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Assessing Treatment Fidelity in Pilot Studies Assist in Designing Clinical Trials

An Illustration From a Nurse Practitioner Community-based Intervention for Pain

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Treatment fidelity refers to the degree to which treatment is administered as intended, and it is key to interpreting and translating research into practice. As an illustration, we report the benefits of examining treatment fidelity in a pilot study of nurse practitioner–delivered Coping Skills Training for chronic pain. Analysis revealed both strengths and weaknesses of protocol design and treatment delivery. This pilot work formed the basis for subsequently modifying the design of a large-scale clinical trial. Monitoring treatment fidelity throughout the pilot and trial phases of research can dramatically improve the research enterprise and facilitate successful dissemination. **Key words:** *behavioral intervention*, *coping skills training*, *osteoarthritis*, *pain management*, *treatment fidelity*

THE development and implementation of a treatment fidelity plan is important to nursing research involving clinical trials. Evaluation of clinical trial outcomes is often limited to statistical testing of change from pretreatment to posttreatment. The researcher identifies an intervention that is hypothesized to have a positive impact on a medical condition. Symptoms of the illness, disability, quality of life, and other relevant constructs that are expected to change in response to the treatment are measured. To evaluate the efficacy of the treatment, statistical testing is conducted to determine whether the observed group differences at posttreatment are significantly greater than chance. Often, what is assumed throughout this process is that the treatment was successfully delivered, and that patients received or used the treatment as intended. While it is likely that much of this takes place when treatment efficacy is demonstrated, what is not clear is the degree to which it did. This is referred to as *treatment fidelity*. Powerful treatments could yield satisfactory outcomes even when delivered or received at suboptimal levels. Likewise, nonsignificance of treatment effects may not be

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due to an ineffective treatment, but rather to ineffective delivery and patient uptake of the treatment. Thus, interpretation of the key factors accounting for clinical outcomes is constrained when treatment fidelity is not monitored.

In this article, we describe the utility of incorporating comprehensive monitoring of treatment fidelity in pilot studies prior to conducting a large-scale clinical trial. Assessment of treatment fidelity, including frequency, timing and number of patient contacts, provider training, provider adherence to treatment, and patient enactment of treatment, provide the researcher with critical insights into the actual therapeutic processes that underlie the observed outcomes. During pilot work, it illuminates the strengths and weaknesses of the protocol, uncovers unanticipated patterns, and furnishes the researcher with information that can be used to improve the design and delivery of the treatment. To the extent that the trial is improved such that treatment is delivered and received as intended, both the external and internal validity of the study are enhanced.

Furthermore, these issues are particularly important when the research involves moving treatment from clinical trials into the "real world" of clinical practice. Efficacy models and effectiveness models represent two ends of the spectrum of intervention research design. Efficacy trials are characterized by strong controls such that the intervention is delivered in uniform fashion under ideal conditions. These trials maximize the internal validity of the study. In contrast, effectiveness trials seek to determine whether the intervention works in a broadly defined population with few exclusions and when delivered by typical community providers. Effectiveness research examines the generalizability of the treatment effect, that is, the external validity. Both types of trials that result in weak clinical change may be due to the lack of proper implementation or weak acceptance by the participants.[1] Treatment fidelity strategies incorporated into study design monitors these issues.

MONITORING TREATMENT FIDELITY IN RESEARCH

The concept of treatment fidelity is especially relevant for clinical trials involving health behavior change interventions. It was first introduced as *treatment integrity*[2,3] and represented whether or not the treatment was delivered as intended. Later, *treatment receipt*, whether the client comprehends and uses the skills during the treatment sessions, and *treatment enactment*, whether the client actually applies the skills in daily life, were added.[4,5] Monicher and Prinz[6] expanded the concept to include *treatment differentiation*, that is, whether the experimental treatment conditions such as length and number of treatment contacts differ from one another in the intended manner. In 2004, the Treatment Fidelity Workgroup of the National Institutes for Health Behavioral Change Consortium (BCC) developed a set of systematic guidelines for treatment fidelity that could be applied to a broad array of health behavior change studies.[7] These guidelines provide researchers with a comprehensive outline that describes specific strategies to enhance treatment fidelity and that offers recommendations for how these may be incorporated into health behavior research.[7] Five guidelines incorporate previous treatment fidelity concepts and add components to further refine design and evaluation of clinical trials. These include strategies for study design, provider training, treatment delivery, treatment receipt, and patient enactment of treatment.[7]

Considering treatment fidelity during study design challenges the researcher to ensure that the study can adequately test the hypotheses based on relevant underlying theory and clinical practice. For example, clearly defining the characteristics of the treatment to be delivered and designing comparison groups that will control for the important factors to elucidate the unique effects of treatment will increase the validity and clinical impact of a study. Likewise, attention to high-quality training of treatment providers and

ongoing evaluation to ensure that they deliver the intervention as intended to study participants will improve the quality of a trial. Two concepts relating to treatment adherence are the "receipt" and "enactment" of the treatment by study participants. *Receipt* focuses on how treatment has been received and understood by patients. In other words, does the participant understand how to perform behaviors or engage in the cognitive strategies learned in treatment? In contrast, *enactment* of treatment strategies monitors the participant's willingness and ability to perform the new skills in real-life settings.[8] Enactment is similar to treatment receipt, but with a subtle difference. The researcher may verify that the patient understood and could use the intervention skills (receipt), however, the intervention strategy may not actually used as intended (enactment). When the research plan systematically incorporates monitoring of these guidelines, the implementation of the protocol is improved and subsequent interpretation of results is informed.

TREATMENT FIDELITY: IMPLICATIONS FOR INTERPRETATION AND TRANSLATION OF RESEARCH FINDINGS INTO NURSING PRACTICE

The tradition in nursing of illness management through patient education and counseling suggests that nurses are well suited to conduct clinical trials involving health behavior change interventions. Self-management interventions for persons with chronic disease are frequently a focus of nursing research. For example, interventions for obesity prevention, smoking cessation, and health maintenance for diabetes control and heart failure are among those that have been studied.[9–19] The evidence to support the assertion that treatment efficacy in these studies is attributable to the delivery of the treatment components, rather than other intervening factors, is variable. In order for research findings to be useful for nurses in achieving health behavior change, it is important to determine whether the results of the study were a function of the intervention, adherence to the protocol, and patient understanding and application of the behavior change skill. In intervention research, *internal validity* is determined by the degree to which it can be inferred that the intervention, rather than uncontrolled factors, is responsible for the observed effects. *External validity* refers to the degree to which the results of the study can be generalized beyond the particular providers and patients participating in the study.[20]

Treatment fidelity is relatively new to nursing research, as it is for much of clinical research. Introducing treatment fidelity monitoring into clinical research expands in important ways the information that is learned from the trial. The absence of this information can limit the interpretation of the results and the ability to identify parameters that need improvement, and will impede effective clinical dissemination of the intervention. A survey of 46 articles published in 24 journals of diabetes self-management interventions brought to light the lack of monitoring that is common place in trials.[21] Leeman and colleagues[21] tabulated the components of treatment implementation reported in the surveyed studies: setting of treatment delivery (76%); mode of delivery (98%); disciplines delivering (87%); provider training (26%); number of treatment contacts (30%); and length of contact time (54%). Description of provider training ranged from detailed to just simple statements that training was provided. Minimally, in order for research findings to be translated into practice, details regarding provider training and the intervention protocol, as well as patient uptake of the intervention, must be described.

Other individual studies have brought to light the value of treatment fidelity monitoring to identify shortfalls in treatment implementation and their impact on observed clinical outcomes. The first involved investigating the efficacy of an intervention incorporating disease information pertaining to heart failure, strategies to increase motivation for change, and targets for behavior change in

58 patients with heart failure.[22] Two advanced practice nurses delivered the intervention across a 15-week period that included 4 group classes plus 3 telephone follow-ups. The researchers developed a treatment manual to ensure consistency of delivery across staff and to provide a document that would permit replication. All classes were audio taped, and 2 independent reviewers rated the audiotapes on treatment components delivered in each class. Results indicated that there was variability in treatment dose received. Most patients (79%) attended at least 2 classes, but only 36% attended all 4 classes; and, only 64% participated in all 3 telephone calls, whereas 74% participated in 2 telephone calls. Thirteen patients (22%) did not attend week 1 class where they were instructed in how to complete a diet diary and daily weight self-monitoring form. Furthermore, less than half of the 45 patients who did attend week 1 class completed the diet diary, and only 29% completed the daily weight form. Finally, only 28% of all participants completed the monitoring forms for behaviors that were targeted for change, citing discontent with recording behaviors. The intervention was successful in offering patients the skills necessary to make behavioral changes, primarily in helping them select and state a goal. However, the intervention had very limited success in motivating change and achieving treatment enactment by the patients. By incorporating monitoring of treatment fidelity into this study, the researchers were able to identify that participants were successful in choosing and beginning a change strategy, but not in continuing and completing these strategies. As a result, the researchers had important insights to assist them in improving treatment implementation in subsequent trials.

Two other articles provide excellent examples of the advantages of incorporating treatment fidelity guidelines into clinical nursing research. Mahoney et al[23] analyzed factors associated with implementing an intervention aimed at assisting caregivers in bathing persons with Alzheimer's disease at home. Observations during the delivery of this intervention were made to measure care receipt and to uncover patterns of behavior that were associated with the quality of delivery of care. Data collected by direct observation, researcher field notes, qualitative data from caregiver journals, caregiver-initiated telephone calls, and team meetings that identified common patterns and problems during the procedure enabled the researchers to refine the intervention subsequently to improve caregiver efficacy. For example, the time preceding the bath was identified as stress prone and created anxiety and negative expectations for both the care recipient and caregiver alike. During the bath, safety, comfort, and apraxia were identified as major causes of care recipient resistance to care and caregiver frustration. Caregiver journals revealed that self-efficacy was a major variable impacting caregiver practice and implementation of the bathing skill. The identification of common patterns and problems during the procedure enabled the researchers to refine the intervention subsequently to improve caregiver efficacy. Specifically, they concluded that delivery of the intervention would be enhanced when a well-trained nurse interventionist was employed who was flexible in scheduling appointments and sensitive to the special issues of the study population. In addition, the length of time for each visit to teach the intervention was increased in order to facilitate the coaching, practice, and support that was needed to improve enactment of the skill by caregivers. Thus, careful monitoring enabled these nurse researchers to refine and improve the treatment, with the goal of enhancing treatment efficacy. The second study had a clear treatment fidelity plan prior to the implementation of the intervention.[24] The study involved a self-efficacy-based intervention to increase exercise in older women following hip fracture that was conducted in their home by skilled exercise trainers. Training of interventionists using manual-based instructions and practice sessions was conducted at the beginning and at regular intervals throughout the study. Checklists related to adherence to the delivery of the exercise component by

the interventionist were completed quarterly throughout the length of the multiyear study and revealed a 91% adherence to the intervention protocol. Thus, deviations from the protocol could be observed and corrected immediately upon identification. An evaluation of whether the treatment was received and understood by the participant demonstrated 92% receipt of intervention as intended. Participants completed postintervention calendars of exercise completion, yielding an adherence rate of 59% to recommended exercise program activities. It appeared from evaluation of the treatment fidelity that the intervention was adequately delivered by the interventionist and received and understood by participants. Enactment (application to real-world settings) data were not as robust. Although treatment endpoints were not explicated in this study article, the authors suggest that the fidelity data helped the research team explain study outcomes such as muscle strength, gait, and balance and why the motivational aspect of the intervention did not work.[24] This study demonstrates the importance of the treatment fidelity plan in ongoing monitoring of the intervention, opportunities to identify protocol weaknesses, and the opportunity to provide immediate corrective action, which can lead to a more successful protocol and more insightful interpretation of study findings.

The advantages of monitoring treatment fidelity can be especially important prior to the start of a clinical trial in the earliest phases of clinical research, that is, in pilot work. This is especially true when the intervention, providers, patient population, or environments are relatively unexplored. The time and costs of a clinical trial are usually substantial. Conducting pilot work inevitably reveals unexpected problems across any number of aspects of the protocol. By systematically incorporating assessment of treatment fidelity into a pilot study, the investigator gathers quantitative and qualitative observations that can pinpoint problems and suggest remedies. These observations and consequent modifications to the clinical trial hold the potential to substantially increase the likelihood of success.

ASSESSING TREATMENT FIDELITY IN PILOT WORK: AN EXAMPLE FROM A NURSE-DELIVERED COPING SKILLS TRAINING INTERVENTION FOR OSTEOARTHRITIS PAIN

In this article, we describe the results of a pilot study that was conducted to evaluate the effectiveness of a nurse-delivered intervention for patients with chronic pain that incorporated treatment fidelity monitoring. Although this intervention has been evaluated in previous efficacy research,[25–27] the provider, patient population, and environment were different in this trial. The intervention, Pain Coping Skills Training (CST), was developed and has been delivered by clinical health psychologists in academic medical settings. However, the limited number and location of psychologists trained to deliver CST have severely limited patient access to the treatment. The tradition in nursing of illness management through patient education and counseling suggests that nurse practitioners (NPs) are well suited to acquire the training and to implement CST for chronic pain. The goal of the planned clinical trial will be to substantially increase access to CST by the millions of patients who suffer with chronic pain due to arthritis. Since the provider, patient population, and delivery setting are very different from those investigated in the original clinical trials of CST, we believed that is was vital that we conduct pilot work and incorporate measures of treatment fidelity to monitor a wide variety of nurse provider behaviors and patient responses to the CST intervention. It was anticipated that examination of these data would generate important insights into improving the design and implementation of the subsequent large-scale randomized, controlled clinical trial.

There were several goals associated with systematically assessing treatment fidelity in this pilot study. The first pertained to

considerations of training NP providers in CST. Second was our interest in monitoring the nurse's ability to provide the treatment as intended. And, third was the desire to ascertain patient receipt and enactment of treatment. Since our healthcare delivery model involves using NPs working in community medical practices, their training would be in adult health, not in mental health. Consequently, it was uncertain how comfortable and competent the nurses would be in delivering CST. Likewise, it was unclear to what degree more typical community-based patients would engage in the treatment and would utilize the skills presented. Consequently, nurse training and supervision were carefully planned, systematic observations of treatment delivery were conducted, and nurse journaling of self-observations and reactions were kept. In the same way for patients, systematic monitoring of the number of treatment sessions attended and self-report of use of coping skills was conducted.

METHODS

Participants

Eleven patients with chronic pain due to knee osteoarthritis were identified by their community rheumatologist for consideration in the pilot study. These patients were screened for inclusion using a telephone recruitment script. Patients with usual pain of 4 or more on a 10-point scale and who were able to attend 10 treatment sessions were eligible to participate. Six patients were initially enrolled in the study. Four of the 11 patients were not interested in participating in the study after the protocol was explained to them. A fifth patient was not able to coordinate available treatment session time with his work schedule. Each of the 6 participating patients provided informed consent following institutional review board approval of the study. Patients were enrolled in a 10-session treatment protocol of CST for pain that was delivered in patients' rheumatology office. The 10 weekly individual sessions were scheduled for 45 minutes. On occasion, because of a patient scheduling difficulty, sessions were scheduled across 2-week intervals.

Treatment fidelity methods and measures

Fidelity of treatment implementation was addressed at 2 levels. The first was training of the NP, and the second was utilization of a therapy manual to ensure that the study intervention adequately delivered the CST components. Use of manual-based interventions standardizes treatment by taking into account different experience levels of providers and ensuring comparable dosing of treatment across patients. In this case, "treatment dose" refers to the number and length of treatment contacts.

Nurse practitioner training

The NP (P.B.) attended a 2-day training by Francis J. Keefe, PhD, an internationally respected developer and expert in CST from Duke University. Standardized training materials (using a CST treatment manual), role-playing, evaluation, and feedback were used to become competent in the rationale and implementation of each of the CST skill components. Following training, the NP began delivery of the treatment to the pilot patients under weekly supervision by a clinical psychologist (J.B.) with expertise in CST. Audiotapes of treatment sessions were reviewed at each supervision, allowing the supervisor to provide technical and clinical guidance with additional role-playing of challenging aspects of treatment implementation. Audiotapes were also used to analyze the conformity by the NP to treatment manual content as well as to assess the quality of the interaction between the NP and patient and are standard procedure in Dr Keefe's training guidelines. Thus, the training was designed to achieve attainment of treatment delivery skills in a standard manner, assessment of skill acquisition, and procedures to prevent drift in treatment implementation over time and across patients. The NP also kept a journal of

observations generated in supervision and after sessions with patients regarding how CST training and supervision could be enhanced for nurses that will be trained for the clinical trial.

Manual-based treatment protocol

All materials for the intervention were located in a treatment manual that was developed in collaboration with the expert in CST; the manual was used at each session by the nurse. The manual specifically outlined the number, length, and the specific CST skills for each session to ensure consistency in content and treatment dosing delivered to each patient. The manual also stipulated in-session guided practice of each skill, patient self-monitoring at home, and assignment of home practice of skills for each of the 10 sessions. The CST treatment educated patients in disease management skills (eg, exercise, activity pacing, sleep hygiene) and psychological coping strategies (eg, relaxation, pain attention diversion, and cognitive coping skills). Each skill was introduced with a rationale that was frequently accompanied by visual handouts of the concepts to facilitate adult learning. The goal of the NP was to follow the treatment manual such that each patient received each session's entire curriculum with minor variations on the basis of the unique conversational interactions with each patient.

Assessment of implementation of treatment

Nurse adherence to treatment manual

All treatment sessions were audio taped, and a comprehensive checklist of skills and instructions for each session was used to rate treatment delivery adherence. Two research assistants were trained to use the checklist until they reached satisfactory interrater reliability. Ten (20%) randomly selected treatment sessions (2 from each patient) were then evaluated, and interrater reliability was assessed using the κ statistic. A κ statistic of 0.7 or above is an acceptable level of interrater reliability.[28]

Ratings of nurse performance

In addition to coding for adherence to treatment, the raters also judged the nurse on her treatment delivery style and her interpersonal skills with the patients. Patients also completed a rating on the posttreatment questionnaire regarding the nurse's performance.

Patient uptake of treatment

Treatment receipt shifts the focus from the provider to the patient. It refers to the degree to which the patient received the treatment as intended. Assessing treatment fidelity on this dimension is designed to monitor the ability of the patient to understand and perform treatment-related cognitive and behavioral skills introduced during treatment. A well-delivered treatment does not ensure patient uptake of the treatment. Assessing the patients' understanding and use of treatment completes the sequence from treatment delivery through measured outcomes. As illustrated in some of the studies described earlier, disappointing outcomes of trials may be just as likely to be due to poor patient uptake of treatment as poor treatment delivery.

Practice sessions and worksheets

Having the patients demonstrate skills during the session, complete homework practice of skills and have it reviewed by the nurse at subsequent sessions provides information about patient understanding and use of the treatment. Each of the 10 sessions contained a section on a coping skill acquisition and/or accompanying patient worksheet designed to assist the patient through practicing the skill. The NP guided the patient through the practice skill set and/or worksheet at each session.

Patient utilization and satisfaction with treatment

At the end of treatment, patients answered a questionnaire as to whether they were using each of the 10 skills taught during treatment. They also provided 2 ratings regarding their experience with treatment: overall

satisfaction with the program and success in their ability to manage their arthritis.

RESULTS

Attrition and treatment dose

Of the 6 patients in the pilot study, 1 dropped out of the study after 3 sessions, stating that she was not putting the time or effort into learning the skills (Table 1). The overall attendance rate for the 6 patients initially enrolled in the study was 88%. Five patients completed all 10 sessions (100% compliance) within 12 weeks. However, a pattern was observed for several of the sessions to consistently run shorter (30 minutes) than the prescribed 45 minutes. Journaling by the nurse identified difficulty with in-session coaching of the skills for 2 particular sessions, 2 ("mini" relaxation technique) and 4 (pleasant activity scheduling), accounting for some of the abbreviated sessions. Sessions 8 (distraction techniques) and 10 (coping skills maintenance) were occasionally delivered for 30 minutes instead of 45 minutes. This was addressed during weekly supervision sessions, and role-playing was conducted to improve delivery of these skills during the study. Nevertheless, these observations suggested some loss of treatment dose.

Clinical outcome measures

Across the 5 patients who completed treatment, results of percentage change from pretreatment to posttreatment on the primary outcome measures indicated less pain and psychosocial disability, and improved use of coping skills. These effects were comparable to previously reported efficacy studies (Table 2). Results of perceived ability to cope with pain and pain self-efficacy were not as robust as previously reported studies. This was felt to be a result of insufficient emphasis by the NP on patients' home practices.

Manual-based protocol

The treatment manual was adequate in providing the necessary guidelines and support materials to deliver the treatment consistently across patients with regard to content and treatment dose. Qualitative analysis recorded in the NP study log indicated ease of use and clear guidance including time frames for delivery of curriculum. No important gaps or difficulty understanding the curriculum were noted.

Ratings of adherence to treatment manual

Two research assistants rated adherence to the treatment protocol by evaluating 10 (20% of total) audio-taped treatment sessions. Interrater reliability was 0.71 using the κ statistics. Adherence by the NP to key training points was 86%. One important pattern of nonadherence that was observed was insufficient attention being given to ensuring that patients completed weekly homework assignments, as well as the limited skill practice. Each of these omissions was considered significant, and they were conceptualized as likely factors in the weak treatment effects found in the self-efficacy and pain control coping outcome measures.

Ratings of quality of treatment delivery

The raters also made an overall evaluation of the nurse's delivery of treatment. Performance effectiveness was defined in relation to the patients' response to the nurse in each session. For example, if patients' interactions with the NP therapist were "flat" (lacking enthusiastic voice cues), a rating of "poor" was assigned. In contrast, if the patient was engaged, receptive, and enthusiastic, a rating of excellent was assigned. A session in which a patient was perceived as interactive, but did not initiate discussion points, was given a rating of satisfactory. A mean score of 4.4 (1 = poor; 5 = excellent) was reported for "therapist overall effectiveness" (see Table 1). A second rating of the NP's interpersonal skills was recorded. If the nurse was flat, tentative, and not perceived as being responsive to the patient's discussion, a rating of "poor" was assigned. Enthusiasm, concern, and warmth

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Table 1. Outcome of treatment fidelity monitoring in pilot study of Coping Skills Training (CST) for chronic pain

Treatment fidelity components	Data collected	Results	Protocol design impact
Study design and materials	Number of treatment sessions attended	Five of 6 enrolled patients completed all 10 sessions; 1 patient dropped out after 3 sessions	No change: attendance for 10 sessions achieved by 88% of patients
	Length of treatment program	Ten sessions delivered weekly, or on some occasions every other week to accommodate scheduling challenges	No change: patients willing to attend 10-session treatment program
	Length of treatment sessions	Four of 10 sessions frequently ran 30 min vs 45 min outlined in the manual	Nurse training will be revised to improve ability to conduct these sessions in greater depth
	Quality and usability of treatment manual	Nurse practitioner (NP) found treatment manual was clearly written and easy to use: CST curriculum, in-session practice, and patient homework exercises	No change
Treatment implementation	Ratings of session audiotapes for nurse adherence to treatment manual and protocol	Overall adherence = 86% Review of homework and adherence to session time frame were items that most consistently accounted for nonadherence Nurse and supervisor observations: tendency over time to abbreviate presentation of skills	Extend initial training of nurses to include delivery of CST to 3 patients prior to working with patients in study protocol, followed by 1 d of additional training with review of "practice" patient audiotapes Conduct treatment adherence ratings periodically throughout protocol to prevent "drift" in delivery of treatment
	Ratings of session audiotapes for NP overall performance Assess patients' perceptions of NP's credibility and competence	Mean rating = 4.4 (1 = poor; 5 = excellent) reported for "therapist overall effectiveness" Mean rating = 4.5 for therapist interpersonal skills Mean rating = 4.8 for helpfulness of NP	Satisfactory ratings, but increased training may result in even higher nurse competence ratings
Enactment	Number of homework assignments completed by patients	Session audiotape ratings: inconsistent review of weekly homework by nurse precluded measurement of homework completion	(1) Collect copies of patients' self-monitoring and homework sheets (2) Emphasize assignment and completion of homework in nurse training and supervision
	Posttreatment questionnaire assessment of patient use of CST skills in daily life Posttreatment questionnaire assessment of patient satisfaction with treatment	Five patients completing treatment reported using 8 of 10 coping skills Mean rating = 4.2 (1 = least satisfied; 5 = extremely satisfied) for overall program satisfaction Mean rating = 4.0 for success in ability to manage osteoarthritis	The use of 8 of 10 coping skills taught is reasonable. Because of individual preferences for types of skills, it was not anticipated uptake of all 10 would occur Satisfactory ratings, but increased training and emphasis on homework assignments may result in even higher satisfaction and ability ratings

Table 2. Percentage change (pre-post) in primary outcomes*

	NP†	Psychologist†	
Outcome measures	**Grant Pilot Study 2005**	**Keefe et al[29]**	**Keefe et al[30,31]**
Aims			
Pain	18	26	10
Physical disability	4	16	6
Psychological disability	10	NR	16
Coping Skills Questionnaire			
Coping attempts	14	13	11
Pain control	66	204	174
Self-efficacy			
Pain	4	27	NR
Function	2	5	NR
Other	36	15	NR
Total	10	15	16

*NR indicates data not reported.
†Provider delivering Coping Skills Training.

conveyed by the nurse to the patient would be rated as excellent, whereas being interactive without positive voice cues would be rated as satisfactory. A mean score of 4.5 (1–5) was given. Thus, general ratings of the nurse's delivery of the manual-based intervention were considered very good to excellent.

Patient satisfaction with treatment

Patients reported a mean of 4.2 (1 = least satisfied; 5 = extremely satisfied) on overall satisfaction with treatment, 4.0 for success in ability to manage osteoarthritis, and 4.8 in helpfulness of NP (see Table 1). Each patient reported using 8 of 10 coping skills, however, there was variability across patients in the 8 skills that were used.

Nurse training in CST

The qualitative and quantitative monitoring of treatment fidelity resulted in several insights that had implications for designing the nurse training for the subsequent clinical trial (see Table 1). The NP received 2 days of training, followed a therapy manual during treatment delivery, and received weekly supervision with the aid of audiotapes of the treatment sessions. The training was well received, and she was comfortable with the CST skills. The program was viewed by her as highly consistent with the nursing tasks of effective patient-clinician communication and patient education to manage disease. Although emanating from the field of clinical health psychology, the nurse viewed the CST treatment program as more similar to disease education programs than to psychotherapy. Thus, the expectation that adult health NPs would be appropriate to deliver this intervention was confirmed.

Nevertheless, although initially confident in her ability to carry out the treatment, challenges were presented in the real-world clinic setting that benefited from supervision and that prompted modifications in the plans for nurse training for the clinical trial. Observations during supervision and nurse journaling documented the need for more intensive training in how to teach several of the CST skills to patients. Consequently, a decision was made to increase the initial training for nurses in the clinical trial to 4 days, with additional role-playing of teaching the skills to patients. Second, since it was apparent that competence in treatment delivery would increase over the course of treating the first few patients, it was decided to have newly trained nurses for the clinical trial deliver the treatment to 3 patients prior to the start of the

clinical trial. This would be followed by an additional day of training with the aid of audiotapes of the treatment sessions to problem solve difficulties with treatment delivery and to hone skills. These observations also confirmed the importance of including weekly supervision in the clinical trial, especially for the first several protocol patients for each nurse. Finally, it was observed that there was a tendency to abbreviate the curriculum of certain treatment sessions, as the nurse treated the last versus the first patients. This resulted in a decision to add a mid-protocol "booster training session" to minimize deviations from the protocol in terms of length of session, ensure a "fixed" amount of information for each session, and to generally eliminate "drift" in treatment implementation over the course of the trial.

DISCUSSION

By incorporating and monitoring treatment fidelity, clinical research is improved. Specifically, issues that impact both internal and external validity can be addressed, and detailed monitoring facilitates identification of treatment delivery and patient enactment problems. Furthermore, this approach to conducting and reporting clinical trials generates greater protocol detail to facilitate dissemination of efficacious interventions into clinical practice.

Several strategies and recommendations for enhancing treatment fidelity in research designs have been identified. To gather the most valuable data, it is essential that the treatment fidelity plan be developed at the onset and maintained throughout the study. Evaluation of the internal validity of the study can take place when the researchers identify the key components of the treatment that are believed to underlie efficacy and then gather systematic measurements of delivery and enactment of those components. These measures either provide confirmatory evidence when fidelity is good that positive changes detected in the study are a true reflection of the intervention and the theory underlying it, or raise concern when fidelity is poor that the effects may have less to do with specific treatment components and more to do with nonspecific or chance effects. External validity is evaluated when recruitment and retention of clinical sites, providers, and treatment recipients are monitored. Furthermore, the goal of dissemination is served when the costs of training and recruitment and retention strategies are fully described.

A reasonable question to ask is what level of treatment fidelity should be achieved? Since perfect fidelity across all of the dimensions can never be achieved in real-world clinical settings, how much loss of fidelity can or should be tolerated? Convention has some part to play in this as it does for acceptable levels of scale reliability and validity. However, different treatments and patient populations will likely require different levels of treatment fidelity to achieve meaningful clinical outcomes. Some treatments may be so powerful that even a 50% adherence would yield adequate results, whereas other treatments might require much higher levels. This highlights the importance of monitoring treatment fidelity during pilot work and clinical trials to relate levels of treatment fidelity with observed levels of treatment effects.

As illustrated in this article, application of treatment fidelity guidelines has particular advantages when conducting pilot work in preparation for the design of large-scale clinical trials and proposals to fund the work. This article describes the application of treatment fidelity guidelines in a clinical pilot study and the important insights gained to improve the design of a multisite clinical trial for patients with chronic pain due to arthritis. On the basis of the BCC recommendations,[7] we chose treatment fidelity strategies at the onset that would expose the strengths and weaknesses of our protocol. Acquisition, retention, and visit attendance of patients was documented. Adherence by the nurse to treatment delivery was evaluated by independent ratings of audio-taped sessions on a checklist containing essential elements of the protocol. Patients were administered questionnaires to provide feedback on effectiveness of nurse delivery of treatment and their use of learned skills.

The purpose of our pilot study was to evaluate the feasibility of training an adult NP in CST for pain management and the effectiveness of that treatment in a community rheumatology practice. We hypothesized that a non–mental health NP employed in rheumatology practices could successfully implement this intervention. Although initially confident in her acquisition of CST skills, results on several fidelity measures indicated that several components of the treatment require more intensive training. Without systematic analysis of treatment implementation, the specific deficits in treatment delivery may not have been evident. Details regarding the length of sessions and the specific treatment components omitted provided insight into the kinds of changes necessary for nurse training to improve treatment implementation in the proposed clinical trial. Moreover, these data helped to explain the pattern of results in the outcome measures. Some measures yielded strong treatment effects comparable to those observed in the original efficacy studies using psychologists as providers, whereas other measures yielded weaker than expected effects. Recognizing these patterns in a pilot study enables the researcher to put into place the necessary steps to make protocol adjustments to increase the success of a clinical trial.

Monitoring of recruitment and retention statistics during a pilot study also informs the design of a trial. An initial survey in the waiting room of the community rheumatology practice where our pilot was conducted indicated that 73% of 43 patients with arthritis would be interested in participating in CST treatment if offered in their rheumatology office. We found that 64% (7/11) patients who were invited into our pilot study were interested. Furthermore, only 16% (1/6) dropped out, and 5 completed all 10 sessions. These data provide a stronger basis on which to anticipate recruitment and attrition during the clinical trial, as well as to predict treatment dosing. Patient reported satisfaction with the nurse provider and with the treatment program also increases confidence in the ability to translate this treatment to a community-based model. Nevertheless, some caution must be exercised in these conclusions, as one of the limitations of this pilot was that only 1 nurse delivered the treatment. Variability across treatment delivery by a number of nurses in the clinical trial is to be expected.

Recognizing the complexity of research designs and the need to establish credibility when testing interventions, the BCC[7] developed a set of treatment fidelity guidelines. No doubt scrupulous attention to treatment fidelity places a burden on the research process in terms of financial and personnel resources both during pilot work and during the trial. The benefits, however, are substantial, as they provide the basis for conducting and evaluating clinical trials at a higher standard. When folded into the early pilot stages of clinical trial design, they can provide invaluable information to improve the intervention, its delivery, and patient uptake and dosing before significant time and resources are devoted to a large-scale trial. Moreover, when collected during a trial, they provide a rich set of quantitative and qualitative data that penetrates deeply into many aspects of the execution of the protocol to guide interpretation of the internal and external validity of the study and the interpretation of the clinical outcomes. This high degree of explication also serves the goal of facilitating study replication and treatment dissemination. By incorporating the treatment fidelity process into nursing research, the integrity of health behavior research outcomes is enhanced and findings will be more apt to be translated into real-world practice.

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