Author's response to reviews

Title: Development and Feasibility Testing of Decision Support for Patients who are Candidates for a Prophylactic Implantable defibrillator: a study protocol for a pilot randomized controlled trial

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Author's response to reviews: see over
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Trials
Editors-in-Chief
D. Altman, C. Furberg,
G. Grimshaw, P. Rothwell

Re: MS 1261793639106257

Title: Development and Feasibility Testing of Decision Support for Patients who are Candidates for a Prophylactic Implantable Defibrillator: a study protocol for a pilot randomized trial.

Dear Editors,

Thank you for reviewing and providing comments to our manuscript. We have considered your comments carefully and addressed each of them as outlined below. All changes to the manuscript are highlighted and referenced by line number.

1. Reviewer Comment:
Study outcomes section largely repeat information elsewhere. Recommend removing & incorporating all information into other sections.

Response:
Thank you for this recommendation. We have removed the study outcomes section (lines 157-169). The content (where duplicated) remains in the methods section (lines 189-198, 343-345).

2. Reviewer Comment:
Visit – 1 – why will usual care group not complete “values”

Response:
The measurement of values associated with the ICD is embedded in the PtDA. Therefore, only the intervention group completes the values section after having had the chance to review the ICD facts, risk, and benefit information presented in the PtDA. At our centre, the usual care group does not receive information in a structured manner and we did not want to pose questions that patients may not be able to address or that could cause concern. We added a “Health / Personal Priorities” survey to capture patients’ priorities at the time of their baseline visit without asking ICD specific questions (see Figure 1 and line 325 in the manuscript). Both groups complete these questions.

3. Reviewer Comment:
Visit 2 – grammar issue in parenthesis in 2nd sentences.
Response:
Thank you. We have inserted the word “weeks” into the sentence (line 337) to correct this.

4. Reviewer Comment:
Visit 2 – why does the usual care group not complete the prep to decision making & some other measures.

Response:
Thank you for this question, we can clarify. The preparation for decision-making questionnaire is intended for the intervention group because it asks patients specifically about the PtDA. The usual care group does not receive the PtDA and therefore cannot comment or complete the Prep survey. Aside from the value items discussed above and content that comprises the steps within the PtDA, we collect the same material from both groups.

5. Reviewer Comment:
Reduce information in discussion that has been included in other sections.

Response:
We have removed information from the discussion that has been included in other sections as suggested. The following content was removed:

Line 415, To develop the decision aid we are guided by the quality criteria put forth by the IPDAS[24] framed by the Ottawa Decision Support Framework[45].

Line 423, As outlined in the protocol, the study has three steps, 1) decision aid development, 2) acceptability testing of the decision aid with experienced ICD recipients and families, and 3) pilot testing of the decision aid with new ICD candidates to determine the feasibility and sample size requirement of a future clinical trial. Pilot RCT outcomes include decision quality (knowledge, values, decision conflict) and HRQL.

Line 428, (necessitating an earlier arrival to clinic to meet with the RA or mail)

Line 435, The decision patients must make to receive an ICD or continue medical management should occur after careful deliberation is given to the risks and benefits balanced with what patient’s value.

We hope that these edits are to your satisfaction and look forward to hearing your response.

*Two additional edits to lines 276 & 343 were included to correct spacing.