

Dear Dr. Dougherty,

Attached is our revised manuscript: Efficacy of theory-based activities for behavioral symptoms of dementia (# 2004/090). We thank the reviewers for their thoughtful comments and suggestions. We have revised the manuscript based on this feedback. Specifically we have revised the following:

**PROBLEM STATEMENT:** We agree with the reviewer that the word "inappropriate" is as pejorative as the word "disruptive". That has been our approach since the publication of our model in 1996. The definition we initially used for agitation is taken from the work of Cohen-Mansfield, who describes these behaviors in that language. To eliminate confusion about our perspective, we have modified the definition on p. 4 by eliminating the word "inappropriate" and on p. 5 we state that "inappropriate" is as pejorative as "disruptive".

**THEORETICAL FRAMEWORK:** Figure 1 has been revised to enhance clarity. Dr. Donna Algate (first author of the NDB model) and I spoke about the NDB model illustration and agree that the new Figure #1 captures the interaction of background and proximal factors with greater accuracy. We elaborated on the model and the interaction of NDB background and proximal factors in the text on p. 5-6. We state how the model guided selection of activities on p. 9 and discuss how our findings support the NDB model on p.20 (particularly the background factor of premorbid personality). As you can see from that discussion, we do not believe we have enough data to support a change in the model at this time. We feel further research is needed to clarify the factor(s) important in producing agitation and negative affect.

Figure 2 was revised to more clearly reflect that our intervention is a proximal factor. We renamed Figure 2: Causal Model Underlying the Treatment Effect of NDB-derived Recreational Activities, and included in that figure the terminology used in the text (ie, skill level and style of interest).

**LITERATURE REVIEW:** We have included literature that indicates that agitation often occurs during direct care to give balance to the review of literature. We have kept literature that indicates that these behaviors also occur during unoccupied time because our intervention works in part by filling unoccupied time with appropriate stimulation.

**DESIGN & ANALYSIS:** We used the revised CONSORT guidelines to better describe the design and analysis in the study as suggested by the second reviewer:

1. The number of subjects in our sample is 30. We clarify the flow of subjects on p.9: six subjects were excluded before baseline because they did not meet all enrollment criteria. Three of the remaining 33 were lost to follow up. The sample (N=30) included those who had completed baseline and all 3 conditions.
2. Convergent validity of the CMAI was with the Ward Behavior Inventory (p. 12).
3. We used ICC for assessing inter-rater reliability of the DMPT (p.12).
4. Randomization details are expanded on p.7. Subjects were randomized using a permuted blocked randomization scheme. We identified who enrolled subjects and who assigned them to their order of treatment presentation.
5. We describe how we used the data from our screening instruments to guide the selection of activities on p. 13
6. We describe the interventionists (undergraduate nursing and recreational therapy students) and their training on p. 13-14.
7. In the results section we explain that we used an "on treatment" approach to our analysis in this efficacy study (p.14). Our analysis included all observations obtained for the 30 subjects who completed baseline and all three conditions.
8. 95% CIs are included in Table 2, as well as notations regarding the significance of differences across

conditions.

9. On p. 17 we report that we experienced no adverse events attributable to treatments.

10. Our discussion section is now organized around each hypothesis.

Finally, we corrected the spelling of Kovach and used the same font and style throughout the manuscript. The one-sentence paragraph on p. 9 was eliminated.

If you need any further clarification about this study, please contact me at [amk20@psu.edu](mailto:amk20@psu.edu). We look forward to hearing your decision on this manuscript.

Ann Kolanowski PhD, RN