Reviewer’s report

Title: Patients' beliefs towards informed consent in low-risk pragmatic trials

Version: 0 Date: 28 Jul 2017

Reviewer: Maureen Smith

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This is a theoretical study comparing the acceptability of written consent vs general notification and written consent vs verbal consent. The study in the general population (of participants in Netquest, an online closed panel of individuals) was previously published. This study focuses on a subset of participants from the original study with self-reported hypertension and two low-risk pRCT for anti-hypertensive medications. The study compared each 2 consent scenarios; the tested consent with written consent in a RCT for two low-risk medications and 2 consent scenarios; the tested consent with written consent in a RCT comparing medication use take at different time points during the day.

The study contributes an interesting analysis to the understanding and use of various consents in clinical trials. The focus of the study is to understand what consent method participants in Spain will agree to for a low risk RCT. Written consent is described as possibly delaying and sometimes prohibiting RCTs. Whereas other forms of consent or nonconsent, in the case of general notification, may more easily allow for RCTs to take place and reduce selection bias. The preamble about the different forms of consent may seem to bias the population against written consent, however, this did not prove to be true based on the results. In brief summary, this study's results in patients with a mild chronic condition, hypertension, were not different from the general study of all participants.

Specific comments by section:

Abstract

Line 40, 2008 should be written out.

Line 50, the first sentence may read better by saying: As in the general public survey, most patients……..

Background

While informed consent is one aspect of the problematic issues related to recruitment of participants to pRCT, it is not the only issue. The ethical issues associated with not informing study participants thoroughly of the issues related to the trial, must also be mentioned. There is good reason for making attempts for consent to occur.
Line 75, trial should be plural

Line 76, sentence after the comma should read, ...written informed consent is asked from all participants.

Lines 79-81, the sentence is difficult to understand. Needs to be revised, particularly starting at line 83.

Methods

The methods were described elsewhere in a previously published study. The methods were appropriate for this study.

The netquest panel should be referenced with the website for readers of this article.

Line 95, 2008 should be written out (two thousand and eight)

Statistical analysis is well described and refers to the previous article in which the full analysis is described. It would have been interesting to see if the primary outcome correlated with any of the demographic characteristics.

Results

Line 151, the word any should be substituted for none.

Paragraph lines 165-169, should reference the specific table. I don't see where these numbers are coming from.

Line 194-196, should mention that this is not statistically significant

Line 197, the word pose should be replaced with face.

Discussion

Line 204, should read: ....suggests that being affected with a chronic -but easily.....

The suggestion that the age distribution had something to do with inaccurate beliefs about participating in a RCT (lines 213-220) could have been tested with the data rather than hypothesized. This should also be mentioned as a later study.

Line 221, the word do is not needed at the end of the line
I would have liked to see more discussion about why this population might prefer general notification as opposed to verbal consent. Is there something about the Spanish medical system that would make it more difficult to interact with a physician about the RCT? Other attitudes and beliefs must play a role in this finding.

The discussion about framing having an effect on responses, is significant, in my opinion. The description of the negative aspects of written consent was biased against written consent.

Line 261, should begin with the word: It

Line 268, belief should be believes

Are the methods appropriate and well described?  
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?  
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?  
If not, please explain in your comments to the authors.

Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?  
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I recommend additional statistical review

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Please indicate the quality of language in the manuscript:

Needs some language corrections before being published

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