Author's response to reviews

Title: Specific barriers to the conduct of randomised clinical trials on medical devices

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Reviewer #1: The manuscript is a systematic review of barriers for randomized clinical trials on medical device. In addition to published literature on the subject, internal communications of an organization (ECRIN) were also considered. The listing of various barriers and description of each barrier should be useful to those interested in the field of medical device research.

The review is primarily descriptive with no quantitative input (no meta-analysis) - this is unclear from the title. It would help to state this upfront in the title.

>>The present review is similar to the rest of the series on general barriers, rare disease and nutrition studies (which we also call systematic reviews). We suggest keeping the term, and have added a line that this is a systematic review of barriers towards the conduct of trials on medical devices and not an intervention-related systematic review. Furthermore, systematic review is a research methodology and not linked with only meta-analyses, although systematic reviews of diagnostic tests, prognostic markers, and intervention do contain meta-analyses.

The discussion on 'acceptability' is unclear and can be improved. In particular, the distinction from 'operator experience (learning curve)' is not fully clear. It would help to state this better.

>>We have made some word changes to improve the discussion as suggested.

It may be useful to refer to 'Trial registration' and 'making trial data available' in the manuscript. Trial registration is a standard requirement in the field of pharmacological trials and should be useful for device trials too. Similarly, the need to make trial data available for secondary analysis is being adopted by medical journals and should be alluded to in relation to medical devices too.

>>We have referred to 'trial registration' and 'making trial data available' in the text as suggested (see ‘transparency’).

Reviewer #2: Neugebauer et al. present "Specific barriers to the conduct of randomised clinical trials on medical devices" a mixed methods systematic and narrative review. The authors are well-known clinical trialists and the rationale to conduct and present this topic is given and lies within the scope of TRIALS. The methods used are solid and the presentation of the systematic literature search is adequate. The identified barriers to conduct RCT with medical devices are accurate.

>> We thank the peer reviewer for the positive comments.

I have only two concerns which should be addressed:

1. Clearly state in the manuscript, that this is a series of articles.

>>We have now improved the language to make it even more clear that this review is one out of a series articles addressing the barriers towards conducting randomised clinical trials.

>>We thank the reviewer for this highly relevant perspective. We have discussed the issue accordingly (see ‘outcome assessment’) and included the reference as suggested.