

June 28, 2011

RE: NRES-D-10-00261

Dear Dr. Dougherty:

Thank you for providing the opportunity to revise our manuscript and for agreeing to extend the deadline for our resubmission to July 1, 2011. I am writing to respond to the editor's and reviewers' comments. Below is an itemized, point-by-point response to the comments. When changes were made, the location (page #, paragraph #, line #) of each response is provided and modifications are highlighted in yellow in the text.

Comments of Editor:

We revised the sections of the manuscript to be in accordance with APA 6th Edition, reserving the discussion for evaluation and interpretation without the introduction of literature not previously included.

Comments of Reviewer #2:

Background- Some restructuring of the content of the introduction and review sections would be helpful.

Item 1: Introduction is brief. It would be helpful to move some material from the subsequent parts of the script to the intro so that the intro presents a clear, basic definition of 'fidelity of technology'	
Response: We moved material from subsequent parts of the script to the intro. Specifically we moved the content about the unique considerations for evaluating fidelity of technology-based behavioral interventions to the intro to underscore the importance of addressing these issues.	Pg 3, Par 1, L1-20

Item 2: Explain the relevance of the topic to nursing/healthcare/research worldwide	
Response: We added a statement regarding the relevance and timely contribution this work will make to the topic of intervention research.	Pg 4, Par 2, L 6-8

Item 3: Explain the relevance of topic to 'health technology assessment' and not just for complex intervention research	
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<p>Response: We considered the reviewer's suggestion to explain the relevance of our topic to health technology assessment (HTA) but decided that to do so would only confuse the readers. HTA is a multi-disciplinary field of policy analysis that examines the medical, economic, social and ethical implications of the incremental value, diffusion and use of a medical technology in health care. While HTA may be performed to advise or inform policy at any level, the primary purpose of HTA is to inform decisions relating to national, regional or local health care systems. Such an evaluation is beyond the scope of this paper that presents a framework to assess an individual's acceptance and adoption of a technology-based intervention.</p> <p>References: International Network of Agencies for Health Technology Assessment www.inahta.org/Home/; National Information Center on Health Services Research and Health Care Technology: www.nlm.nih.gov/nichsr/hta101/ta10104.html#Heading10</p>	<p>No changes made to the document</p>
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Research design/method/data analysis:

<p>Item 4: Paper does not have a clearly defined research design or data analysis section</p>	
<p>Response: We considered this paper to be a 'methods paper' based on the author guidelines for <i>Nursing Research</i>, as opposed to a regular article (original report of completed research), which is why the paper does not have a clearly defined research design or data analysis section. We clarified the purpose in the text and abstract.</p>	<p>Pg 3 Par 2, L3, through Pg 4, Par 1, L1-2</p>

<p>Item 5: It is unclear how the paper draws on research conventions.</p>	
<p>Response: As a 'methods paper,' as opposed to a report of completed research, the paper does not draw on research reporting conventions. We clarified the purpose in the text and abstract.</p>	<p>Pg 3 Par 2, L3, through Pg 4, Par 1, L1-2</p>

<p>Item 6: It is unclear how objective 1 and 2 are intended to relate to each other?</p>	
<p>Response: The reviewer astutely identified 3 possible explanations for how objective 1 and 2 are intended to relate to each other. From our perspective, the reviewer's first explanation is accurate, "... that a literature review (emphasizing discourses) was undertaken to serve as background..." to identify how technology-based behavioral interventions challenge conventions about how fidelity is conceptualized and evaluated, and to inform the development of the proposed 'intervention fidelity framework.' Therefore we stated this purpose more clearly in the introduction. While the above explanation is accurate, the authors respectfully disagree with the suggestion that the proposed framework is merely 'TAM' applied to healthcare.</p>	<p>Pg 4, Par 2, L 1-6</p>

Research design/method/data analysis-

<p>Item 7: This section should review each element of the framework and how the elements are related to each other (some of this is presented earlier in the text).</p>

Response: We added a review of each concept of the framework and how the concepts are purportedly related to each other. Details regarding how they are measured when monitoring fidelity of the Pocket PATH [®] intervention are shown in Table 1.	Pg 11, Par 2, L3-12; and in Table 1
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Item 8: Page 11 states that 'adoption' and 'enactment' are not part of the intervention fidelity, so it is unclear why they have been included in the framework.
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Response: Although adoption and enactment are not considered to be components of the proposed intervention fidelity framework, they are often included in other models of treatment fidelity and conflated with other concepts of intervention fidelity. We describe them in this paper to differentiate our use of these concepts from that of others and to describe how adoption and enactment are measured as dependent variables when testing the influence of intervention fidelity as independent variables (table 1).	Pg 3, Par 1, L 14-16; Pg 8, Par 1, L 9-13; Pg 11, Par 1, L 1-7; Pg 21, note to table 1
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Item 9: This section should clearly state that the 'delivery' element is the role of the person initiating the intervention and that other elements of the process focus on the person/patient who will use the intervention.

Response: We further clarified that delivery referred to the role of the person delivering the intervention	Pg 5, Par 1, L8-9 and 15.
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Item 10: I am uncertain why 'technology acceptance' occurs after 'receipt', it perhaps intervenes earlier and more widely than this, i.e., on whether the intervention is received (or not) through to enactment.

Response: While it is true that individuals' views on the general acceptability of technology can be assessed at any point, we measure technology acceptance after 'receipt' because we are interested in the relationship between participants' perceptions about the ease of use and usefulness, their attitudes about the technology, and their intention to use a specific technology-based intervention (as opposed to technology acceptance in general). As described by Davis, 1998, the TAM was developed to be administered after a specific intervention has been delivered and the user has demonstrated receipt, but before users have any significant experience with the system. Measuring the TAM at this point allows one to examine whether technology acceptance of the specific intervention is a predictor of an individual's actual usage (adoption) and enactment.	Pg 12, Par 2, L2-6 through Pg 13, Par 1, L1-9
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Item 11: There needs to be a discussion on how the proposed framework (as a whole) compared with existing 'non-technology' or generic fidelity frameworks (e.g., Carroll et al, 2007), somewhere in this paper.

Response: We introduce other models of fidelity early in the paper and begin the conclusion by comparing the proposed framework with existing generic fidelity frameworks.	Pg 14, Par 2, L1-10
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Item 12: Limitations of the framework and its derivation should also be discussed.	
Response: We added a discussion of possible limitations and cautions to the conclusion.	Pg 15, Par 1, L4-6

Exemplar section-

Item 13: The outline of how the framework can be applied to Pocket PATH was very helpful and clarified what the different elements of the framework meant. I was uncertain, however if this section was a research proposal or a hypothetical example- this should be clarified.	
Response: We presented our multi-dimensional plan to evaluate the intervention fidelity of the Pocket PATH® intervention as an exemplar not as a research proposal. The exemplar is intended to provide practical guidance to other researchers about how to apply the proposed framework to evaluate the fidelity of their specific technology-based behavioral interventions.	Pg 12, Par 2, L1-3

Item 14: I also do not know if this section contains a report of previous psychometric testing or if there is presentation of new psychometric information found through exploratory empirical research. (if the latter is the case, then empirical conventions and standard for writing up evaluation of psychometric scales should be included in this section).	
Response: We included previous reports of the psychometric properties of the TAM as evidence of their reliability and validity and therefore acceptability for use in our proposed fidelity evaluation plan.	Pg 13, Par 1, L1-14

Item 15: This text has a high standard of writing and expression, a few sentences were difficult to understand-e.g. page 10, sentence that runs from line 10-13.	
Response: We divided several run on sentences throughout the paper.	Pg 10, Par 1, L 8-10

Item 16: Page 6 line 2-5 could be contested' pharmacotherapy adherence is more complex than dose delivery.	
Response: The authors accept the reviewer's point that pharmacotherapy adherence is more complex than dose delivery, therefore we omitted reference to such a statement from the manuscript.	Pg 6, Par 3, L 9

Comments of Reviewer #3

Item 17: The concept ' fidelity of technology behavioral intervention' loses focus once the author begins to address the evaluation components. The confusion may stem from the author's point concerning the need to customize, thus can fidelity actually occur in all studies using the same definition and method?	
Response: A final paragraph was added to this section to reduce confusion about the need to include universal concepts (delivery, receipt, technology acceptance) in the model yet customize the monitoring activities to the specific intervention.	Pg 11, Par 3, L1-3 through Pg 12, Par 1, L1-3

Item 18: While the author includes the importance of the human dimension and individuality, it is almost in a challenging manner. For a behavioral intervention to be meaningful, alternative and individuality is crucial. We are not all one in the same.	
Response: Statement was deleted	Pg 10

Item 19: The theoretical model needs to be tested and better explained before application.	
Response: We agree that model testing is important, but the purpose of this paper is to share the rationale for proposing a different model of intervention fidelity for technology-based interventions and to provide an exemplar for applying the framework to evaluate intervention fidelity as a 'thought and methods paper.' Model testing is currently underway. Data regarding delivery, receipt, and technology assessment are currently being collected as part of a randomized, controlled trial to evaluate the efficacy of the Pocket PATH intervention in promoting self-care behaviors. These data will be used to empirically test the relationships that are purported in the framework.	Pg 11, Par 2, L3-7; Pg 12, Par 1, L14-18; Pg14, Par 2, L8-11

Item 20: Much time is spent on defining and refuting prior technology fidelity, with less than a page focused on the exemplar.	
Response: The exemplar section has been expanded to 2 full pages and includes more detail regarding the concepts, measures and purpose of implementing the intervention fidelity evaluation plan for Pocket PATH.	Pg 12-13

Item 21: It is not clear how the technology was evaluated and there is little focus on the evaluation method.	
Response: It is not clear what the reviewer is referring to when asking how the 'technology' was evaluated. If the reviewer is referring to how the Pocket PATH intervention was evaluated, we have added a statement about the current RCT that is underway to evaluate the efficacy of the intervention. If the reviewer is referring to how the intervention fidelity framework will be evaluated, we have added a description of how data regarding the concepts of intervention fidelity (delivery, receipt and acceptance) are being collected during the current RCT to test the relationships purported in the model and to draw conclusions about the consistency, validity, and effectiveness of the Pocket PATH® intervention.	Pg 12, Par 2, L14-18; Pg 14, Par 2, L8-11

Item 22: Definitions and measures in table 1 are very good; however, more time needs to be spent in the article discussing these findings.	
Response: Table 1 is intended to present the components, definitions and measures that will be used to collect data to evaluate the intervention fidelity of the Pocket PATH intervention. We are not presenting findings in this paper.	No changes

Item 23: Many of the references are outdated and extend longer than the customary 5 years for a journal article of this caliber.

Response: Selected older references were deleted because they were not integral to the paper. Some selected older references were retained because they are integral to the paper and/or classic references in the area of intervention fidelity (Bellg, 2004; Carroll, 2000; Dumas, 2001; Dunesbury, 2003; Moher, 2001; Santecroce, 2004; Waltz, 1993), or technology acceptance and social context of technology (Bijker, 1987; Davis, 1989; Dixon, 1999; Goodhue, 1995; Morris & Dillon, 1997; Pinch, 1987; Pincher, 1987; Rogers, 1983; Winner, 1993)

Removed selected old references from paper and reference list.

Item 24: Title page- supply title and credentials for each author

Response: Title and credentials for each author added to title page

Pg 1

Item 25: Abstract- provide a discussion in the abstract

Response: Discussion added to the abstract

Pg 2, L 23-27

Item 26: References- the following reference is not cited Carroll, 2000

Response: The Carroll, 2000 citation was added to the reference list

References Pg 15

Item 27: References- check the spelling of Dillon or Fillon in the Morris citation

Response: Correction made to citation (Dillon)

References Pg 18

Item 28: use only 4 citations per point (page 4)

Response: Reduced number of citations per point to less than 4 throughout the paper.

Removed selected citations from paper and reference list.