinical and Translational Research.

You will receive the proofs of your article shortly, which we kindly ask you to thoroughly review for any errors.

Thank you for submitting your work to JCTR.

Kindest regards,

Michal Heger
Editor-in-Chief
Journal of Clinical and Translational Research

Comments from the editors and reviewers: