Reviewer's report

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

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Reviewer: Amal Idrissi Janati

Reviewer's report:

This study aims to standardize outcome measures in orthodontic trials, it relies on a mixed methods approach. The manuscript is well written. I only have very few comments and I also need that authors clarify these following points:

-I suggest to remove the abbreviations from the abstract (NHS -line 9 and COMET -line 36) and replace them but the whole terms/sentences.

-In the background:

Line 25: The abbreviation "NHS" appears for the first time in the text, but has not been defined before. So replace by: National Health Service (NHS)

In the second paragraph, the authors show the relevance of standardizing outcomes for effectiveness and intervention research (4th paragraph, which is very pertinent to highlight the need for their study. However, authors also mention the disadvantage of using the IOTN for defining eligible patients to NHS orthodontic treatment (2nd paragraph): An opinion that I approve completely, but I don't see how the results of this study will be useful in changing that issue? It looks like the study defines the orthodontic outcomes from patients and their parents' perspectives. However, the need of orthodontic treatment depends on the the clinical evaluation, not on the patient perception only. I think that patient perception is specially important to know what patients expect from a treatment, so we can take their expectations into account as clinicians and researchers. I may be wrong, but I have a real doubt that NHS will rely on these kind of outcomes, rather than clinical criteria, to establish its eligibility criteria for orthodontic treatment.

-Methods/Design:

For the first paragraph of this section (line 56-58), that is related to ethical approval: I suggest to move it to the end of the section. First, the reader has to have an idea about the methodology used in the study, to justify the ethical approvals that were needed/obtained.
Stage 1: Scoping review: In the section Participants (Line 15), I suggest to specify either a range of age or at least the maximum age for the participants.

Stage 3: Delphi surveys - Parents and young people sample (line 29): are these participants (parents and children) different from the ones who participate to stage 2? it's not clear here! Also, since this stage 3 will provide quantitative data for quantitative analysis, did you estimate a sample size for this stage 3 (for both groups: Clinicians and parents-young people)?

Also, authors will rely on the SAG in different steps of the study, is it possible to clarify who are the members of SAG (are they researchers and experts only, or also patients)?

The last paragraph of stage 3: Final data analysis: is the classification that will be used for the consensus based on some previous research? there is no reference.

Stage 4: Consensus meeting: About the first sentence line 13 "Finally, consensus meetings will be held with all stakeholders involved (patients, parents,clinicians and commissioners)". All along the text before, I didn't see the commissioners being part of the study procedures. I understand that researchers may involve them when the study comes to this stage (4). But, even in this part, it's not explained how they will be part of the study. There are no details about which commissioners will be participating, and how they will do? In fact, the use of the term of "stakeholders" in the manuscript will be inappropriate and confusing if only parents, children and clinicians will participate to the study.

Depending on the authors' answer to these question, it may be necessary to review the table 1, because it's mentioned in the last line Consensus meeting (service users, providers and policy makers)

- List of abbreviations: The is no need of having abbreviations for some sentences that won't be mentioned more that once in the manuscript. It's the case of: BOS; CCT; CENTRAL; CINAHL; CSGBI. So, please remove these abbreviations from the list and from the text.

For the abbreviation "MOMENT", it's also written mOMEnt in other places in the text: please write it in one right way throughout the text

For RCT, in the paragraph Stage 1, line 12, remove Randomised Controlled Trials (RCTs), let only RCTs, because the abbreviation was already introduced in the text before (the second page of background section,line 3: Specifically, randomised controlled trials (RCTs)in orthodontics published between 2008 and 2012 were analysed....)
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