

Treatment Fidelity in Behavior Change Research: A Case Example

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Treatment fidelity has been addressed in social and behavioral studies since the late 1970s (Quay, 1977; Johnson, 1981; Peterson, Homer & Wonderlich, 1982), however Moncher and Prinz's 1991 article was the first paper that formally introduced a definition and guidelines for enhancement of treatment fidelity. Prior to Moncher and Prinz treatment fidelity was generally considered as treatment integrity, i.e. was the treatment condition implemented as intended. Moncher and Prinz (1991) expounded upon this earlier definition to include the concept of treatment differentiation, or whether the treatment conditions differ from one another in the intended manner. Lichstein, Riedel and Grieve (1994) further recommended that treatment receipt, or the degree to which the participant understands the treatment; and treatment enactment, the degree to which the participant applies the skills learned in treatment to his or her daily life be included when considering treatment fidelity. Taken together, delivery, receipt, and enactment were believed to comprise a comprehensive review of treatment fidelity (Burgio et al., 2001; Lichstein, Riedel & Grieve, 1994).

In 1999, the Treatment Fidelity Workgroup, which was part of the Behavioral Change Consortium (Ory, Jordan & Bizarre, 2002), developed a model of treatment fidelity that added two new components: fidelity related to study design and fidelity related to the training of those who implement the intervention (Table 1). Taken together this model of treatment fidelity includes five components: design, training, delivery, receipt, and enactment, and provides a more comprehensive evaluation of treatment fidelity of a study that tests the effectiveness of behavioral change interventions.

Rationale for Considering Treatment Fidelity

Treatment fidelity is essential to consider as it impacts the internal and external validity of a study, as well as the effect size of a tested intervention and statistical power. If the treatment being tested does not adhere to the stated protocol then the study will have poor internal validity, the results may not be truly informative as to the utility of the treatment, and it will be impossible to know if the results of the study are actually a function of the proposed treatment or are due to extra-treatment factors. If there is no standardized protocol then the study can't be replicated and external validity will be decreased. Assuring optimal treatment fidelity may also decrease the costs of a study as power can increase and findings may be recognized with a smaller sample utilized. Moreover, the information obtained during the course of the study on treatment fidelity will help the research team explain findings and revise the intervention as appropriate.

Despite the numerous advantages to considering treatment fidelity, treatment fidelity is rarely rigorously evaluated (Borelli, Resnick, Bellg et al., manuscript submitted; Moncher & Prinz, 1991). Addressing treatment fidelity requires careful planning and allocation of resources at the onset of the study. Testing the Effectiveness of the Exercise Plus Program (The Exercise Plus Program), conducted as part of the Baltimore Hip Studies, provides an excellent example of how to realistically incorporate treatment fidelity into intervention research focused on changing behavior.

Study Overview: The Exercise Plus Program

The Exercise Plus Program is a self-efficacy based intervention to increase exercise in older women who have sustained a hip fracture (Table 2). Testing of the Exercise Plus Program is being done using a 2 X 2 factorial design so that the two

different components of the intervention can be tested: the Exercise Training component and/or the Plus component. At this point in time 196 out of the total 208 older women post hip fracture have been recruited from acute care settings into the study over the past 3.5 years. The average age of these women is 81.0 ± 6.9 , and the majority are white (97%) and unmarried (67%). The intervention is implemented in the home setting when traditional skilled rehabilitation services are completed. Depending on treatment group, exercise trainers provide a one-on-one intervention a maximum of 38 times during the 12 months post hip fracture (Table 3).

Treatment Fidelity in the Exercise Plus Program

A treatment fidelity plan (Table 4) was developed prior to implementation of the intervention to consider all five components of treatment fidelity previously described. Each quarter (i.e. four times per year) randomly selected observations were made of the trainers during an intervention session with a participant. These observations were done by two members of the investigative team, one with expertise in the Exercise Training component and one with expertise in the Plus component. Consideration was given to any possible non-treatment effects during these visits, as well as careful observation of the sessions to monitor delivery, receipt and enactment of the intervention. Tools used as part of the intervention such as calendars for recording exercise time, and log books used by the trainers were incorporated into the treatment fidelity plan and used as treatment fidelity data. The plan and results to date for each aspect of treatment fidelity for the Exercise Plus Program are described individually.

Treatment fidelity related to design.

Treatment fidelity related to design focuses on assuring that the study can adequately test its hypotheses in relation to the underlying theory and was considered in the Exercise Plus Program by assuring that the standardized intervention was consistent with the theory of self-efficacy and that it was implemented in such a way as to eliminate extraneous factors. Adherence to the theory was assured by consultation with experts in the theory of self-efficacy through the Behavioral Change Consortium. The research team established clear guidelines and protocols for the intervention sessions and interventionists were instructed on these protocols. Monthly reviews of the trainers log books, which detailed visits, were completed and it was assured that visits adhered to the designated protocol (i.e. the set number and timing of visits as per the protocol described in Table 3). At the onset of the study there was some confusion by one of the trainers who continued to see participants beyond the 12 months post fracture. Monitoring of treatment fidelity related to the design of the study allowed the research team to identify this error and saved the study considerable costs.

Treatment fidelity related to training.

Treatment fidelity related to training focuses on assessing the training of interventionists to ensure that they have been satisfactorily trained to deliver the intervention to study participants. Training of the interventionists (i.e. the exercise trainers) was carefully planned and implemented. Separate training manuals were developed for different treatment arms (Exercise Training component, Plus component, and Exercise Plus groups). Training manual guidelines were adhered to and training was consistent and repeated throughout the course of the study. Training was provided by the two investigators who developed the Exercise Plus Program and initial training was done

with volunteer older adults who had experienced a hip fracture. Ongoing training occurred during monthly meetings with the interventionists in which a careful review of what was done during each visit with participants currently enrolled in the study was completed. The interventionists were encouraged to ask questions and discuss problems and challenges associated with the intervention. In addition, three years after the first participants were recruited into the study, a retraining of the Exercise component of the intervention was done to prevent drift from the intervention.

Treatment fidelity related to delivery of the intervention.

Delivery of the intervention was a major focus of treatment fidelity in this study as it was important to establish that the different intervention groups were only exposed to the intervention they were intended to receive (i.e. Exercise Training component , Plus component, or Exercise Plus). Check lists related to delivery of the Exercise Training component and the Plus component of the intervention were completed for each of the randomly selected quarterly observations (Table 5). At each observed session feedback was provided to the interventionists and concerns related to the delivery of the intervention addressed. In addition, during the monthly meeting of the interventionists with the exercise physiologist, each current participants' exercise log books were reviewed and although these data were not quantified, monitoring was done to assure that the intervention was being delivered as intended (i.e. followed the standardized visit schedule as indicated in Table 3) and exercise progression was done as appropriate.

A total of 70 direct observations of the delivery of the intervention completed by five interventionists were made by the investigators in the participants' home setting. Overall, there was a 90.8% adherence to delivery of the intervention across all of the

treatment groups. Feedback was provided to the interventionists regarding their adherence to the intervention and any deviation was addressed immediately. There was one interventionist that was not adhering to the Plus component of the intervention and was implementing additional interventions (i.e. visiting with participants outside of the scheduled visits established by the protocol). Retraining of this individual was completed, additional follow up observations were done, and she was removed from the study due to a persistent inability to adhere to the intervention.

Treatment fidelity related to receipt.

Treatment fidelity related to receipt focuses on the participant and assures that the treatment has been received and understood, i.e. that the participant can perform a given behavioral intervention. In the Exercise Plus study receipt involved being able to perform the exercises and/or the activities associated with the Plus component such as utilizing the exercise calendar and goal sheets. The evaluation of treatment receipt in this study was based on guided observations of the interventionists and participants using a checklist (Table 4). A total of 17 sessions were observed focused on receipt of the intervention. Overall 92% of the time the participants demonstrated evidence that they received the intervention as intended.

Treatment fidelity related to enactment.

Treatment fidelity related to enactment monitors that the individual performs treatment-related behavioral skills and cognitive strategies in relevant real life settings. Consideration of enactment is different than consideration of major study outcome measures. Enactment of the intervention is focused on skills and activities that will result in the ultimate outcome being achieved. Moreover, enactment is a snapshot of the

outcomes taken on a case by case basis, rather than a cumulative evaluation of all participants over the course of the study.

In the Exercise Plus Program enactment was considered by reviewing the calendars completed by the participants. The calendars, which were intended to serve as a cue to exercise and were not a source of outcome data, provided evidence of whether or not the individual was actually engaging in the exercise daily and using the motivational strategies recommended. In a random sample of 42 collected calendars the total number of minutes of recommended exercise completed in 12 months ranged from 11 to 21,350 minutes with a mean of $3,425 \pm 3,920$ minutes. Based on the protocol, participants should have completed 6,200 minutes of exercise over the 12 month period (assuming rehabilitation was complete at 2 months post hip fracture). There was 59% adherence to the recommended exercise program with regard to exercise activities. Evidence of enactment related to the Plus Component was based on evidence that the participant completed at least one entry in a calendar per month. In the sample of 42 calendars evaluated there was 95% adherence to use of the calendars.

Discussion

The development and implementation of a treatment fidelity plan requires a careful conceptualization of what is relevant to treatment fidelity in any given study (Bellg et al., in press). Treatment fidelity related to design of the intervention is most appropriately considered either via direct observation, ongoing training to assure design adherence, and/or indirect observation via videotapes. The research team however, must explore what is practical and realistic for the investigators and what type of observation, for example, will not interfere with the intervention.

Treatment fidelity related to training is generally considered by developing and using training manuals or a protocol book for the intervention. This should be developed prior to the onset of the study. It is important, as was done for the Exercise Plus Program, that different manuals be developed for the different intervention arms of the study. Ideally, checklists and observations of the training should be done by an outside observer to quantify whether or not there was adherence to the training program that was developed for the study. Moreover, a skill list could be used to check off the interventionists' ability to complete a given skill or component of the intervention.

Delivery and receipt of the intervention are traditionally the most commonly evaluated aspects of treatment fidelity. Delivery of the intervention should be evaluated either by direct or indirect observation of the intervention. It is generally not feasible to observe every treatment session. Therefore, as was done in the Exercise Plus Program treatment fidelity plan, a random selection of treatment sessions can be observed in an attempt to consider the delivery process. Study specific checklists, such as those developed for the Exercise Plus Program, should be used during the observation sessions. This will allow the research team to quantify how much of the time the delivery of each aspect of the intervention was performed.

Receipt of the intervention by the participant should also ideally be quantified. This is particularly important when working with populations such as older adults who may have some degree of cognitive impairment. Receipt can most practically be considered based on use of a pencil and paper test. Test taking, however, for some individuals is threatening and performance on the test may have more to do with test

taking skills and abilities than knowledge. Direct observation, as was done in the testing of the Exercise Plus Program, is an alternative option.

Enactment of the intervention is generally the most challenging aspect of treatment fidelity to consider, and is often confused with actual 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. There should be evidence to demonstrate that the participant performed what he/she was supposed to do as part of the intervention in real world settings.

Making Treatment Fidelity Real, Practical, and Useful

As addressed in this study, it is generally not practical to observe all intervention sessions. Alternatively, random observations done directly or via video cameras are a realistic, albeit not perfect, alternative. These random observations allowed the research team to quickly address any deviations from the true testing of this intervention based on the five identified areas of treatment fidelity. There were concerns initially by the investigative team that the observations might be threatening to the interventionists. It became evident, however, that the treatment fidelity visits were a positive experience for all involved. The visits provided the interventionists with positive feedback and any needed ongoing education about the intervention. The experience for the investigative team members who participated was likewise extremely worthwhile. In addition to using the visits to strengthen adherence to the intervention, observations of problems with the intervention were also considered. Participants shared feelings and experiences related to the study and all of this information will be used for revisions of the intervention in future research.

Testing the Effectiveness of the Exercise Plus Program was not budgeted to consider treatment fidelity, however treatment fidelity plans should be incorporated into grant proposals and the costs of this aspect of the study clearly articulated. Costs should be considered for the use of staff to observe the training of interventionists, investigator or observer time in completing treatment fidelity visits, data management, and data analysis time. Treatment fidelity should be addressed when research findings are reported related to behavior change research. The recommendations for basic reporting of treatment fidelity have been addressed by Davidson et. al. (2003) in their revisions of the Consolidated Standards for Reporting Trials (CONSORT).

Complete follow up data collection is still ongoing for the Exercise Plus Program, and the relationship between treatment fidelity and the effectiveness of the intervention has yet to be considered. The research team is confident, however, that the data collected on treatment fidelity will help to explain and understand findings, regardless of the effectiveness of the treatment intervention. Treatment fidelity findings will also be used to consider dose effects as appropriate, and plan for future research. It is in the process of truly testing proposed interventions that the impact of behavior change interventions can be established and appropriate interventions can be adjusted and/or implemented to ultimately improve the overall health and wellbeing of individuals.

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Table 1 Definition of Components of Treatment Fidelity

Component of	Definition and Description
Treatment Fidelity	
Design	Treatment fidelity practices related to study design are intended to ensure that a study can adequately test its hypotheses in relation to the underlying theory and clinical processes.
Training	Assessment and ongoing evaluation of training of interventionists to ensure that they have been satisfactorily trained to deliver the intervention to study participants.
Delivery	Treatment fidelity processes that monitor that the intervention is delivered as intended.
Receipt	Receipt of treatment focuses on the participant and assures that the treatment has been received and understood by the individual (for example that he or she is able to perform treatment-related behavioral skills and cognitive strategies as intended)
Enactment	Enactment of treatment skills monitors that the individual performs treatment-related behavioral skills and cognitive strategies in relevant real life settings as intended.

Table 2 Description of the Exercise Plus Program

Exercise Plus Program	Description
Exercise Component	<p>-Exercise intervention designed for women post hip fracture that combines a warm up/cool down, 2 days/week of resistive exercises and 3 days/week of aerobic exercise.</p>
Plus Component	<p>-Trainer teaches the exercise intervention, individualized to ability and needs of the participant, and provides posters describing the program, and/or written material.</p> <p>-Trainer identifies weekly short term goals and a long term goal related to exercise, provides verbal encouragement related to goal achievement and a weekly prize if goals are achieved.</p> <p>-Trainer gives a weekly written prescription on goal form to remind individual of what exercises to do and when to do them.</p> <p>-Trainer teaches the individual, using the “Exercise After Your Hip Fracture Booklet” about the benefits of exercise and how to overcome barriers to regular exercise.</p> <p>-Trainer reviews unpleasant sensations related to exercise and provides interventions to decrease these unpleasant sensations</p> <p>-Trainer takes pictures of the individual exercising at intervals to demonstrate progress over the 12 months.</p> <p>-Weekly telephone calls are made in months 7 to 12 when</p>

visits are decreased to once a month. Weekly aspects of the motivational intervention are implemented via telephone contact (i.e. goal setting, verbal encouragement, education about exercise).

Table 3 Schedule of Visits by the Interventionists in the Exercise Plus Program

Months Post-Initiation of Program*	Number of Sessions Per Month Trainer Supervised (Independent exercise sessions recommended)
1-2	12 (8)
3-4	8 (12)
5-6	4 (16)
7-8**	2 (18)
9-12**	1 (19)

* Program will be initiated upon termination of post-fracture skilled rehabilitation services and will continue until 12 months post-fracture.

**During months 7-12, trainers will contact (telephone) participants once each week during the weeks they do not do a supervised exercise session. Telephone contact will include reviewing the Exercise After your Hip Fracture booklet, providing verbal encouragement regarding progress towards goals, and discussing any unpleasant sensations associated with exercise.

Table 4 Description of the Treatment Fidelity Plan for the study Testing the Effectiveness of the Exercise Plus Program

Component of Treatment Fidelity	Hip Study Treatment Fidelity Protocol
Design	<p>Standardized intervention with scheduled visits and clear protocol with regard to length of interaction and activities involved.</p> <p>Intervention consistent with theory of self-efficacy.</p> <p>Observations made for non-treatment effects during intervention.</p>
Training	<p>Use of training manuals and standardized training program.</p> <p>Role playing during training.</p> <p>Direct observation of interventions.</p> <p>Ongoing training throughout the course of the study</p>
Delivery	<p>Observation of delivery of randomly selected session.</p> <p>Completion of checklists (Table).</p> <p>Correction of any observed problems in delivery of intervention.</p>
Receipt	<p>Direct observation of randomly selected sessions. Checklist of observed activities (Table 4).</p>
Enactment	<p>Completion of calendars.</p>

Table 5 Examples of Checklists for Treatment Fidelity Observations

<p>Checklist: Delivery of Intervention by Trainer [Plus Component Only]</p> <p>Observed Intervention trainer _____ Participant _____</p> <p>____ Reviews achievement towards short term goals set for the previous week and provides verbal reinforcement for progress</p> <p>____ Develops new weekly goals and writes these on the goal form and places this in participant's notebook</p> <p>____ Re-evaluates long term goals to ensure achievement and appropriateness</p> <p>____ Asks the participant if they are having pain, fear of falling, or fatigue associated with exercise that makes them not want to exercise</p> <p>____ Implements appropriate interventions for pain, fear or fatigue</p> <p>____ Reviews calendar (if it is the time of the month to do this) and provides positive reinforcement for exercise completed and encourages continued exercise</p> <p>____ Reviews the exercise booklet (if it is the time of the week to do this)</p> <p>Response options: Yes (if activity is performed); No (if activity is not performed); NA (if not applicable)</p> <p>Total completed _____</p>
<p>Checklist Receipt of the Intervention [Plus Component Only]</p> <p>Date:</p> <p>Participant: _____ Observer: _____</p> <p>For Each Supervised Session:</p> <p>____ Demonstrates use of posters/exercises</p> <p>____ Demonstrates ability to perform exercises</p>

_____ Demonstrates learning about exercise by reviewing booklet

_____ Demonstrates ability to establish goals and review goals

_____ Demonstrates ability to engage in behaviors to overcome unpleasant sensations related to exercise.

_____ Demonstrates ability to complete calendar

