

Dear Dr. Dougherty,

Thank you for the very thoughtful review of the manuscript, Treatment fidelity in behavior change research: A case example (#2004/099). In addition to the editorial suggestions related to length of the manuscript and removal of references in the reference list that were not included in the text, we have addressed each of the questions raised by the reviewers. Changes have been made in the text as appropriate related to these questions. Each question is addressed individually in this letter:

Question/suggestions and responses:

1. Confusion about how one trainer continued past the 12 month time frame when the study ended after 12 months.

This is a randomized clinical trial and the intervention team and the evaluation team work independently. Consequently, the trainer would not have known that the participant had the final 12 month post hip fracture study evaluation done. The trainer assumed that since we followed patients for a year post hip fracture that she would work with these individuals for the full year. The study is designed so that trainers initiate the Exercise Plus Program once skilled rehabilitation services were completed. For some individuals this is 2 months post fracture and for other it is 2 weeks. Identifying this confusion regarding the ending time of the intervention impacted fidelity in that some participants were given a different intervention, i.e. beyond 12 months post fracture. We did not collect follow up data at this point of course, but psychologically it could impact the individual. More importantly, identifying this error early on in the study saved significant costs (i.e. the cost of the trainers time and travel related costs).

Included in text:

At the onset of the study there was some confusion by one of the trainers regarding length of time participants were followed post hip fracture. Monitoring treatment fidelity related to the design of the study allowed the research team to identify this error, assured that all participants received the same opportunity for exposure to the intervention, and saved the study considerable costs.

2. Provide examples of feedback that was given to the interventionists.

Feedback was actually positive reinforcement for great motivation work with participants, and also problems with not implementing the intervention as intended were discussed. If the trainer did not review the Exercise After Your Hip Fracture Booklet with the participants they were reminded to do so, or if they missed an opportunity to provide verbal encouragement to a participant this was pointed out. Likewise corrections related to exercise techniques were provided.

Included in text:

Feedback to the interventionist was provided and ranged from specific exercise intervention techniques to reminders to use the exercise calendars, review the exercise booklets, or incorporate verbal encouragement.

3. Questions about informed consent.

This was a very interesting question related to informed consent and making sure that this is addressed in the initial consent procedure for participants. Our consent form addresses observational activities, moreover we asked participants prior to making visits if they were comfortable with having an additional individual in the home setting with them. It was explained that this was the principal investigator of the study and in all cases the response was very positive. The text now reflects that the participants had signed consent to participate in the study and it is suggested that treatment fidelity plans be included in the consent process if there is going to be observation over the course of the study, or tapings done.

4. Question related to removal of a trainer from the study.

The trainer that was removed from the study was not only non-adherent with the full motivation intervention but she was noted to be making social visits with several of the participants outside the scope of the study. Retraining was done after the first indication of these types of visits. The individual persisted in making social visits and she was asked to leave the study. The description of this was moved to the section of the text on treatment fidelity related to design as the real issue here was being able to limit extraneous factors that might influence outcomes.

Included in text:

Retraining of this individual was completed, additional follow up observations were done, and she was removed from the study due to persistent social visits that were not part of the intervention. This served as an extraneous factor that might influence study outcomes and thereby had an influence on treatment fidelity.

5. Clarification of the threshold to determine “intervention as intended” , and who the participants were (patients or the trainers).

This question was focused on the section on treatment fidelity related to receipt. Receipt of the treatment is demonstrated by evidence that the participants (i.e. the older women post hip fracture) received the intervention as it was intended to be received; that they knew and were able to do what they were supposed to working on in the home setting. This was tested by direct observation using a check list to calculate the percentage of time the participant demonstrated the ability to perform the exercise, use the calendar or other motivational techniques implemented in the study. The average score for all observations was 92%.

Included in text:

A total of 20 sessions were observed and 92% of the time the participants [women post hip fracture] received the intervention as intended. Given the challenges associated with any intervention, the research team was comfortable with this level of receipt.

6. Clarification of enactment data and explanation for findings.

This question was based on the data presented to provide evidence of treatment fidelity related to enactment. Enactment is often the most challenging area of treatment fidelity as it is often confused with treatment outcomes. The case study example here considered the daily performance of exercise and use of the calendars as two ways to demonstrate that the participant was *enacting* the intervention in her own real world setting. The amount of time reported exercising and written on the calendars is not outcome data for the study. Study outcomes include physical activity survey data using the Yale Physical Activity Survey and objective data from the Step Activity Monitor. The calendars were for treatment fidelity purposes only and served as a motivational technique. There is no need, therefore, to explain “noncompliance” as that is not the intent of the treatment fidelity evaluation. Knowing, however, that the intervention was not done as intended will help the research team explain study outcomes such as muscle strength and gait and balance, and or why the motivational intervention did not work. The theory and techniques may not be bad, but the intervention was not done.

Included in text:

Enactment of the intervention is the most challenging aspect of treatment fidelity to consider and is often confused with study outcomes. Ideally the focus of enactment in behavior change studies should be on the skills required to achieve the ultimate outcomes in the study. Therefore, techniques to evaluate enactment will vary for each study. Knowing, however, that the intervention was not done as intended will help the research team explain study outcomes such as muscle strength and gait and balance, and or why the motivational intervention did not work. The theory and techniques may not be bad, but the intervention was not done by the participants.

Again we thank you for the very helpful review and are willing to address additional concerns or questions. This is an important area of research to consider and Treatment Fidelity protocols are now required in some grant proposals for the National Institutes of Health. We believe, therefore, that it would be useful to the readers of Nursing Research.

Sincerely,
Barbara Resnick, PhD,CRNP, FAAN,FAANP