Author's response to reviews

Title: Internet based patient education improves informed consent for elective orthopaedic surgery: A randomized controlled trial.

Authors:

Andrew Fraval (afraval@mac.com)
Janan Chandrananth (janan.chandrananth@gmail.com)
Yew M Chong (yewming.chong@hotmail.com)
Phong Tran (contactphong@gmail.com)
Lillian S Coventry (lillianc@student.unimelb.edu.au)

Version: 4 Date: 25 December 2014

Author's response to reviews: see over
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Janan Chandranath (janan.chandrananth@gmail.com)
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Lilian S (lillianc@student.unimelb.edu.au)

Version: 3 Date: 25 November 2014

Author's response to reviews: see over
The Biomed editorial team,

Object: Internet based patient education improves informed consent for elective orthopaedic surgery: A randomized controlled trial. Dr Andrew Fraval et al.

Thank you for consideration of our manuscript for publication in your journal. We greatly appreciate your review and have found your comments useful. We have reviewed the above manuscript according to your reviewer’s comments.

Reviewer 1: Mark Cote

Version: 3 Date: 25 November 2014

Reviewer’s report:

Major Compulsory Revisions

I commend the authors on undertaking a randomized trial to examine Internet based education to augment informed consent for operative procedures. This is an important issue and conducting a randomized trial is not easy to say the least. My rationale for listing comments 1-3 in this section is that if addressed, they will strengthen the manuscript as a whole.

Comment 1: The selection of a randomized clinical trial study design helps strengthen the validity however there are areas that I believe need to be improved to get a complete appreciation of the strength of the study. Line 115: I’m not sure how the sequence of randomization was generated. I understand STATA was used but was it simple randomization? Block randomization? Line 122: Please elaborate on the method of facilitation for the experimental arm. For example, Was their oversight during viewing of the website? Did the viewing of the website take place on site? Were there measures in place to ensure the website was viewed? Was assistance available and or provided at any point? How long after viewing the website did they fill out the survey? Were the research personnel present during any part of this process? These details go to the validity of your study as influence by the research personnel may impact the results. Without a more detailed description, I’m concerned the reader will not have the information needed to make a decision on the validity of the results.

Response:
Line 115: Amendment made to clarify method of randomization.
Line 122: Amendments have been made to clarify the points raised by the reviewer.

Comment 2: Participants undergoing a wide array of procedures were eligible for the study. This included patients undergoing arthroscopy and ACL reconstruction to lower extremity arthroplasty (Lines 108-109). These procedures likely encompass a wide range of ages and experience and comfort with the Internet. Was a subgroup analysis for example by age or procedure considered? Are you able to report the proportion of participants from each of these procedures both for the entire cohort as well as a breakdown between the groups? We’re they balanced? A subgroup analysis or discussion that subgroups were considered as well as their potential impact would be helpful.

Response: Subgroup analysis was performed for both variables of the operation and education level. There was no difference between the two arms of the study across these two variables. I have included a table here to demonstrate this subgroup analysis. I have also made reference to this within the results section of the manuscript. We did not perform an evaluation of the outcome measures across the subgroups as the numbers within each subgroup were not large enough to reach the target of our power calculation. As such, a type II error could not be ruled out and this type of evaluation is statistically insignificant.

<table>
<thead>
<tr>
<th>Education level</th>
<th>Internet</th>
<th>Control</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No formal education</td>
<td>4.85% (n = 5)</td>
<td>3.70% (n = 4)</td>
<td>0.682</td>
</tr>
<tr>
<td>Primary school</td>
<td>10.68% (n = 11)</td>
<td>8.33% (n = 9)</td>
<td>0.562</td>
</tr>
<tr>
<td>High school</td>
<td>47.57% (n = 49)</td>
<td>49.07% (n = 53)</td>
<td>0.826</td>
</tr>
<tr>
<td>Trade or Tafe certificate</td>
<td>14.56% (n = 15)</td>
<td>22.22% (n = 24)</td>
<td>0.152</td>
</tr>
<tr>
<td>Tertiary education</td>
<td>17.47% (n = 18)</td>
<td>12.96% (n = 14)</td>
<td>0.312</td>
</tr>
<tr>
<td>Post graduate education</td>
<td>4.85% (n = 5)</td>
<td>3.70% (n = 4)</td>
<td>0.660</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Operation</th>
<th>Internet</th>
<th>Control</th>
<th>P value</th>
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<tr>
<th>Operation</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procedure</td>
<td>Group A (%) (n = a)</td>
<td>Group B (%) (n = b)</td>
<td>p-value</td>
</tr>
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<td>-------------------</td>
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</tr>
<tr>
<td>THR</td>
<td>17.47% (n = 18)</td>
<td>20.37% (n = 22)</td>
<td>0.589</td>
</tr>
<tr>
<td>TKR</td>
<td>24.27% (n = 25)</td>
<td>20.37% (n = 22)</td>
<td>0.497</td>
</tr>
<tr>
<td>ACL</td>
<td>10.68% (n = 11)</td>
<td>13.89% (n = 15)</td>
<td>0.478</td>
</tr>
<tr>
<td>Knee arthroscopy</td>
<td>33.01% (n = 34)</td>
<td>28.70% (n = 31)</td>
<td>0.4965</td>
</tr>
<tr>
<td>Shoulder arthroscopy</td>
<td>14.56% (n = 15)</td>
<td>16.67% (n = 18)</td>
<td>0.674</td>
</tr>
</tbody>
</table>

Comment 3: Line 156: Statistics- if patients were randomly assigned to groups, then inferential statistics in Table 1 comparing baseline variables is not necessary and discouraged. The question isn’t whether the differences are due to chance or randomness (you already know that they are as you randomized them to the study groups) but rather whether the differences are clinically important. Also, the Chi Square is not the appropriate test to compare a continuous variable and Table 1 suggests that a two-sample t test was used. Lines 173-174 may need to be rewritten as they reference statistical significance rather than clinical significance.

Response:

Regarding table 1: This has been excluded from the manuscript and reporting on statistics amended to reflect clinical rather than statistical differences.

Regarding the Chi Square reference to age. This is an error and has been amended to reflect the actual statistic used. The Chi Square test was used for gender.

**Minor Compulsory Revisions**

Comment 3: What you’ve shown is the website is useful for immediately improving the quality of informed consent as it pertains to risks of surgery. In the Discussion starting at Line 207), the utility of the website is in part framed as a resource for patients while they wait to a specialist. The referral to a specialist insinuates that the treatment plan has not yet been established. This may seem small but your study is designed around the idea that the website can augment the traditional informed consent process. I agree that having a website with accurate information is important but your findings should be discussed in the context in which the Internet education was provided.

Response: I agree our research in no way investigates the process we have outlined in the discussion. Is the place for the discussion section to raise potential further research questions to be investigated in the future which relate to the
current study? I can see that there were statements mate with language which would suggest that these potential ideas are in fact true. The language has been amended to reflect the hypothetical nature of these statements with an additional question of further research added at the end of this paragraph. We hope that this is a satisfactory response to the reviewer’s suggestion.

Comment 5: Lines 183 to 186: are these meaningful between group differences?

Response: I think that this is a difference which has reached a significance of <0.05 and as such should be noted. I agree that this mass effect is not of the magnitude that represents a large improvement in satisfaction but I believe the manuscript makes reference to this fact.

Discretionary Revisions
Comment 6: Line 48. I assume this is a score out of a 100?

Response: It is a percentage so yes, it reflects a score out of 100

Comment 7: Line 69: Recommend the use of “information” over “message”

Response: amendment has been made using the term information rather than message.

Comment 8: Line 143: Recommend providing the survey.

Survey has been provided

Comment 9: Line 210: Recommend changing “message” to “information”

Response: amendment has been made

Level of interest: An article of importance in its field

Quality of written English: Needs some language corrections before being published

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests: I declare that I have no competing interests.

Thank you for consideration of our manuscript for publication in your journal. We greatly appreciate your review and have found your comments useful. We have reviewed the above manuscript according to your reviewer’s comments.
Internet based patient education improves informed consent for elective orthopaedic surgery: A randomized controlled trial” is an interesting to read manuscript on improving informed consent in orthopaedic surgery.

Overall the manuscript is well written and the data presentation appears to be sound. Nevertheless there are some major revisions to be addressed before considering publication:

Title:
Nothing to add

Authors:
For the reviewer it seems uncommon to declare all authors to contribute equally. The reviewer is of the opinion, that only first and last authorship may be shared.

Abstract:

Background (lines 26-33): Please shorten

Response: Background shortened

Methods (lines 35-44): Please be more precise

Response: Amendments made to attempt a more precise description of methods.

Conclusion (line 54): What does the authors mean with “properly designed website”

Response: Amendment made to avoid ambiguous statement.

Background:
Lines 62-64, 64-67, 68-72, 72-74, 76-77, 93-95: Please proof with citations.

Response: Citations provided

Please add a section on different approaches to obtain informed consent.

Response: Section on different approaches added.
Line 92: The reviewer is of the opinion, that [5] is a not appropriate citation.

Response: I believe it is appropriate to provide a link to the website which has been utilised. The BMC musculoskeletal recommendations on citations relating to websites make the following statement:

All web links and URLs, including links to the authors’ own websites, should be given a reference number and included in the reference list rather than within the text of the manuscript. They should be provided in full, including both the title of the site and the URL, in the following format: The Mouse Tumor Biology Database [http://tumor.informatics.jax.org/mtbwi/index.do].

Could the reviewer provide more information on why this is not an appropriate citation?

Lines 95-97: What is so special about the setting of your study?

Most interventions investigating consent augmentation have been carried out by either a single surgeon or investigating the usefulness of consent augmentation of a single procedure. Our research is the first that I am aware of which has investigated consent augmentation at a departmental level with patients of multiple surgeons being waitlisted for multiple procedures. It more closely represents a generalised practice of informed consent augmentation within a public orthopaedic department. This is unique to our study and I am unaware of any other study conducted in this manner.

Please add your question to be answered with this study and define your hypothesis(es), this is fundamental.

Response: Question and hypothesis has been added.

Methods:
Lines 125-127: Please proof with citation(s).

Response: Sentence has been amended and citation provided for the guiding principles of design of the website

Lines 130-131: The reviewer appreciates your work, but would rather expect a more detailed description on the ratio behind the website, than the time it took to complete the project. Please change.

Response: I presume the reviewer meant ‘rational behind website’? This section has been amended. I thank the reviewer for their interest in our website. The driving force behind this project is that our orthopaedic department is seeking
ways to better prepare our patients for their operations. We are a public hospital which means we receive funding from the government and health care is provided to our patients free of charge. Our hospital services a catchment area of approximately 800,000 people. It is a very diverse socioeconomic and cultural demographic. The website is an initiative that our orthopaedic department has supported with the goal of providing better education to our patients. We have designed the website with the help of medical students, orthopaedic registrars, orthopaedic surgeons, physiotherapists, occupational therapists and nursing staff. We have used patient feedback to improve the useability of the website. It continues to be improved with ongoing input from all these stake holders. The small cost of the annual server fee is provided by the orthopaedic unit. This is a very small amount of money. Other than this, the website runs from the voluntary work of all the previously mentioned stake holders. I have amended this section and hope that the information I have provided is adequate for people reading the article to be able to evaluate the website.

Please provide information about financing the project.

Response: See above response regarding the financing of the project.

Lines 134-144: Please provide your self-administered survey as a supplement.

Response: Surveys provided as a supplement

The reviewer would like to know how much (extra) time it took to provide your patients the extra education (website).

Response: We did not record the time it took patients to read the website. It certainly does represent extra time dedicated to the consent process. Unfortunately we did not record the data on how long it took for patients to read the website.

Lines 162-165: What kind of test did the authors use for power-analysis? Overall, please shorten Methods.

Response: The parameters of the power calculation has been explained within the body of the text. I'm not sure what additional information the reviewer would like outlined. Would the reviewer like the actual formula printed in the text? I am not aware of an eponymous name for the power calculation utilised.

Response to shortening the methods: Amendments have been made to shorten sections of the methods. However due to requests from other reviewers to outline details of the methodology more clearly, I the length has not been shortened overall.

Results: Nothing to add.
Discussion:

Lines 225-228: Are the authors able to proof this? Otherwise the reviewer feels this should be a hypothesis that has to be proofed.

Response: We agree that this statement is not proven and as such we have amended this to reflect the hypothetical nature of the statement.

Please include information on other approaches to improve informed consent and discuss these with your findings.

Response: Section in discussion added.

Conclusion:

Lines 240-242: The reviewer is of the opinion, that the authors missed to describe the criterias for a “properly designed website”. Please include a precise definition within the manuscript to fulfill this conclusion.

Response: This statement has been amended as we agree it is ambiguous.

Lines 243-244: The reviewer feels not confided with this conclusion. There are many ways to improve informed consent, and web based education tools are one of them.

Response: We agree this statement is overreaching and have amended it accordingly.

Competing interest:

The reviewer is not absolutely convinced about the declaration. Since several authors are obviously involved in the development of the website (besides there is no information about how this project was financed) it seems appropriate to name the authors that were involved in realizing “orthoanswer”.

Response: As outline previously, no authors have benefited financially either from the website or from this research. I have amended this section to include the authors which have contributed to the Orthoanswer website.
Authors contribution:
Who did actually write the manuscript?

Response: This has been amended and clearly stated.

References: No comment

Figures & Tables: No comment

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:
'I declare that I have no competing interests’