**Reviewer’s report**

**Title:** Development of a core outcome set for orthodontic trials using a mixed-methods approach: protocol for a multicentre study

**Version:** 0  **Date:** 15 Jun 2017

**Reviewer:** Cláudio Leles

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This is a very interesting study protocol that addresses an important limitation in RCT in dentistry. Poor reporting, lack of standardized outcome measures and the selection of inappropriate outcomes make it difficult any attempt to combine data in systematic reviews and meta-analysis and limit the whole potential of well-conducted clinical studies to provide valuable information for patients, healthcare providers and health managers.

The relevance of this issue in Orthodontics was clearly summarized in the introduction, considering both the ethical and economic aspects of clinical research in health sciences.

Some minor comments that should be addressed by authors:

1 - The aim of the first stage (scoping review) should be clearly stated - this is mentioned only in the abstract. In addition, a brief description of the main characteristics of a scoping review (and how it differs from a systematic review) would be useful for readers to understand that why it was chosen as the hypothesis-generating strategy for this study protocol.

2 - Please give a more detailed information about the Study Advisory Group (definition, components, duties...).

3 - The rationale for adoption a mixed-methods approach should be considered in the discussion section, reinforcing the complimentary aspects of the different steps of a multimethod research. The use of a quantitatively driven approach may also be justified, considering its advantages to provide more complex answers to the research questions, and by using high quality qualitative data derived from well planned data collection and analysis.
**Level of interest**  
Please indicate how interesting you found the manuscript:  

An article of importance in its field

**Quality of written English**  
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Acceptable

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**Statistical review**

Is it essential that this manuscript is seen by an expert statistician? If so, please give your reasons in your report.

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