Reviewer's report

Title: Barriers encountered during enrollment in an internet-mediated randomized controlled trial

Version: 1 Date: 4 June 2009

Reviewer: Amanda Graham

Reviewer's report:

I would like to acknowledge the contributions of Mr. Jose Moreno, a Master’s level research assistant in my research lab, in completing this review.

Overview

The purpose of this study is to identify the obstacles that potential participants encountered during the enrollment phase of an Internet-based randomized trial of a walking intervention. Identifying such obstacles has important practical relevance for other researchers conducting web-based trials and represents an important contribution to web-based implementation research. As the authors note, there have been few reports of the barriers and challenges related to online recruitment and enrollment, and thus, there is little published information to guide researchers in implementing online protocols that maximize recruitment and retention of potential participants. The use of help tickets as a source of data to address these questions is a novel approach. In general, this is a well-written manuscript. However, in order for this manuscript to benefit other researchers conducting web-based research, more detailed information about specific aspects of the study protocol are needed to better understand the barriers encountered by participants and to enable the reader to more clearly understand the results.

Major Compulsory Revisions

It would be helpful to understand more clearly at what point help tickets were generated and whether it influenced a participant’s progression to the next phase of the study. The descriptive information presented about help ticket themes and demographic predictors of help ticket generation is interesting, but the ultimate question is whether difficulties at any point during enrollment into a web-based trial influence randomization rates. A flowchart may be the optimal presentation for this kind of data. Of the 880 individuals who visited the website, only 36% (N=324) went on to be randomized into the trial. Were the other 556 people who were not randomized the ones generating help tickets? Were there differences in help ticket themes between those who were a) eligible but not consented, or b) consented but not randomized? Are there any important conclusions to be drawn here about barriers/difficulties and ultimate enrollment status?

Minor Essential Revisions
1. On page 7, please provide additional information about the enrollment process. Specifically, what information about participating in the trial was provided to potential participants on the website during their first visit? It sounds like many of the help tickets were generated as a function of unclear or missing information about the trial and specific aspects of the protocol. It would be useful to other researchers to understand what information was provided and where the potential disconnect may have occurred. For example, if general/broad information was provided in the initial invitation and on the website and detailed information about the study protocol was included only in the consent form, this would suggest that different communication strategies are needed to assist potential participants in understanding protocol specifics.

2. Also, please provide additional information about the three pre-randomization tasks. Specifically, how were participants instructed to send documentation of medical clearance? When were they told this information? What was included in the mailed study materials? Was the baseline survey completed paper and pencil and included in the mailed study materials, or were they required to return to a website to complete this online?

3. Additional information about the automated process involved in the participant management system would also be helpful. For example, from the text provided on Page 8, it is not clear how the study system or study staff determined whether contact from a participant should be designated as a new help ticket or follow-up to an existing help ticket.

4. As a related issue, what was the study protocol for responding to help tickets (i.e., respond within 24 hours, 1 week)? Is it possible that multiple help tickets were generated for the same issue for participants who were eager to enroll in the study but who had not yet received a response from study staff? Was any information collected about response times? Were all issues able to be resolved, and if not, was resolution status related to enrollment rates? This information would be useful to other researchers developing online recruitment and enrollment protocols.

5. Please provide more information about the individuals who coded help ticket content and who participated in the inter-rated reliability subsampling. Were these individuals involved in intervention delivery? How was agreement reached between the two individuals in cases where there were discrepant ratings?

6. On page 9 in the results section, it states that 18% of help tickets were generated by study staff. There is no information in the Sub Study Description that clarifies under what circumstances study staff would initiate a help ticket.

7. Were help ticket themes developed a priori?

8. The results that are reported seem quite limited. Additional questions that could be addressed with the available data include the following:
   a. Were certain issues more common in user-initiated versus staff-initiated help
tickets?

b. Were certain issues more common in phone-reported versus web-reported help tickets?

c. Were any demographic characteristics predictive of the modality of help ticket creation (e.g., web-savvy users more likely to report via web; older adults more likely to call in issues)?

9. The authors may want to include in the discussion some comment on the importance of usability and feasibility testing with the target audience prior to full implementation of a research protocol.

Discretionary Revisions

In the discussion, the authors conclude that some of the obstacles could have been avoided if there was “automated feedback regarding the participant’s status within the enrollment process.” Although this conclusion seems intuitive, it is not clear how it is supported by the data. The authors report that 48% of help-tickets involved some sort of process obstacle, defined as issues “that include, but are not limited to requests for status updates regarding where a potential participant stands in the randomization process or instructions regarding how to proceed with study, questions about when to unblind pedometers, discussion of when potential participants should start wearing pedometers, requests for more information concerning the study, etc.” Did questions about status updates represent the majority of this category? A breakdown of this 48% would help the authors to substantiate their conclusion that feedback about enrollment status would have reduced the number of help tickets.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

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

Declaration of competing interests:

I have no competing interests.