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Enhancing Treatment Fidelity in Health Behavior Change Studies: Best Practices and Recommendations From the NIH Behavior Change Consortium

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Treatment fidelity refers to the methodological strategies used to monitor and enhance the reliability and validity of behavioral interventions. This article describes a multisite effort by the Treatment Fidelity Workgroup of the National Institutes of Health Behavior Change Consortium (BCC) to identify treatment fidelity concepts and strategies in health behavior intervention research. The work group reviewed treatment fidelity practices in the research literature, identified techniques used within the BCC, and developed recommendations for incorporating these practices more consistently. The recommendations cover study design, provider training, treatment delivery, treatment receipt, and enactment of treatment skills. Funding agencies, reviewers, and journal editors are encouraged to make treatment fidelity a standard part of the conduct and evaluation of health behavior intervention research.

Key words: treatment fidelity, health behavior, translational research, reliability, validity

Treatment fidelity refers to the methodological strategies used to monitor and enhance the reliability and validity of behavioral interventions. It also refers to the methodological practices used to ensure that a research study reliably and validly tests a clinical intervention. Although some strategies to enhance treatment fidelity in research may be quite familiar (e.g., the use of treatment manuals, videotape monitoring of therapist adherence to research protocols, and testing subject acquisition of treatment skills), there is inconsistency in their use, particularly in health behavior intervention research. Methodological procedures for preserving internal validity and enhancing external validity in studies, though critical to the interpretation of findings, are not emphasized in research-training curricula, and their relative lack of perceived importance is also evidenced by the scant reporting of treatment fidelity practices in journal articles. By comparison, procedures for evaluating the reliability and validity of questionnaires and other measurement instruments are well understood. Our purpose in this article is to provide a useful conceptualization of treatment fidelity, describe specific treatment fidelity strategies, and offer recommendations for incorporating treatment fidelity practices in health behavior intervention research. We believe that adopting these practices will contribute to the continued development of innovative, credible, and clinically applicable health behavior interventions and programs.

The concept of treatment fidelity has evolved over time. Although treatment fidelity was mentioned in a few social and behavioral studies in the late 1970s and early 1980s (e.g., Peterson, Homer, & Wonderlich, 1982; Quay, 1977), Moncher and Prinz's

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(1991) article was the first to formally introduce a definition and propose guidelines for the enhancement of treatment fidelity. Prior to Moncher and Prinz's article, treatment fidelity was generally considered as *treatment integrity*—that is, whether the treatment was delivered as intended. Moncher and Prinz added the concept of *treatment differentiation*, or whether the treatment conditions differed from one another in the intended manner (Kazdin, 1986). Subsequently, Lichstein, Riedel, and Grieve (1994) argued that two additional processes needed to be assessed in order to properly interpret the results of studies: (a) *treatment receipt*, which involves both assessing and optimizing the degree to which the participant understands and demonstrates knowledge of and ability to use treatment skills, and (b) *treatment enactment*, which involves assessing and optimizing the degree to which the participant applies the skills learned in treatment in his or her daily life. They considered treatment delivery, receipt, and enactment to constitute a full treatment implementation model (Burgio et al., 2001; Lichstein et al., 1994).

Lichstein and colleagues (1994) used a medical example to illustrate these different components. Assessment of whether a physician wrote a prescription (delivery) is inadequate for ensuring that the treatment has been implemented as intended. To receive an active dose of the treatment, the patient must then fill the prescription (receipt) and take the medicine as prescribed (enactment). Although enactment is identical to treatment adherence in their example, there are numerous situations in health behavior research in which enactment is distinguished from adherence. For instance, in a Behavior Change Consortium (BCC) study on smoking cessation for parents of children with asthma, smokers motivated to quit were given strategies that would help them do so (delivery), and the strategies were discussed with them to verify that they understood and could use them (receipt). However, the strategies may or may not have actually been used (enactment), and if they were used, they may or may not have led to smoking cessation (adherence to the treatment recommendation to stop smoking). In both examples, assessment and potential intervention with therapist behavior (in relation to treatment delivery) and with patient behavior (in relation to treatment receipt and enactment) are integral to maintenance of a study's reliability and validity.

Rationale for Considering Treatment Fidelity

Treatment fidelity influences a variety of study issues. Questionable internal and external validity may make it impossible to draw accurate conclusions about treatment efficacy or to replicate a study. For example, in evaluating a new intervention, if significant results were found but fidelity was not monitored and optimized, one does not know whether the outcome was due to an effective treatment or to unknown factors that may have been unintentionally added to or omitted from the treatment (Cook & Campbell, 1979). If, however, nonsignificant results were found and the level of treatment fidelity is unknown, one does not know whether the outcome was due to an ineffective treatment or to lack of treatment fidelity (Moncher & Prinz, 1991), because internal validity and effect size are highly correlated (Smith, Glass, & Miller, 1980). In the latter case, new, potentially effective treatments may be prematurely discarded, whereas in the former case, unsuccessful treatments may be implemented and disseminated in clinical and public health settings at a high cost to patients, providers, and organizations.

By assessing treatment fidelity, however, investigators can have greater confidence in their results. If they go a step further and use quantitative methods for assessment, they can use treatment fidelity measures in data analyses to determine the extent to which their results are actually due to the study intervention. For instance, one might use a measure of nonspecific treatment effects associated with different therapists (a treatment delivery variable) as a covariate to better define the effects of the intervention apart from the effects of the therapists. Treatment fidelity may also be assessed with the goal of improving the design of a study (Kazdin, 1994). For example, in a study with poor treatment adherence among participants, if measures of treatment receipt are found to be associated with adherence, the study procedures may be redesigned to improve receipt and thereby provide a better test of the intervention.

By reducing random and unintended variability in a study, improving treatment fidelity can also improve statistical power. Monitoring and optimizing treatment fidelity over a series of studies may increase effect sizes and reduce the number of subjects required in later studies, thereby decreasing costs and improving the efficacy of an intervention research program. Even during a single study, optimizing treatment fidelity increases the chance that investigators will find significant results. For instance, evaluation of treatment delivery over time might reveal a drift in interventionist adherence to a smoking cessation treatment protocol, perhaps warranting retraining of those providing the intervention to minimize the problem's impact on the internal validity of the intervention.

Procedures to maximize treatment fidelity also have implications for research focusing on theory development, comparison, and application (Nigg, Allegrante, & Ory, 2002b). Only when there is a high degree of awareness and control over factors associated with a study's internal validity, such as the impact of nonspecific treatment effects and unintended clinical processes on an intervention (e.g., a treatment provider's inadvertent use of a cognitive procedure in a behavioral protocol) is it possible to evaluate the efficacy of a theory-based intervention, test a theoretical question, or compare the impact of two or more theoretical processes on an outcome. Unless treatment fidelity is explicitly maintained, the extent to which the theory-based intervention being tested is the primary mechanism for the observed changes in the dependent variables of interest will remain unclear.

Finally, treatment fidelity is also a potentially important component of successful research dissemination. Behavioral medicine practitioners are often in the position of attempting to implement new procedures in medical settings where medical and nursing staff have clinical expertise but limited familiarity with behavioral change research. Translating effective behavioral change interventions from research settings to clinical practice can be facilitated when investigators employ and describe treatment fidelity strategies that can be used as guidelines for implementing the new interventions in the clinic.

Addressing Treatment Fidelity in the BCC

In July 1999, the National Institutes of Health (NIH), along with the American Heart Association, established the BCC to provide an infrastructure to foster collaboration among 15 projects that had been funded under a request for applications calling for proposals to test innovative approaches to health behavior change in diverse populations. The studies either test two theories of health behavior change or the effectiveness of one theory across multiple health behaviors such as diet, exercise, or smoking (Ory, Jordan, &

Bazzarre, 2002); details of the studies are available in a special issue of *Health Education Research* (Nigg et al., 2002a). The BCC consists of principal investigators and coinvestigators on these projects, key staff, program representatives from the NIH who were involved in the projects, and representatives from the American Heart Association and foundations such as the Robert Wood Johnson Foundation that provided additional support.

Because of the complexity of research designs, the diversity of populations, and the greater than usual need to maintain credibility when testing innovative interventions, issues of design and implementation in the BCC studies were particularly challenging. This resulted in formation of a set of BCC work groups to address these issues across studies. As part of this effort, the Treatment Fidelity Workgroup was formed and charged with advancing the definition, methodology, and measurement of treatment fidelity both within the BCC and, more generally, for the field of health behavior change (Belinda Borrelli, Albert J. Bellg, and Susan Czajkowski were the cochairs). In pursuing that mission, the Treatment Fidelity Workgroup developed new recommendations for treatment fidelity that expand upon the Lichstein et al. (1994) model and increase the relevance of treatment fidelity for health behavior change studies. A detailed survey of all 15 BCC studies was also conducted to identify the strategies the studies used to address their particular treatment fidelity issues. From the responses, a list of "best practices" in treatment fidelity was created to provide examples of how the BCC recommendations may be used in health behavior intervention research.

BCC Treatment Fidelity Recommendations

The BCC treatment fidelity recommendations intend to link theory and application in five areas: study design, training providers, delivery of treatment, receipt of treatment, and enactment of treatment skills. The five areas (with examples from BCC studies) are intended to provide behavioral health investigators with a comprehensive way to conceptualize and address treatment fidelity issues in their studies.

Design of Study

Practices. Treatment fidelity practices related to study design are intended to ensure that a study can adequately test its hypotheses in relation to its underlying theory and clinical processes. Ensuring that interventions are congruent with relevant theory and clinical experience involves operationalizing treatments to optimally reflect their theoretical and pragmatic roots and precisely defining independent and dependent variables most relevant to the "active ingredient" of the treatment (Moncher & Prinz, 1991). The active ingredient of a treatment may vary substantially depending on whether an intervention is designed to influence cognitions, behavior, or a subjective motivational state. In addition, the effect of an intervention can only be adequately assessed when the research design does not confound treatment effects with extraneous differences between treatment groups or treatment and control groups. Therefore, treatment fidelity goals in this category (see Table 1) include establishing procedures to monitor and decrease the potential for contamination between active treatments or treatment and control, procedures to measure dose and intensity (e.g., length of intervention contact, number of contacts, and frequency of contacts), and procedures to address foreseeable setbacks in implementation (e.g., therapist dropout over the course of a multiyear study).

For example, a BCC study looking at dietary change controlled treatment dose by using group sessions of the same length for both

Table 1
Treatment Fidelity Strategies for Design of Study

Goal	Description	Strategies
Ensure same treatment dose within conditions.	Ensure that treatment "dose" (measured by number, frequency, and length of contact) is adequately described and is the same for each subject within a particular treatment condition.	Use computer prompts for contacts; ensure fixed length, number, and frequency of contact sessions; ensure fixed duration of intervention protocol; record deviations from protocol regarding number, length, and frequency of contacts; ensure fixed amount of information for each treatment/control group; use scripted curriculum or treatment manual; externally monitor sessions and provide feedback to providers; have provider self-monitor or keep log of encounter; monitor homework completion; give specialized training to providers to deal with different types of patients equally.
Ensure equivalent dose across conditions.	Ensure that treatment dose is the same across conditions, particularly when conditions include multiple behavioral targets (e.g., exercise, smoking).	Have equal number of contacts for each intervention; use equal length of time for each intervention; use same level of informational content for each intervention. When dose is *not* the same, stipulate the minimum and maximum amount of treatment provided and track number, frequency, and duration of contacts.
Plan for implementation setbacks.	Address possible setbacks in implementation (e.g., treatment providers dropping out).	Have pool of potential providers so that new providers need not be trained in a hurry; train extra providers beyond those needed; have human backup for computer-delivered intervention; track provider attrition.

treatment and control conditions, with attendance at all sessions encouraged by a reward at the end of the study. A study providing a smoking cessation intervention to individuals, however, could not reasonably control the length of contact with subjects as closely and so encouraged treatment providers to stay within a certain range of time and had them record the exact amount of time spent delivering the intervention so that the possible effect of this variable could be examined.

Addressing possible setbacks in implementation at the outset is important to ensure consistency throughout the course of the study. For example, unanticipated provider dropout may result in hurried attempts to recruit and train new providers, which may lead to performance differences between the new and existing providers. The majority of the BCC sites reported that they were taking measures to prevent setbacks in implementation, such as training extra providers or, when the intervention is delivered by computer and the study design permitted it, training humans as a backup for the computerized intervention.

Recommendations. Strategies for enhancing treatment fidelity related to study design should be well defined and thoroughly described prior to study implementation. We recommend that researchers consider the following questions during the design phase of their study: How well does the intervention itself reflect its theoretical foundations, and in what specific ways does it do so? What are the areas where it might not do so? How does the study ensure that each participant receives the same "dose" of the treatment or treatments? How does the study ensure that treatment dose is the same across multiple interventions or multiple behavioral targets? How does the study anticipate and address possible implementation setbacks?

Training Providers

Practices. An important area of treatment fidelity is assessing and improving the training of treatment providers to ensure that they have been satisfactorily trained to deliver the intervention to study participants. Training in a specific intervention often requires the acquisition of new skills, which may interact significantly with a clinician's existing clinical training and experience. The adequacy of training to implement the intervention needs to be evaluated and monitored on an individual basis both during and after the training process. General strategies in this category include standardizing training, measuring skill acquisition in providers, and having procedures in place to prevent drift in skills over time (see Table 2).

The first strategy in Table 2, standardization of training, involves ensuring that all providers are trained in the same manner in order to increase the likelihood that the intervention will be delivered systematically across providers, decrease the likelihood that there will be Provider × Treatment interactions, and prevent differential outcomes by provider. Standardization, however, does not preclude individualization of training, which includes accounting for different levels of education, experience, and implementation styles. Some methods of standardizing training include using standardized training materials, conducting role-playing, and observing actual intervention and evaluating adherence to protocol.

Standardized training of providers to criteria also needs to be viewed as an ongoing effort rather than as a one-time event. This is especially important when it is likely that there will be turnover of staff throughout the intervention period. When multiple training sessions are required, it is helpful to have the same trainers conducting training workshops in order to maintain and reinforce standards across providers and throughout the study period. Certification or recertification of providers is another way to enhance and document adequacy of provider training and standardization of training procedures. Using standardized and pretested training materials and manuals can also increase the likelihood that all providers are receiving similar training. Setting performance criteria and documenting that all providers meet those standards before delivering interventions also help to ensure the required skill level of all providers.

Measuring provider skill acquisition both during and after training is necessary to ensure that training has been successful. Nearly all BCC sites measured skill acquisition either by direct observation, written pre- and posttests, or some combination of the two methods. However, although initial skill acquisition may be adequate, such skills may be vulnerable to deterioration over time. Intervention components may be unintentionally omitted or extraneous components unintentionally added, thus contaminating delivery of the intervention. It is essential that procedures be put in place to address provider deficiencies throughout the study. "Drift" from the original protocol can be minimized in a variety of ways, such as by scheduling periodic training "booster" sessions with providers or having regular supervision with providers. All but one BCC site systematically evaluated provider skills and implemented measures to prevent skills drift over time. The sites that reported using layperson providers used many of the same training strategies outlined previously but also made training more intensive and took professional experience into account when evaluating the intervention's effectiveness.

Recommendations. Most researchers make sure that provider training is addressed at the beginning of studies. There is less focus, however, on monitoring and maintaining provider skills as the study progresses. We recommend that researchers be able to answer the following questions: How will training be standardized across providers? How will skill acquisition in providers be measured? How will decay or change in provider skills be minimized? How will providers of differing professional training or skill levels be trained to deliver the intervention in a similar way?

Delivery of Treatment

Practices. Treatment fidelity processes that monitor and improve delivery of the intervention so that it is delivered as intended are essential. Even well-trained interventionists may not always deliver an intervention protocol effectively when clinical circumstances or their training or involvement in other types of interventions interfere with their doing so. General goals in this category include using procedures to standardize delivery and checking for protocol adherence (see Table 3).

The gold standard to ensure satisfactory delivery is to evaluate or code intervention sessions (observed in vivo or video- or audiotaped) according to a priori criteria. Requiring providers to complete process evaluation forms or behavior checklists after each intervention session may remind them to include the requisite skills and content appropriate for each intervention and minimize contamination from comparison interventions. Checklists, however, are less reliable correlates of what actually happens in a

Table 2
Treatment Fidelity Strategies for Monitoring and Improving Provider Training

Goal	Description	Strategies
Standardize training.	Ensure that training is conducted similarly for different providers.	Ensure that providers meet a priori performance criteria; have providers train together; use standardized training manuals/materials/provider resources/field guides; have training take into account the different experience levels of providers; use structured practice and role-playing; use standardized patients; observe intervention implementation with pilot participants; use same instructors for all providers; videotape training in case there needs to be future training for other providers; design training to allow for diverse implementation styles.
Ensure provider skill acquisition.	Train providers to well-defined performance criteria.	Observe intervention implementation with standardized patients and/or pilot participants (role-playing); score provider adherence according to an a priori checklist; conduct provider-identified problem solving and debriefing; provide written exam pre- and posttraining; certify interventionists initially (before the intervention) and periodically (during intervention implementation).
Minimize "drift" in provider skills.	Ensure that provider skills do not decay over time (e.g., show that provider skills demonstrated halfway through the intervention period are not significantly different than skills immediately after initial training).	Conduct regular booster sessions; conduct in vivo observation or recorded (audio- or videotaped) encounters and review (score providers on their adherence using a priori checklist); provide multiple training sessions; conduct weekly supervision or periodic meetings with providers; allow providers easy access to project staff for questions about the intervention; have providers complete self-report questionnaire; conduct patient exit interviews to assess whether certain treatment components were delivered.
Accommodate provider differences.	Ensure adequate level of training in layperson providers or providers of differing skill level, experience or professional background.	Have professional leaders supervise lay group leaders/paraprofessionals; monitor differential drop-out rates; evaluate differential effectiveness by professional experience; give all providers intensive training; use regular debriefing meetings; use provider-centered training according to needs, background, or clinical experience; have inexperienced providers add to training by attending workshops or training programs.

session (W. Miller, personal communication, March 22, 2002). Alternatively, creating forums or case conferences where providers can discuss intervention cases and review skills required for each intervention can help ensure that interventions are standardized across providers and are being conducted according to protocol.

Whether the treatment is being delivered in the way in which the intervention was conceived may be affected by providers not having enough time to implement the intervention, by having unforeseen obstacles to intervention delivery, or by nonspecific treatment effects such as the warmth and credibility of the provider. Behavior Change Consortium sites reported using audiotapes, videotapes, in vivo observation, or behavioral checklists to ensure that providers adhered to the treatment protocol. Most research sites used more than one method. All but one site reported that their providers used a treatment manual or an intervention protocol or script to aid in standardization of delivery. Several studies reported that they were using the same provider to deliver both treatment and control interventions. These sites reported that they were taking steps to reduce cross-contamination between treatments by using direct observation, audiotape monitoring, or subject exit interviews to ensure that control participants did not receive any of the intervention components.

To control for subtle expectations on the part of interventionists, one BCC study emphasized to treatment providers that it was important to give both treatment and control interventions the same emphasis because a primary outcome was long-term dietary adherence, and the posttreatment baselines needed to be similar for both groups. Behavior Change Consortium studies reported measuring other nonspecific treatment effects by self-report questionnaires completed by study participants, or in some cases, rating audiotaped intervention sessions for therapist–provider nonspecific effects.

Recommendations. Verifying the extent to which treatment was delivered as intended (and having a mechanism to improve delivery as needed) is crucial to preserve both internal and external study validity. We recommend that researchers be able to answer the following questions: How will the study measure and control for nonspecific treatment effects? How can you ensure that pro-

Table 3
Treatment Fidelity Strategies for Monitoring and Improving Delivery of Treatment

Goal	Description	Strategies
Control for provider differences.	Monitor and control for subject perceptions of nonspecific treatment effects (e.g., perceived warmth, credibility, etc., of therapist/provider) across intervention and control conditions.	Assess participants' perceptions of provider warmth and credibility via self-report questionnaire and provide feedback to interventionist and include in analyses; select providers for specific characteristics; monitor participant complaints; have providers work with all treatment groups; conduct a qualitative interview at end of study; audiotape sessions and have different supervisors evaluate them and rate therapist factors.
Reduce differences within treatment.	Ensure that providers in the same condition are delivering the same intervention.	Use scripted intervention protocol; provide a treatment manual; have supervisors rate audio- and videotapes.
Ensure adherence to treatment protocol.	Ensure that the treatments are being delivered in the way in which they were conceived with regard to content and treatment dose.	Provide computerized prompts to providers during sessions about intervention content; audio- or videotape encounter and review with provider; review tapes without knowing treatment condition and guess condition; randomly monitor audiotapes for both protocol adherence and nonspecific treatment effects; check for errors of omission and commission in intervention delivery; after each encounter, have provider complete a behavioral checklist of intervention components delivered; ensure provider comfort in reporting deviations from treatment manual content.
Minimize contamination between conditions.	Minimize contamination across treatment/control conditions, especially when implemented by same provider.	Randomize sites rather than individuals; use treatment-specific handouts, presentation materials, manuals; train providers to criterion with role-playing; give specific training to providers regarding the rationale for keeping conditions separate; supervise providers frequently; audiotape or observe sessions with review and feedback; conduct patient exit interviews to ensure that control subjects did not receive treatment.

viders deliver the intended intervention? How will you ensure that providers adhere to the treatment protocol? How will you minimize "contamination" across treatments when they are implemented by the same provider?

Receipt of Treatment

Practices. The last two treatment fidelity categories shift the focus from the provider to the patient. Receipt of treatment involves processes that monitor and improve the ability of patients to understand and perform treatment-related behavioral skills and cognitive strategies during treatment delivery. If the intervention seeks to increase motivation for change or alter other subjective states conceptually related to motivation (e.g., readiness to change, self-determination, self-efficacy), receipt refers to the extent to which the patient's speech or behavior endorses the increased level of motivation. Note that treatment receipt specifically relates to the ability of patients to demonstrate *during the intervention* that they understand and can perform the behavioral skills (e.g., relaxation techniques, completing food diaries) or cognitive strategies (e.g., reframing, problem solving) that have been presented to them or that they are able to experience the desired change in subjective state induced by the intervention. If a patient does not understand or is not able to implement the new skills, then an otherwise effective intervention may be incorrectly deemed as ineffective.

For receipt of treatment (see Table 4), most BCC sites reported that they verified that participants understood the intervention during treatment sessions. Methods of measurement included administering pre- and posttests, structuring the intervention around achievement-based objectives, and reviewing homework assignments. A majority of sites also reported employing strategies to verify that participants were able to use the cognitive, behavioral, and subjective skills provided in the intervention. For instance, a BCC study that focused on changing exercise behavior used monthly review-of-goal forms and activity calendars to confirm that participants were able to perform the treatment activities during training sessions.

Recommendations. It is important to choose measures of receipt that take into account the specific types of information and skills that are part of the intervention. We recommend that researchers be able to answer the following questions: How will you verify that subjects understand the information you provide them with? How will you verify that subjects can use the cognitive and

Table 4
Treatment Fidelity Strategies for Monitoring and Improving Receipt of Treatment

Goal	Description	Strategies
Ensure participant comprehension.	Ensure that participants understand the information provided in intervention, especially when participants may be cognitively compromised, have a low level of literacy/education, or not be proficient in English.	Use pre- and posttest process and knowledge measures; have providers review homework or self-monitoring logs; have providers ask questions/discuss material with subjects; use scripts that prompt providers to paraphrase/summarize content; complete activity logs; structure intervention around achievement-based objectives; conduct structured interview with participants; have providers work with subjects until they can demonstrate the skills; have providers monitor and give feedback on practice sessions.
Ensure participant ability to use cognitive skills.	Make sure that participants are able to use the cognitive skills taught in the intervention (e.g., reframing, problem solving, preparing for high-risk situations, etc.).	Conduct structured interviews with participants; have providers review homework; have providers work with participants until they can demonstrate skills; use measures of mediating variables; have providers monitor and give feedback on practice sessions; measure participant performance and completion of training assignments; have providers assess cognitive skills; have participants provide feedback on ability; use questionnaires; use problem-solving structured interview that sets up hypothetical situations and asks participants to provide strategies for overcoming obstacles to changing their behaviors.
Ensure participant ability to perform behavioral skills.	Make sure that participants are able to use the behavioral skills taught in the intervention (e.g., relaxation techniques, food diaries, cigarette refusal skills, etc.).	Collect self-monitoring/self-report data (participants verbally confirm competence); observe subjects; use behavioral outcome measures; complete training assignments; monitor (electronically/objectively) behavioral adherence; follow-up telephone contacts/counseling.

behavioral skills you teach them or evoke the subjective state you train them to use? How will you address issues that interfere with receipt?

Enactment of Treatment Skills

Practices. Enactment of treatment skills consists of processes to monitor and improve the ability of patients to perform treatment-related behavioral skills and cognitive strategies in relevant real-life settings. In the case of an induced motivational or subjective state, enactment is the degree to which the state can be adopted in the appropriate life setting. This treatment fidelity process is the final stage in implementing an intervention in that it involves patients' actual performance of treatment skills in the intended situations and at the appropriate time.

Enactment of treatment skills may seem to be confounded with treatment adherence or treatment efficacy, and making clear distinctions between these three concepts is useful. Enactment specifically relates to the extent to which a patient actually implements a specific behavioral skill, cognitive strategy, or motivational state at the appropriate time and setting in his or her daily life (e.g., fills a pill organizer at the beginning of the week, uses a cognitive strategy to deal with a craving for cigarettes, or tries out new recipes to identify healthy and appealing dinners). In contrast, treatment adherence relates to whether the patient performs the tasks definitive of medical treatment or a healthy lifestyle change (e.g., actually takes medications, avoids smoking, or eats a healthy diet). Treatment efficacy relates primarily to whether the intervention influences the research or clinical endpoint of interest (e.g., whether a cholesterol-lowering medication lowers cholesterol or reduces acute medical events or hospitalization, whether stopping smoking reduces asthma severity, or whether eating a low-salt diet results in lower blood pressure).

It is therefore possible to have a study with adequate or excellent enactment of treatment skills that has poor treatment adherence or treatment efficacy (e.g., someone who fills a pill organizer but never takes his or her medications or gets the health benefit of taking them, deals with cravings for cigarettes but does not stop smoking or have fewer asthma symptoms, or tries out healthy low-salt recipes but does not keep eating them or achieve a reduction in blood pressure). Such a study would provide a good

test of the intervention, because treatment skills are being used by patients but are not effective at changing their health behavior or their health outcomes. In a study with poor enactment, however, neither treatment adherence nor efficacy is likely to be high, but the researcher will be unable to state whether this is due to poor enactment or to an ineffective intervention.

It should be noted that in psychological intervention studies in which the outcome is incorporation of a set of psychological, social, or behavioral skills into daily life (e.g., mental health or psychotherapy outcome studies) and in biomedical studies that involve routine use of medication or medical devices, treatment goals may be defined in such a way that treatment enactment may be the same as adherence to treatment. For example, in a study examining ways in which to train patients with heart failure to care for a ventricular assist device, the patient's proper response to warning alarms may be defined as both enacting the skill the patient is trained in and adhering to the health behavior outcome of interest. However, for behavioral change studies in which behavioral, psychological, or social treatments are used to alter behavioral risk factors such as diet, physical activity, or smoking behavior, enactment is appropriately distinguished from adherence, as in the previous examples.

As for enactment of treatment skills in real-life settings (see Table 5), most BCC sites reported assessing whether participants actually used the cognitive skills that are part of their intervention. Enactment assessments and interventions included questionnaires and self-reports, structured follow-up interviews, and telephone calls. All but one study site also reported assessing whether subjects actually used the behavioral skills in the intervention. Along with the above strategies, enactment of behavioral skills was monitored with activity logs, participation in social-learning games that provided a record of the desired activity, electronic monitoring of behavior (engaging in exercise or pill taking), and measurement of biological markers associated with the desired behaviors. For example, a BCC smoking cessation study measured enactment by tracking the use of nicotine patches, and a study intervening with diet and exercise tracked participants' reports of using problem-solving and emotional expressiveness skills taught during treatment with their spouse or partner.

Recommendations. Enactment is one of the most challenging aspects of treatment fidelity, both conceptually and pragmatically. Even so, we believe that an important distinction needs to be made between what is taught (treatment delivery), what is learned (treatment receipt), and what is actually used (enactment). We recommend that researchers be able to answer the following questions: How will you verify that subjects actually use the cognitive, behavioral, and motivational skills and strategies you provide them with in the appropriate life situations? How will you address issues that interfere with enactment?

Discussion and General Recommendations

The following are our general recommendations to the research community for improving the current state of the art in treatment fidelity and making it a practical and useful part of health behavior research.

We recommend that plans for enhancing and monitoring treatment fidelity be conceptualized as an integral part of the initial planning and design of health behavior intervention studies. This is particularly important for studies venturing into less well-understood areas. The needs of each study are different, and ideally the components of the treatment fidelity plan are selected

Table 5
Treatment Fidelity Strategies for Monitoring and Improving Enactment of Treatment Skills

Goal	Description	Strategies
Ensure participant use of cognitive skills.	Ensure that participants actually use the cognitive skills provided in the intervention in appropriate life settings.	Use process measure; assess with questionnaire; use self-report regarding achievement of goals; provide contact form to monitor participant interaction with staff; use structured interview with participants; use exercises, goal sheets, and other printed material to foster adherence; assess mediating processes periodically; record telephone contacts; discuss ongoing use of skills with subjects; conduct follow-up discussions with participants.
Ensure participant use of behavioral skills.	Ensure that participants actually use the behavioral skills provided in the intervention in appropriate life settings.	Assess with questionnaires; observe participants' in vivo interactions; assess during provider encounter; use social-learning game, providing record of behaviors; conduct self-report or self-monitoring and maintain activity log; measure objective biological or physiological markers; maintain longitudinal contact (telephone, mailed information, etc.) to encourage adherence; record time spent at facility; monitor frequency of sessions; use specific behavioral skill use measures; electronically monitor behavior; follow up discussions with participants; conduct follow-up discussions/telephone calls/counseling with participants.

on the basis of the theoretical and clinical framework for each intervention. For example, a participant's demonstration of certain behavior- and knowledge-based skills in his or her life might be an appropriate indication that the participant is enacting an educationally based intervention but may not accurately reflect enactment of a motivational intervention. Enactment of a motivational intervention may be better indicated by a participant's self-statements reflecting confidence in being able to make changes to improve his or her health. With multilevel interventions, it is also important to assess treatment fidelity issues at both the micro and the macro levels, examining, for instance, whether interventions both incorporate specific behaviors and achieve broader behavioral objectives.

We also recommend that investigators not only institute treatment fidelity plans at the outset of the study but also maintain consistent efforts to adhere to a comprehensive treatment fidelity plan throughout the study period. We recognize, however, that such plans may need to be modified to accommodate practical needs and other study demands. In studies where intervention providers work exclusively for the study, for example, it may be possible to use numerous strategies to maintain high standards of treatment fidelity. However, in situations where intervention providers are integrating the intervention into their current clinical practice, it may not be feasible to use all desirable treatment fidelity strategies. In these situations, a more pragmatic and limited plan may be necessary and should be documented. Therefore, it is important to consider the setting, other study demands, and provider and participant burden in order to design a plan that is practical, achievable, and effective for monitoring and improving treatment fidelity.

Overall, we believe that having a specific plan to enhance and monitor treatment fidelity concerns addressed in all five areas covered by the BCC treatment fidelity recommendations will help counter threats to the study's internal and external validity and therefore enable investigators to draw more accurate conclusions about the validity and effectiveness of study interventions. It also will help guide future researchers and program developers in testing and selecting intervention components that have the most positive impact on behavioral and treatment outcomes. For clinicians, it will make it possible to identify interventions appropriate to the available resources and implement them with the reasonable expectation that the results will be similar to those achieved in clinical trials.

It is particularly important that funding agencies, reviewers, and journal editors who publish behavioral change research consider treatment fidelity issues. It is our hope that funding initiatives (e.g., Requests for Applications and Requests for Proposals), reviewer guidelines, and publishing requirements will include an explicit focus on the methods used by researchers to monitor and enhance treatment fidelity in health behavior intervention studies. As is the case with current efforts to ensure adequate representation of women and minorities in clinical research studies, those charged with oversight of the funding, review, conduct, and reporting of behavioral change research need to take the lead in encouraging researchers to address treatment fidelity issues. By asking researchers to address this issue in funding applications and by making report of treatment fidelity methods a part of journal editorial policy, methods to enhance and measure treatment fidelity are more likely to become standard features in health behavior intervention studies. Ultimately, this will lead to increased credibility for the field of behavioral medicine research.

Some researchers may be concerned that such efforts will be time-consuming and costly. It is not our intention to add to the work and cost of health behavior intervention studies but to make them more efficient and effective in identifying useful interventions. Each study deals with unique circumstances, and there is no fixed set of treatment fidelity practices that must be added to the budgets of research projects and the burdens of researchers. Indeed, our list of "best practices" compiled from BCC studies represents existing assumptions and strategies for the use of treatment fidelity practices in research. However, it is our hope that the BCC treatment fidelity recommendations will play a role in identifying and organizing treatment fidelity practices so that they may be more easily and regularly applied by the research community.

Our contention is that not devoting resources to treatment fidelity is ultimately more costly in time, financial resources, and credibility than doing so. Moreover, with the current focus on translation of research findings into real-world settings, treatment fidelity issues become all the more important. Funding agencies and researchers clearly have an interest in minimizing the chance that the studies they are involved in produce equivocal results or cannot be replicated in the laboratory or the clinic. Health behavior intervention research and behavioral medicine as a whole can only benefit from studies that are more reliable, valid, and clinically applicable. Our final recommendation is that treatment fidelity should become an integral part of the conduct and evaluation of all health behavior intervention research.

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