

REVIEWS AND CHECKLIST FOR FORMATTING

RE: NRES-D-08-00008, titled "Testing an Alternate Informed Consent Process"

Reviewer Comments:

Reviewer #1: Problems Statement. This methodological brief addresses a critical issue related to the recruitment of human subjects. The author(s) address an important and critical topic that needs much attention in nursing. Since this is a short brief, there is not a need for a theoretical framework. The author(s) only cite one reference related to their statement "One of the main problems faced in conducting clinical trials is participant recruitment" (Prout, Butler, Kinnersley, Robling, Hood, & Tudor-Jones, 2003). Other authors could be cited here to indicate the degree of significance of this work. Additionally, much of the research in this area has reported concerns related to recruitment of minority subjects which is not addressed here.

Background Literature. Background literature was brief but clearly identified the importance of this area. The author(s) could use literature from bioethics which identifies issues related to informed consent in research. Also, in light of the mean age of subjects (N = 61), it might be worth highlighting research in the elderly and strategies on informed consent in this population.

Theoretical framework. Not necessary given the brief nature of the commentary.

Research design and method. Although the authors indicate that this was a nonprobability survey design, it is not clear how the author(s) determined 35 subjects would be appropriate and what was the expected percent increase in response rate that they were estimating, if any. I am assuming that this was another pilot study given the first feasibility study and low participation rate, but the authors should clarify.

Data analysis. N/A

Results. Demographics are presented as were the increase in response rate of participants. The authors stated that "In response to the flip chart, participants overwhelmingly stated that it was informative, helpful, explained the study well, and that the photographs were effective in communicating the purpose of the study." What percent of subjects here indicated this?

Discussion. The majority of the subjects in this study were White and educated but the authors do address limitations of their study and tie the literature nicely to their purpose. I might also add a sentence or two related to informed consent in the elderly population given your mean age group of 62.

Organization and style of presentation. Very nicely organized and well presented brief.

Summary: Very nice to read a well organized and significant bioethics topic of interest to nurse researchers.

Reviewer #2: In this study, the authors tested a novel strategy for obtaining informed consent for a "hypothetical" randomized controlled trial on traditional versus home based cardiac rehabilitation. In the manuscript, they correctly summarize the literature on barriers to obtaining informed consent for clinical trials and designed their intervention based on earlier evidence that extended discussion with potential subjects boosted participation rates. The authors provide a clear rationale for the present study in that an earlier feasibility study for the same project yielded a participation rate of only 22%. They go on to describe their novel strategy and its outcomes, noting that the new approach yielded a greatly enhanced, albeit hypothetical, participation rate. They also summarize participants' reactions to the strategy. From their findings, the authors make the recommendation that, among other issues, there should be future research on methods to address the format and complexity of informed consent documents, which I think is a particularly salient point. In their description of limitations, I think the authors are correct to point out that it might be easier for participants to agree to a hypothetical rather than a real study, which would require an actual time commitment. To my knowledge, the approach described in this article has not been described elsewhere, and I think it is exciting. I look forward to future articles by the authors to learn if it works in a real situation. I think articles such as this one are important because without adequate participants, even the most well-designed studies will fail.

My recommendations are primarily related to the clarity of presentation. On pg 2, line 9, I would eliminate the word, "previous" in that it is initially unclear to the reader if the feasibility study is the same one described in the immediately preceding paragraph (I assume that it is). On pg 5, line 12, I would change the word, "current" to "earlier". On page 7, I suggest moving the sentence beginning at the end of line 5 and ending in the middle of line 8 to the middle of line 12 after the word, "survival". In short, summarize the barriers to cardiac rehabilitation research first and then summarize the barriers to clinical trials. Even though it is not the primary point of the current article, I wondered if the home-based cardiac rehabilitation would be monitored.

CHECKLIST FOR STYLE

References:

For 6 or more authors, use only the first author's name with et al. (i.e., Prout et al., 2005)

Figures:

Figure 1 is not clear enough for print; provide a better image (Nursing Research does not print color figures).

Other: Please cite Figure 1 in the text.