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Treatment Fidelity in Mind–Body Interventions

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Abstract

Purpose—To contribute to the treatment fidelity literature by providing real-world examples and suggestion for future research and potential clinical application, this article reports on implementation, assessment, and evaluation of treatment fidelity in mind–body self-care approaches in at-risk women.

Method—Aligning with best practices, treatment fidelity was integrated into three randomized clinical trials. The first examined the effects of a tai chi intervention designed to decrease cardiometabolic risk factors in women; the second examined the effects of a tailored guided imagery intervention on pregnancy outcomes in African American women; and the third explored effects of a mindful physical activity intervention (yoga) on psychological outcomes in women with moderate to severe depressive symptoms

Findings—Each of the studies successfully designed, implemented, and evaluated strategies to address recommended treatment fidelity components. These strategies provided qualitative and quantitative data that informed intervention refinement, directions for future research, and application in clinical practice.

Conclusions—The treatment fidelity framework used here is based on best practices and was a feasible and reliable approach for ensuring and reporting on treatment fidelity, which is contributing to future research to foster translation of potentially effective mind–body self-care approaches into practice.

Keywords

treatment fidelity; tai chi; guided imagery; yoga; mind–body

Introduction

A key component of building a strong evidence base and efficiently translating effective interventions into clinical practice is to employ a process that ensures an intervention was delivered as intended (Breitenstein et al., 2010). Treatment fidelity contributes to a study's methodological rigor by enhancing both internal and external validity. It increases confidence that changes in dependent variables can be attributed to the independent variable (intervention). Furthermore, treatment fidelity supports refinement of the intervention, study

replication, as well as translation to clinical settings. However, only when there is a high level of awareness and control over factors associated with the fidelity of an intervention can researchers demonstrate the effectiveness of the intervention (internal validity) and facilitate implementation in clinical practice (external validity; Bellg et al., 2004).

While there are currently several terms used to describe this process, including intervention integrity, intervention fidelity, and implementation fidelity, they each share the common idea of ensuring that an intervention is delivered as designed (Breitenstein et al., 2010). The term *treatment fidelity* is used here because it aligns with best practices and recommendations from the National Institutes of Health Behavior Change Consortium, which were used to develop treatment fidelity strategies for behavioral intervention studies (Bellg et al., 2004). Building on the work of the consortium, a framework for assessing and evaluating treatment fidelity in behavioral research was developed (Borrelli et al., 2005). The framework encompasses five components for ensuring treatment fidelity: (1) treatment design, (2) training providers, (3) delivery of treatment, (4) receipt of treatment, and (5) enactment of treatment skills. These five strategies frame the reporting of the treatment fidelity processes, procedures, and outcomes of the mind–body self-care studies reported here.

Historically, the quality of mind–body research has lacked methodological rigor in part because processes related to intervention fidelity, if implemented, are not reported; furthermore, this omission is typically not cited as a study limitation. This hinders advancing the science as well as translation of these potentially effective self-care approaches into clinical practice. To address this issue, treatment fidelity was a specific focus in three community-based prevention studies of mind–body interventions. The first was a study examining the effects of a tailored tai chi (TC) intervention on cardiometabolic risk factors in women. The second was a study examining the effects of a tailored guided imagery (GI) intervention on pregnancy outcomes. The third study evaluated the effects of yoga on psychological outcomes in women with moderate to severe levels of depressive symptoms.

All studies were approved by the institutional review board of the authors' respective institutions and included written informed consent of participants. An overview of each study is provided with a focus on the strategies used to ensure treatment fidelity.

Tai Chi and Cardiometabolic Risk in Women

Study Overview

To explore the feasibility and acceptability as well as effects of a TC intervention on biobehavioral factors associated with cardiometabolic risk in women, a randomized clinical trial was conducted between June 2011 and December 2012. A total of 63 women ($n = 31$, intervention; $n = 32$, control) aged 35 to 50 years with increased waist circumference and a family history of cardiovascular disease completed the study. A full report of study results has been previously published (Robins, Elswick, Sturgill, & McCain, 2013).

Treatment Fidelity

Treatment Design—In relation to treatment fidelity, design should ensure that the study hypotheses are tested in relation to both underlying theory and clinical processes.

Development of the TC intervention was grounded in a holistic psychoneuroimmunology (PNI) based biobehavioral framework (McCain, Gray, Walter, & Robins, 2005). PNI is concerned with stress appraisal and involves investigation of the mechanisms of multidimensional psycho–neuroendocrine–immune system interactions, including the influence of psychosocial, spiritual, and behavioral factors on disease risk. This framework exemplifies and is consistent with current conceptualizations that cardiometabolic risk arises from the interplay of psychosociodemographic stress perception and physiological responses. Based on this framework, the TC intervention was designed to incorporate both TC and medical qigong movements to specifically target cardiometabolic risk factors by incorporating physiological, psychosocial, spiritual, and behavioral dimensions.

The TC intervention consisted of eight weekly 60-minute sessions. The intervention dose was based on prior studies done by the principle investigator (PI) as well as participant feedback from a previous feasibility pilot study, which indicated that in this age-group, a shorter intervention (less than 12 weeks) was easier to commit to (Robins, Elswick, & McCain, 2012). Data were collected immediately prior to and following the intervention and 2 months postintervention. While there is discrepancy about the optimal comparison/control group in mind–body interventions (Kinser & Robins, 2013), a wait-list control group design was used because it is a valid comparison group and a placebo for TC is highly controversial and difficult to achieve. Additionally, this design can enhance recruitment and retention. Contact with the control group consisted of enrollment and data collection visits at baseline, 2 months, and 4 months followed by receipt of the 8-week TC intervention.

To facilitate fidelity in treatment design, delivery, receipt, and enactment, a TC booklet and DVD were created. Both were composed of weekly “chapters” reviewing each of the TC movements. The booklet included the following: (1) Study overview; (2) Outline of weekly class content; (3) TC overview (definition, brief philosophy, and tips for safe practice); (4) Tips for successful home practice; and (5) Lined pages for taking notes. The DVD was professionally recorded and produced. The PI created a written script using the same words and instructions contained in the TC booklet. The DVD tracts were recorded consecutively on the same day in a university-based dance studio. Music and images from nature were incorporated into the background. While the PI was aware this might confound the TC intervention effects, it was deemed, based on prior work with TC research participants, they were more likely to watch and practice with the DVD in this format.

Training Providers—Provider training is focused on assessing and optimizing training processes for intervention delivery. In this study, while the interventionist was also the PI, the design included the training of a new interventionist for future studies. The trainee had been formally educated in her doctoral program using a PNI model and for several years had led spirituality focused group interventions. She was trained by the PI prior to the beginning of study recruitment. Training consisted of eight weekly 60-minute sessions with the PI using the same format and training materials designed for participants. Training materials included the aforementioned TC booklet and DVD. Additionally, an extensive study manual outlining all study and intervention processes and procedures was reviewed and given to the trainee.

Once participants were enrolled, the trainee attended the first two 8-week intervention groups conducted by the PI and then began to conduct the wait-list control TC groups. The PI attended the first wait-list 8-week group conducted by the trainee and provided critique and feedback to the trainee regarding the conduct of the group and the instruction of each element of the intervention using the Tai Chi Treatment Fidelity Review form designed for the study. This form was developed based on the TC booklet and DVD. Periodically, during subsequent wait-list groups, the PI attended sessions and provided feedback to the trainee as needed.

Delivery of Treatment—Ensuring fidelity through treatment delivery is focused on processes that ensure the treatment is delivered as designed and focus on standardizing and improving delivery as well as assessing adherence. A priori development of evaluation forms to be completed by providers after each intervention session is the gold standard for monitoring and optimizing treatment delivery. In alignment with the “Tai Chi Treatment Fidelity Review” form, the “Treatment Fidelity Tai Chi Session” form was developed and then completed by the interventionist and trainee following each class and included documentation of any deviation from the prescribed intervention. Additionally, to further enhance internal validity, the PI and trainee periodically attended each other’s sessions to review and document adherence to the intervention.

The interventionists were attentive to nonspecific treatment effects in the delivery of the intervention. Ensuring adherence to the prescribed intervention by following the study manual and notebook as well as the use of the “Treatment Fidelity Tai Chi Session” form helped minimize nonspecific treatment effects. Additionally, discussion in the TC sessions was limited to the first 10 to 15 minutes of class each week and included brief reports of home practice facilitators and barriers and application of TC principles in daily life. This was done to prevent a social support group effect. Changes in the perception of social support were measured using the Social Provisions Scale and no significant changes were found pre- to postintervention. At the completion of the study, all “Treatment Fidelity Tai Chi Session” forms were reviewed and indicated there were no significant deviations in intervention delivery.

Receipt of Treatment—The focus of the last two components of treatment fidelity shifts from providers to participants. Processes of treatment receipt involve monitoring and optimizing participant understanding and performance of intervention skills during treatment delivery. The TC intervention was designed and delivered to help ensure TC skill acquisition. Each week, in alignment with the TC booklet and DVD, TC practice began with the warm up movements followed by reviewing and practicing previously learned movements and then introduction and demonstration of the next scheduled movement. Participants then practiced all movements with the interventionist. Each week, participants performed movements for the interventionist to monitor skill.

Participants were expected to attend all intervention sessions and required to attend at least six of the eight weekly sessions or they were administratively withdrawn from the study. If participants missed a session, they were instructed to use the booklet and DVD to review and

practice that week's movements. The booklet and DVD helped ensure receipt as well as enactment of treatment skills.

Enactment of Treatment Skills—Processes for treatment enactment focus on ensuring that cognitive and behavioral intervention elements are applied in relevant daily life situations. To this end, the TC intervention was designed with both cognitive (incorporating the meaning and purpose with the skill of learning the movements) to facilitate daily life application. For example, one does not have to perform Embrace Tiger, Return to Mountain in order to remember that we have the capacity to face fears while feeling empowered in the face of change. During each session, participants were observed by the interventionist while enacting movements to ensure there was adequate performance of each movement. To enforce personal TC practice, participants were encouraged to use the TC booklet and DVD for home practice between intervention sessions. The recommendation for practice was 15 minutes most days of the week. Each week, participants were asked to turn in a practice log documenting daily home practice. Approximately two thirds ($n = 44$) of participants completed practice logs, which revealed an average of 12 minutes of daily practice.

Finally, postintervention evaluation forms were completed by all participants and two focus groups were conducted to help assess feasibility and acceptability. Feedback indicated that the intervention was well received by 100% of participants. Additionally, all participants indicated they had read the booklet and reviewed the DVD outside of class. While participants thought home practice expectations were practical and appreciated the brief class discussions on home practice facilitators, barriers and daily life application of TC principles, challenges related to lack of time and energy remained barriers throughout the study. Participants repeatedly suggested sending text messages with specific TC movement practice reminders between intervention sessions.

Guided Imagery and Stress Management in Pregnancy

Overview

In order to investigate the effect of a 12-week GI intervention on biobehavioral measures of maternal stress in pregnant African American women, a randomized controlled clinical trial was conducted between June 2010 and September 2012. A total of 72 women ($n = 36$, intervention; $n = 36$ control) ranging in age from 18 to 39 years at 14 to 17 weeks estimated gestational age were enrolled in the study. While the study findings have been previously presented (Jallo, Ruiz, Elswick, & French, 2014), the methodological strategies used to monitor and enhance the reliability and validity of this mind—body intervention have not been addressed in detail.

Treatment Fidelity

Treatment Design—When designing the study, the degree to which the intervention itself reflects the study theoretical framework was an important component (Bellg et al., 2004). This study was guided by the transactional model of stress and coping. Within the transactional framework, stress refers to a particular relationship between the person and the environment that is appraised by the person as taxing or exceeding one's resources (Lazarus

& Folkman, 1984). It is through this cognitive appraisal process that the individual evaluates whether a particular event is a threat to her well-being as well as her ability to cope with the situation and manage negative emotional responses (Folkman, 2010; Lazarus & Folkman, 1984). This appraisal process has the potential to generate negative emotions thus jeopardizing one's well-being (Folkman, 2010). Coping, a complex process involving behavioral and cognitive responses, is a critical mediator of stressful person–environment transactions and the symptoms of distress (Folkman, Lazarus, Dunkel-Schetter, DeLongis, & Gruen, 1986). The coping strategies aimed at negative emotional responses give rise to psychological well-being (Folkman, 2010). GI, a mind–body intervention, is a dynamic, psychophysiological modality in which a person imagines and experiences an internal reality in the absence of external stimuli (Menzies & Gill, 2004). GI has been demonstrated to modulate psychological and physiological activity (Giedt, 1997). Thus, a GI intervention may be used to alter psychosocial processes such as decreasing perceived stress and related symptoms.

To ensure the intervention reflected the theoretical framework, the fidelity of the intervention content was a major factor. When considering the fidelity of the content of the intervention, several factors were taken into account. First, the actual content of the GI compact disc (CD) tracts was important. To ensure consistency, the researcher who was certified in GI developed the four scripts. The overall content in terms of selected images and words as well as the order of the CD tracts were sequenced to focus on the desired outcomes and were based on professional literature and the Academy for Guided Imagery (Jallo, Bourguignon, Taylor, & Utz, 2008; Rossman, 2000). Second, the fidelity of the recording and duplication process was taken into consideration. The written scripts were narrated and recorded by the same member of the research team who developed and wrote them. The four CD tracts were recorded consecutively on the same day in the same recording study and the recording was managed by the same experienced record producer. Thus, the intervention was standardized in terms of content, voice, and production style. No potential confounders such as music, nature sounds, or white noise were added. The master CD was uploaded on a computer located in a locked research office. Members of the research team made copies from the master CD for the study participants. Each duplicate copy was assessed for quality prior to use in the study. The use of a quality controlled professionally recorded intervention facilitated the maintenance of consistency of the intervention.

One overarching goal was to ensure that each participant received the same treatment dose. Thus, the fidelity of the dose of the intervention was another major consideration in the research design. Treatment dose can be viewed in terms of the duration of the intervention, the number of weeks or length of time over which the intervention occurred, and the recommended use of practice (Van Kuiken, 2004). To that end, several strategies were incorporated into the design. A treatment protocol for this study was developed, which called for the participant to listen to one of four 20-minute CD tracks once a day in a prescribed manner for 12 weeks. The protocol called for 20 minutes of daily intervention use over a period of 12 weeks because this intervention dose was associated with skill acquisition (Good, 1995) and a reduction in stress-related variables (Jallo, Bourguignon, Taylor, Ruiz, & Goehler, 2009; Mandle, Jacobs, Arcari, & Domar, 1996; Wynd, 1992; Zahourek, 1988). The scripted, recorded intervention ensured that a fixed amount of

standard content for a fixed duration was available to the participants. However, one of the more challenging aspects of intervention research is to ensure the dose available to the participant is actually the same dose received for each subject within the treatment group. The design of the study called for the participant to self-monitor or keep a log of treatment dose. Each day participants in the GI group were asked to document how stressed they were during the day, which GI tract they listened to that day, how long they listened, and any barriers or benefits they experienced in a daily practice log form designed for the study. Each daily log was labeled as to the appropriate week and day of the study. For example, at the start of the study, the first page would say Week 1, Day 1, next page Week 1, Day 2, and so on. They were also asked to write the day of the week in the designated space on the page as a back-up to verify treatment dose. All 84 daily practice log forms were maintained in a three-ring binder for the participants' convenience and to assist in keeping track of intervention use. The daily practice logs were collected by a member of the research team at the study visits and reviewed with the participant.

In addition, a member of the research team contacted the participant weekly using a designated script via phone or text to monitor intervention use and trouble shoot any identified problems. The advantages of using telephone/text follow-up included the ability to deliver scripted messages to ensure the same level of information was provided and the same opportunity to address any problems, thus ensuring consistency (Whitmer, Sweeney, Slivjak, Sumner, & Barsevick, 2005). This regular monitoring of intervention adherence was another strategy incorporated into the treatment design.

Training Providers—Although the recorded intervention was delivered via a CD player, the entire research team was trained and competent in the study goals and objectives, the theoretical framework guiding the intervention development and study, as well as the study protocol. Training was consistent across team members using standardized protocol manuals, a common and well-accepted intervention fidelity strategy (Santacroce, Maccarelli, & Grey, 2004). In addition, to assure the research team member's skills in explaining and implementing the study protocol were maintained, the PI periodically assessed the interaction between participant and team member during the recruitment process, return visits, and weekly telephone calls.

Delivery of Treatment—As mentioned previously, the intervention in this study was delivered using a CD player. To increase the likelihood that the content and dose of the intervention was delivered as intended, the participant was provided with additional batteries for the delivery mechanism. In the event the player developed problems, the participant contacted the researcher who replaced the equipment. The documentation of any problems with the delivery of treatment was documented by the participant in the daily logs as well by the research member during the weekly calls.

Receipt of Treatment—Treatment receipt refers to whether the client comprehends and uses the treatment skills during the session (Borrelli et al., 2005). To ensure the participant in this study understood the information provided about the intervention and delivery system, the pregnant woman participated in a demonstration of the first tract on the CD. A member of the research team verbally explained and demonstrated the equipment and then requested

the participant to return demonstrate accessing the four CD tracts and the ability to listen to the first tract using the CD player and headphones. A member of the research team observed and was available for questions. Written instructions on the sequencing and use of the CD tracts were also provided, to optimize participant understanding and engagement (Bellg et al., 2004).

At each prenatal visit, participants were asked to turn in their daily logs documenting home practice. Based on the return of the daily logs, the pregnant women were engaged in the intervention. For example, at 4 weeks, 100% of participants had completed their daily logs; at 8 weeks, 90% of participants returned their logs; and at 12 weeks 70% returned their logs.

Enactment of Treatment Skills—The ultimate goal of this stress coping intervention was for the participants to actually apply the learned skills in daily life to help them cope with stressful situations and manage negative emotional responses. This is an important component of treatment fidelity as effectiveness trials become more prevalent (Borrelli et al., 2005). To assess this important aspect, the participants were asked to document daily in their log book if they had an opportunity to use the skills and, if so, any benefits they noticed. In addition, semistructured interviews were conducted at the completion of the 12-week intervention. Participants were asked to share their experiences with the GI intervention related to the integration and use of techniques in daily life. The written comments on the daily logs suggested the participants found the intervention to be helpful in coping with the stress of daily life, controlling their emotional response to stressful situations, and helping them problem solve.

Yoga for Depressive Symptoms in Women

Overview

A randomized controlled clinical trial was conducted from May 2011 to June 2013 to evaluate the effects of an 8-week mindful physical activity (yoga) intervention on measures of depressive and related symptoms in women with major depressive disorder or dysthymia and at least moderate levels of depressive symptoms despite the usual care. A total of 27 women participated in the study ($n = 15$, yoga intervention group; $n = 12$, active control group) with a mean age of 43 years ($SD = 15.6$). The short-term and long-term study findings have been presented previously (Kinser, Bourguignon, Taylor, & Steeves, 2013; Kinser, Bourguignon, Whaley, Hauenstein, & Taylor, 2013; Kinser, Elswick, & Kornstein, 2014). In this article, we present details about methods used to monitor and enhance treatment fidelity of this intervention.

Treatment Fidelity

Treatment Design—The design of this study was guided by a conceptual framework of the relationship between stress vulnerability and depression in women (Kinser & Lyon, 2014), based on the concept that there is a bidirectional relationship between the individual, social/environmental, biological, and psychobehavioral factors involved in depression. This model focuses on the particular needs and experiences of women, particularly the role that mind–body therapies may play in addressing consequences of stressful life events, self-

silencing in social roles, and rumination (persistent negative self-talk) as components of depressive symptomatology. For example, mindful acceptance (nonjudgmental noticing of thoughts and feelings) and physical movements may be adaptive interventions to help women deal with ruminations (Kinser, Goehler, & Taylor, 2012), both of which were important components of the yoga intervention in this study.

A thorough description of the components of the study and groups may be found elsewhere (Kinser, Bourguignon, Whaley, et al., 2013). Briefly, the yoga intervention consisted of eight weekly 75 minute gentle yoga sessions, taught by trained and certified yoga instructors. These sessions involved a basic introduction of yogic principles for mental wellness, intention-setting and centering, breathing practices, physical movements, and guided relaxation. The active attention-control group involved eight weekly 75 minute “Health and Wellness Program” sessions, taught by trained registered nurses. The active control group was designed to help control for group effect, expectations, and interactions with study staff. Both groups were encouraged to engage in home activities, such as practicing yoga with a DVD (yoga intervention group) and watching videos and reading handouts (control group).

Intervention fidelity was essential for ensuring the intervention reflected the conceptual framework of the study. First, a manual for each of the groups (intervention, attention control) were designed carefully to focus on desired outcomes and based on relevant literature. Working with an interdisciplinary team of nurse researchers, psychiatrists, and expert yoga therapists, the researcher developed a yoga intervention specifically designed for women with depression, involving group yoga classes and home yoga practice adaptable according to an individual woman’s mood (Kinser, Bourguignon, Whaley, et al., 2013). Second, the topics of both manuals were sequenced purposefully to promote advancing levels of competence with the material. For example, the following weekly themes for discussion and practice in the intervention manual were sequenced purposefully: self-care and self-awareness, meeting the mood, mindfulness, finding balance, awareness of joy and gratitude, and loving kindness. Similarly, the topics of the active control group focused on health education topics relevant to depression in the following sequence: introduction to health and wellness, depression and anxiety, stress, nutrition, healthy sleep, alcohol safety, bone health, and heart health. Third, the fidelity of the home practice opportunities was taken into consideration. The intervention group received a DVD of gentle yoga for home practice, which had been vetted by the researcher and the yoga teachers. The attention control group received links to videos on websites that had been closely vetted by the researcher and the instructors of the control group activities; to maintain internal validity, there was no overlap in content of these videos with that of the yoga intervention group. The use of professionally developed tools such as the DVD and the websites assisted in ensuring consistency of the intervention. Finally, the study was designed to ensure equal treatment dose between the intervention and attention control groups. Both groups met for in-person sessions for the same time (once weekly for 8 weeks for 75-minute sessions) and logs were maintained by instructors for groups. Attention to dose was purposeful and according to recommendations about randomized controlled trials evaluating mind–body therapies. Interestingly, dose of the intervention (total minutes of yoga practiced during the study) was not a significant covariate in any of the analysis models (Kinser, Bourguignon, Whaley, et al., 2013).

Training of Providers and Delivery of Treatment—The interventionists were trained about the study protocol in two 90-minute sessions with the PI about the respective activities of each group. The interventionists were provided with hard and electronic copies of the training manual, mentioned above, as well as given access to the DVD and website videos used for home practice by the participants. Numerous interventionists were trained in the study protocol, in case there was a need for substitutions due to illness or emergency; fortunately, there was consistency of instructors for both the control and the intervention groups.

Delivery of Treatment—During the intervention phase of the study, the PI held biweekly in-person and/or electronic sessions with the instructors to ensure fidelity to the study manual and to discuss and address any issues, questions, and concerns. Furthermore, the PI held debriefing meetings with the instructors at the end of the 8-week sessions to review whether deviations in the intervention/attention control activities had occurred. During all of these sessions, the training manual was used as a checklist; all checklists were reviewed and there were no noted deviations from the protocol.

Receipt of Treatment—Data about treatment receipt by participants were collected in three ways: First, participants were invited to document their thoughts and feelings about yoga and mood (yoga group) or about health (attention control group) in the form of weekly logs. It was recognized that complete adherence to 20 minutes of daily home activities could be difficult in a population with a diagnosis characterized by anhedonia and lack of motivation; hence, the adherence data from the logs were relevant for evaluating feasibility of the study design. The team learned from these logs that participants in both groups spent more time in group activities than with the home activities involving the DVD or websites. Second, the PI conducted semistructured interviews with participants at the end of the 8-week intervention period to explore participants' experience with the study and their impressions of individual aspects of the intervention and attention control group activities. Findings from these interviews suggested that participants in both groups engaged in the materials provided during the in-person sessions, but generally were less interested in the home activities (Kinser, Bourguignon, Taylor, et al., 2013).

Enactment of Treatment Skills—Long-term engagement with materials provided in an intervention may be one of the most effective reflections of enactment of treatment skills. In this study, participants were asked to engage in data collection 1 year after completion of the intervention sessions. Although only a subset of participants were able to participate in the long-term follow-up ($n = 9$ out of the original $n = 27$), the findings were striking. During semistructured interviews, participants consistently described long-term benefits from having experienced the yoga intervention, despite that many of them denied continued formal yoga practice. These comments were substantiated in quantitative analyses of unadjusted means in which trends suggested that a sustained yoga practice, even if infrequent, was associated with decreased depressive symptoms over time (Kinser et al., 2014). Despite the limitation of a small sample size, these data suggest that future studies should evaluate long-term effects of an intervention as a reflection of enactment of treatment skills.

Discussion

Inclusion of well-defined and described strategies for enhancing treatment fidelity prior to study implementation was a significant strength in these studies. In terms of *treatment design*, each of the studies presented here included interventions that were grounded in sound theoretical frameworks. Additionally, based on prior research, considerable attention was given to intervention dose as well as development of intervention-based recordings (CD and DVD) for participant use.

With regard to *provider training*, all PIs have extensive training and experience in the design and delivery of their respective mind–body interventions. In the TC study, the PI recruited a doctorally prepared nurse with experience in delivering group interventions using a similar theoretical framework and then developed and implemented an extensive training protocol for a new interventionist for future studies. In the GI and yoga studies, the PIs trained and monitored all study personnel who interacted with participants.

While *delivery of treatment* was different in the three studies, each incorporated processes for ensuring the interventions were delivered as designed and fostered improving delivery in future studies. A weakness of these studies was the absence of strategies to assess the nonspecific treatment effects such as the quality of the researcher-participant relationship or the assessment of the characteristics of the researcher (e.g., warmth, empathy, respect for the patient; Borrelli et al., 2005). Because these factors have in and of themselves been shown to have moderate to strong relationships with outcomes (Borrelli et al., 2005; Klein et al., 2003), future research examining these issues is warranted.

Treatment receipt was more easily assessed in the TC study given the weekly face-to-face delivery, structure, and process of how the movements were taught and the requirement of attending at least six sessions to remain in the study. In the GI study, treatment receipt was assessed by the daily logs, weekly phone conversations, and face-to-face conversations at subsequent prenatal visits. Similarly, in the yoga study, treatment receipt was assessed via a number of methods including weekly logs, semistructured interviews, and debriefing sessions with the instructors.

All studies employed self-reported documentation of *enactment of treatment skills*. While self-reported daily logs are often used to track enactment of treatment skills as well as intervention dose, compliance with paper diary logs limits the ability to rigorously examine treatment fidelity. In the TC study, daily practice logs were included in the TC booklet as well as during intervention class time, and participants were reminded before and after class to complete and turn in the logs. However, limited and missing data prohibited meaningful analysis of daily or weekly practice time. In the GI study, equipment issues interfered with enactment to some degree. While the researchers monitored treatment delivery and intervened quickly if the participant had an issue with the CD player, several participants commented on problems with the CD player such as skipping or cutting off as well as the batteries ran low and did not last long. To address these issues, future studies will employ mobile computer technology to deliver the intervention and provide real-time information on when and for how long a participant accessed the intervention as well as if it was continuous

or interrupted use. Also the treatment design did not stipulate a minimum amount of treatment dose necessary to be included in the analysis. In other words, the data from all participants were analyzed regardless of the actual self-reported treatment dose received. Mobile health technologies are designed for daily personal use and may address these limitations. Real-time assessment of an intervention provides proactive information on when and for how long a participant accessed the intervention as well as if it was continuous or interrupted use. In addition, pocket computer technology has the potential to improve data capture through real-time assessment, which may reduce biases associated with retrospective recall (Proudfoot et al., 2010) support examination of fidelity to treatment protocol adherence (Mauriello, Gokbayrak, Van Marter, Paiva, & Prochaska, 2011).

The yoga study revealed the importance of long-term follow-up in intervention studies. Although many studies are designed for short-term evaluation only, the benefits of long-term follow-up are numerous, such as the ability to evaluate the effects of an intervention on cumulative outcomes, to enhance understandings about feasibility of an intervention, and to explore continuity/inconsistencies in application of interventions by participants over time. Long-term evaluations also contribute to our understandings of translatability and interpretability of findings. A limitation of the long-term follow-up described in the yoga study is the potential for selection bias, whereby the small sample size may have reflected a sample of participants for whom the intervention was helpful, thus contributing to inflation of Type 1 error (Hill, Woodward, Woelfel, Hawkins, & Green, 2016). Future studies are advised to consider carefully a study design to enhance retention over time and address other possible data collection issues (Udtha, Nomie, Yu, & Sanner, 2014).

Conclusion

In alignment with best practices, the studies presented here successfully designed and implemented strategies to address all five components of treatment fidelity. The studies provide real-world examples of enacting strategies that can be used to guide incorporation of treatment fidelity in future studies. The treatment fidelity framework used here was a feasible and reliable approach for ensuring and reporting treatment fidelity, which will strengthen the evidence base for mind–body interventions and ultimately foster more efficient translation of effective interventions into holistic clinical practice.

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Biography

Jo Lynne Robins, PhD, ANP-BC, AHN-C is an associate professor at the Virginia Commonwealth University School of Nursing. Her biobehavioral research focuses on

cardiovascular risk reduction through patient-centered stress management strategies to foster resiliency and empowered, effective self-care.

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Patricia A. Kinser, PhD, RN, WHNP-BC, FNAP, is an associate professor at the Virginia Commonwealth University School of Nursing. Her research is focused on enhancing wellness in women across the lifespan, including a focus on the biobehavioral effects of complementary health approaches for depression.

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