Author's response to reviews

Title: Identifying common impairments in frail and dependent older people: Validation of the COPE assessment for non-specialised health workers in low resource primary health care settings

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Address to Editors:
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Dear Editor,
We would like to thank you very much for considering our manuscript entitled: “Identifying common impairments in frail and dependent older people: Validation of the COPE assessment for non-specialized health workers in low-resource primary health care settings ”, for publication as an original article.

Please see my responses to the reviewer’s comments in detail below. I will certainly happy to give more clarity if necessary.

Major Compulsory Revisions

The type of older patient should be described, even briefly, in either the methods or results section of the abstract. Perhaps include median age, sex, percentage living alone and country/city studied. The abstract gives the reader no idea about the sample included or how it was sampled.

My response: I have mentioned the sample size in the abstract. Please see the method section.

Further, “local physicians” should be clarified. It seems they were as the CHWs were described in the title also “non-specialised”.

My response: I have clarified this in the revised manuscript.

The conclusion of the abstract should include some mention of the limitations later highlighted in the discussion in the main text, namely that the neither the COPE nor EASY-CARE scale are gold standards, limiting the ability to draw conclusions about the utility of the instrument and thereby necessitating the need for further validation.

My response: I agree, COPE and EASY care do not show high sensitivity, but as for as utility is concerned, this study clearly demonstrated that COPE was highly feasible to administer in low resourced primary health care settings and received high acceptability among community health workers.

Minor Compulsory Revisions
“Modest” agreement should be defined by a range in the results section of the abstract. From my reading of the results later in the main text, “weak-modest” would be more accurate. Whether differences in the prevalence of impairments were significantly different should also be included. In the conclusion, I’m not sure that effective is the right word to use. I agree that it is feasible.

My response: I have included the range for modest agreement. Removed the word effective from the conclusion. We would like to retain the word modest agreement.

Minor Compulsory Revisions

The tone of the introduction is a little too general. Some facts and figures about the demographics and if known, the prevalence of co-morbidities, of older adults in Goa & India should be provided. This will improve the accessibility of the manuscript to international readers not familiar with the region.

My response: We have cited relevant papers that described the prevalence of comorbidity in the Indian population. For the introduction, we would like to orientate the readers on the health system problem, which is relevant for this study.

Methods

Major Compulsory Revisions

The methods are described in great detail. While it is very well written, it is overly long, distracting and perhaps arguably unnecessary as these instruments are commonly used in geriatric practice. I suggest shortening the description of the individual components of the COPE and the evidence behind them. This could be provided in an appendix.

My response: we added sufficient detail as requested by other two reviewers who reviewed the manuscript. I agree, we this given in great detail, but this much may be required for reader to understand the results.

Please clarify in detail who the clinicians were and what level of experience/training they had.

My response: I have described the details of the clinicians (their experience and training) in the method section.

Was any attempt made to assess inter-rater reliability or test-retest reliability?

My response: We did not attempt to assess inter-rater reliability or test-retest reliability.
How was the sample size calculated, was a power calculation performed?

My response: This study was conducted in the preclinical stage of cluster randomised clinical trial. Therefore, the sample of N=150 was estimated for main clinical trial which was carried out after this study. The sample size calculation for this stage of work is as follows: A sample size of 60 in each of the Phase 2 intervention component exploratory trials will allow me to estimate a proportion of 80% with a standard error of 5% and a proportion of 50% with an SE of 6%. A standardised change score (representing the likely effect size in the intervention group) could be measured with an SE of +/- 0.13 – since this has been computed on units of standard deviation, it does not vary according to the outcome or the observed effect size. I believe that this degree of precision is adequate to be used to inform the design and methodology for a subsequent definitive randomised controlled trial, and Dr Michael Dewey (a senior trials statistician in our Department) has confirmed this to be the case.

Minor Compulsory Revisions

Clarify why an interval of two weeks was selected between the COPE and EASY-CARE assessments or was this the median duration to follow-up?

My response: This is median duration of follow-up. This study was carried out in real world (primary care settings). Health workers were functioning in 14 sub-health centres and only two medical doctors visit these centers on alternative days. Therefore, we planned to complete the follow-up visit within two weeks given the workload of medical officers.

Please state when the study took place.

My response: Yes, we mentioned in the method section.

The methods used to analyse the qualitative data should be included. Were categories & codes developed. These are not included in the appendix either. The numbers of CHWs and participants who responded and how these were selected for inclusion in the qualitative analysis should be described.

My response: I have a method applied for analysing qualitative data in the data analysis section.

Results

Major Compulsory Revisions

Describe how sub-health centres were sampled/selected.
My response: Except one, we selected all sub-health centre functioning under the PHC in Goa. One sub-centre was excluded due to practical reasons as one of the health workers was on maternity leave during the study period.

Define “consulted”.

My response: We changed this word “consulted” to referred.

Were there any other inclusion or exclusion criteria? Define family record. If sampling included “recollections of family visits” were any systematic approaches to sampling conducted? Were records selected consecutively or randomly using a defined method. If not, this should be included as a limitation and a potential source of bias (recall bias at the least).

My response: As this was pragmatic study, which looked at issues within the public health care system. We followed indicated screening and training for the health workers were mainly orientated on the nature of problems and pattern of presenting symptoms experienced by frail and care dependent older people.

How were patients defined as frail? There is no consensus on a definition of frailty so without using a validated frailty or dependency instrument it is difficult to suggest the sample was frail or dependent a priori. Why were these the main target?

My response: we have operationalized the frailty in Low and middle-income countries context in my earlier publication in BMC medicine (http://www.biomedcentral.com/1741-7015/13/138). WE found strong evidence for many indicators measured in this study for their association with premature mortality and dependence. Given the level of need for care and bed and house bound status, we are certain that majority of our participants are frail and care dependent.

The results suggest that this was indeed a very frail population. Would it not have been important to include some subjects representing a cross-sectional “snap-shot” of the older adult population to more accurately assess if the COPE battery was able to identify people with deficits from those without? Again this is a potential limitation of the study.

My response: Performing cross sectional study was not our intention. This is health system research; we agree that there are limitations. But we also need to keep in mind that perfect epidemiological study may offer very limited practical implication for changing health system behaviour and practice.

How long did the COPE assessment take compared to the EASY-CARE/physician assessment? Were the times presented for the COPE recorded in practice or estimates based upon pre-testing?

My response: we have mentioned in the appendix attached with the paper.
Please clarify if the other aspect of the COPE, section 4, was assessed and if not why not.

My response: other aspect of COPE was assessed.

Minor Compulsory Revisions

The results note that 82% had care needs (line 334). Please clarify how/who determined this. Similarly, it is suggested that 35.5% needed care much of the time. Again, please clarify what this refers to.

My response: Care dependency (whether the participant needed no care, some care or much care) was ascertained through a series of open-ended questions administered to the informant. I have included in this information in the method section.

I would suggest that in line 385 in the section exploring the concurrent validity of the COPE that the correlations are “weak to moderate” at best.

My response: We would like to retain this as moderate.

Discussion and Conclusion

The discussion is balance but many of the potential limitations relating to the methods, as described above, are not considered.

My response: We have discussed the main limitations that are essential for readers to understand the results.

Minor Compulsory Revisions

I think some of the domains of the EASY-CARE/Clinician assessment were not comparable to the COPE assessment. In particular, I think the use of a standardised cognitive screen versus a selection of short questions seems unbalanced. I think this might account for differences in the prevalence of cognitive impairment between the two assessments and should be considered as a limitation. Were the clinicians allowed to do any cognitive screening test, if so could the results of this be obtained and compared to the CHWs scores. This sample includes those with high levels of multi-morbidity and apparent high levels of dependency and frailty. It should be considered in the discussion that the results of this study suggest that in such a population there is little advantage to pre-assessing patients, particularly given the at best modest correlation/agreement between CHWs and physicians, albeit neither are specialised/sufficiently trained to assess frail older adults. While conflicting with the hypothesis it is nevertheless a potentially valuable observation. Instead it could be argued that the COPE assessment could be performed after a short pre-screen in those unlikely to be benefit from
more detailed assessment but still requiring some basic assessment/screening. A frailty screen or a risk-prediction instrument used in conjunction with the COPE might therefore be more productive/targeted. Otherwise I suggest that if used in this fashion, it will only duplicate work as some of the CHWs may have alluded to. This could be included as a direction of further study. This model has been used elsewhere e.g. the InterRAI assessment in the community and more recently the CARTS project which uses the RISC screen (BMC Geriatrics 2014).

My response: I think the research questions answered in this paper are relevant for influencing primary care practice. The measure selected for COPE has been already proved to be sensitivity enough to identify older people with specific impairments (references were cited in the paper). However, the real world question, whether existing community health workers who are functioning in public health system and loaded with responsibility of 20 national programme and targeted intervention, can perform assessment and identify older people with care need. This question was never answered in any literature from developing countries so far. Therefore, the result of the study showed that it is feasible to employ existing professionals to offer minimal care for older people in high need for care. In the follow up (manuscript under preparation) we have also trained the health workers to provide nutritional and other intervention for older people and found significant benefit in improving functional ability of older people in low resourced health care settings. I think, this study should not be viewed as classical epidemiological study rather as study that answers real world questions that are relevant for changing primary care policy a

Sincerely,

**Corresponding author**

Dr.A.T.Jotheeswaran