Self-administered Acupressure for Persistent Cancer-related Fatigue: Fidelity Considerations

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ABSTRACT

Context • Complementary therapies are frequently used by breast cancer patients for symptom management; however, documentation of the components of intervention fidelity for studies is not widely available.

Objective • This report examines the components of intervention fidelity, as put forth by the Treatment Fidelity Workgroup of the Behavior Change Consortium at the National Institutes for Health (NIH-BCC Workgroup), within an ongoing acupressure study of breast cancer survivors with persistent cancer-related fatigue (PCRF).

Design • For the acupressure study, the research team designed a randomized, controlled trial (RCT) with 3 parallel groups: (1) stimulating acupressure (intervention group); (2) relaxing acupressure (intervention group); and (3) standard care (control group).

Setting • At baseline and at wk 3 and wk 6 of the study, women in the acupressure study attended sessions for training and data collection at clinics in the counties of Michigan where they lived. The self-administration of acupressure occurred in participants' homes.

Participants • Targeted enrollment for the acupressure study is 300 breast cancer survivors who had experienced moderate-to-severe PCRF lasting longer than 1 y beyond treatment. The women are being recruited from 5 counties in Michigan, using the Michigan Tumor Registry to identify potential participants. The subsample report includes 183 participants who have completed all 10 wk of the acupressure study. Most participants in the acupressure study are Caucasian, are married, and have some college education.

Intervention • The acupressure study's educators teach participants in the intervention groups to self-administer either relaxing or stimulating acupressure for a 30-min period on a daily basis for 6 wk. All 3 groups receive the usual care for breast cancer survivors.

Outcome Measures • For the acupressure study, the participants log the frequency of the self-administered acupressure sessions and their fatigue levels. Symptom assessments are made for all groups by telephone in the acupressure study at wk 2 through wk 5 to assess fatigue. A competency checklist is used at each session of training and retraining of both acupressure educators and participants. For this report, the 5 recommended fidelity components for interventions are (1) dose, (2) training, (3) intervention delivery, (4) intervention receipt, and (5) enactment of the intervention.

Results • The ongoing RCT incorporated all 5 components of fidelity and can serve as a model for future work in this area.

Conclusions • Research protocols that address intervention fidelity can provide results that support internal and external validity. Clinicians should consider recommending complementary interventions that have incorporated fidelity components into their efficacy testing. (*Altern Ther Health Med.* 2015;21(4):18-23.)

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A clear description of fidelity components has been missing from many intervention studies in the past, including studies of complementary and alternative medicine (CAM). A missing or abbreviated discussion of fidelity makes it difficult to promote internal consistency and replication.[1] The effort toward consistency is most commonly referred to as *intervention fidelity*. Fidelity consists of the measures taken to assure that an intervention is carried out as prescribed by the intervention protocol.[2-4] Intervention fidelity also considers whether an intervention is delivered by an expert clinician or by a participant or patient who is taught the skill to allow them to self-administer the intervention.

A variety of standards are being established to help address the issues surrounding intervention fidelity for both situations (ie, when an intervention is delivered by an expert or when it is delivered by a participant who has been trained in a new behavior, such as self-administration of an intervention). The randomized, controlled trial (RCT) is the gold standard for testing efficacy of interventions and advancing the science in a field,[4] and a quality feature is often used in reporting such studies. This feature is referred to as the Consolidated Standards of Reporting Trials (CONSORT), which provides for the reporting of the flow of participants through a study and recommends documentation of intervention fidelity.[5,6]

In the field of acupressure and acupuncture, a new version of the CONSORT has become popular for reporting the detailed processes used by an expert clinician in the delivery of an intervention; it is the Standard for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA).[7] According to MacPherson et al,[7] journal editors are now recommending that authors publish a separate article to comply with manuscript length when clinical experts report using the STRICTA guidelines.

Because the study discussed in this article involves a self-administered intervention, rather than an expert's delivery of the intervention, the current research team used behavioral change components to report intervention fidelity as outlined by the Treatment Fidelity Workgroup of the Behavior Change Consortium at the National Institutes for Health (NIH-BCC Workgroup).[1] As such, the purpose of the current report is to explain and examine the key components of intervention fidelity that were used in the ongoing study by Zick et al[8] on breast cancer survivors with moderate-to-severe persistent cancer-related fatigue (PCRF) who are taught to self-administer acupressure for relief of their chronic fatigue.

DESCRIPTION OF NIH-BCC INTERVENTION FIDELITY GUIDELINES

The NIH-BCC Workgroup components, developed to assure fidelity for interventions involving behavioral change, are as follows: (1) study design (ie, dose parameters of sessions); (2) participant training; (3) participant self-delivery of the intervention; (4) receipt of the intervention; and (5) enactment of intervention skills.[1] The 5 components serve as a guide in the current report on intervention fidelity involving the application of each in the ongoing acupressure study for breast cancer survivors with PCRF. Guidelines such as these help researchers identify and fill gaps in fidelity and adds to the science by establishing a standardized protocol for any specific self-administered therapy.[3]

Dose Parameters. The central component of design in intervention studies is dose, including the number of sessions, the length of each session, and the interval between sessions of the intervention.[1]

Training. Participants' training involves ensuring the use of standardized elements, including initial and periodic quality assurance checks of skills.[4,9] The expert trainers must assess participants' skill levels against a competency checklist to ensure successful standardization of the intervention.

Self-delivery. Delivery must be monitored to document the accuracy of each step that a participant completes within a single session.[1,9] Also, periodic competency checks allow for retraining on any missing protocol steps and/or delivery skills.

Receipt of the Intervention. This component involves the determination of the extent to which the participant understands the skills and can demonstrate his or her knowledge of them, showing a behavior change during the intervention period.[1,9] The number of complete protocol sessions that a participant has self-administered can be obtained through a participant's log, and attrition can also serve as an indirect indicator of receipt.

Enactment of Skills. This component pertains to a participant's performance and use of skills that he or she has acquired, performing interventions to achieve a long-term behavior change[1] in a manner that integrates the change into real-life settings.[9] Although the intent of this component is to teach a life skill that will continue to be used by the participant, it is seldom possible within a study to follow participants long enough to ensure the enactment of a permanent change.

Researchers who investigate CAM are increasingly becoming aware of the need to standardize interventions to provide consistent delivery and replication. For example, studies testing reflexology have taken the lead in describing fidelity within CAM studies (D. Frambes, unpublished data, 2013).[3] Although the same components are recommended for assessing fidelity in all studies, not all studies incorporate all 5 behavioral changes. For example, when the intervention is delivered to the participants by a CAM expert or a caregiver, the participant's behavior change components of receipt and enactment do not apply (D. Frambes, unpublished data, 2013; G. Smith, G. Humphris, unpublished manuscript, 2005).[10-14] However, when the participant is expected to self-administer the intervention following training, all 5 areas of behavioral change should be included in the evaluation of a study's procedure for intervention fidelity.

When searching for similar work for purposes of comparing and contrasting the ongoing acupressure study in the current report, the research team found only 1 pilot study

(N = 47) by Molassiotis et al[16] that included the behavioral change of self-administered acupressure for PCRF. As the ongoing study and the Molassiotis et al[16] study both involve a self-administered intervention, the following objectives are explored: (1) Describe how the intervention dose is measured; (2) discuss intervention training; (3) explain how fidelity is maintained during self-administration of the intervention; (4) describe intervention receipt; and (5) describe intervention enactment.

METHODS

The ongoing acupressure study by Zick et al[8] serving as the basis for this intervention fidelity discussion of behavioral change is a randomized parallel group trial with 3 study groups, in which treatment consists of (1) stimulating acupressure and standard care (intervention group); (2) relaxing acupressure and standard care (intervention group); or (3) standard care only (control group). The standard care control group members receives no acupressure in the course of their participation in the study, whereas the 2 acupressure groups self-administer their randomized protocol daily for 6 weeks. Participants assigned to the 2 acupressure treatment groups are blinded to which acupressure treatment they are administering.

Participants

The current report includes the first 183 female breast cancer survivors who qualified for the ongoing study and completed the protocol. The women's characteristics reflect the population of breast cancer survivors enrolled in the 5 study counties of the lower peninsula of Michigan and the research team used the Michigan Tumor Registry to identify potential participants. The majority of women are white, are not of Hispanic or Latino descent, are married, have completed some college, and have a mean age of 59 years. Clinically, they are, on average, 64 months postcancer treatment and the majority are postmenopausal. Key inclusion criteria for participants are (1) diagnosed with stage 0 to IIIA breast cancer; (2) ≥12 months post–breast cancer treatment other than hormonal therapy; (3) aged 18 years or older; and (4) experiencing moderate to severe chronic fatigue (ie, a score of ≥4 on the Brief Fatigue Inventory).[15] A complete discussion on eligibility and screening can be found in the Zick et al[8] publication.

The criteria for the acupressure educators are (1) being a study staff member, a nurse, or physician's assistant; and (2) being able to be trained in intervention protocols by the study's coprincipal investigator, who is a certified Diplomate of Acupuncture from the National Certification Commission for Acupuncture and Oriental Medicine. The acupressure educators recruited are primarily female nurses.

Demographics for the 183 participants and 17 acupressure educators are included in Tables 1 and 2. The investigators' universities (University of Michigan and Michigan State University) and all study sites covered by the Michigan Tumor Registry have granted human subjects approval.

Table 1. Demographic Characteristics of Participants (N = 183)

Demographics	n (%)
Race	
Caucasian/White	173 (94.5%)
Other	10 (5.5%)
Ethnicity	
Not Hispanic or Latino	169 (94.5%)
Education	
Some high school	1 (0.5%)
Completed high school	17 (9.4%)
Some college	42 (23%)
Some college or more	66 (36.1%)
Unanswered	57 (31.1%)
Marital Status	
Single	9 (4.9%)
Married/committed relationship	89 (48.6%)
Divorced	18 (9.8%)
Widowed	10 (5.5%)
Unanswered	57 (31.1%)
Yearly Household Income	
$0-$25 000	13 (7.1%)
$25 001-$50 000	41 (22.4%)
$50 001-$75 000	22 (12%)
>$75 001	50 (27.3%)
Unanswered	57 (31.1%)
Menopausal Stage	
Premenopausal	72 (40.4%)
Perimenopausal	13 (7.3%)
Postmenopausal	93 (52.2%)
Stage of Cancer	
0	35 (31.2%)
I	62 (33.9%)
II	47 (25.7%)
III	21 (11.5%)
Unsure	18 (9.8%)
Treatments	
Surgery (N = 183)	182 (99.5%)
Chemotherapy (n = 182)	83 (45.4%)
Radiation (n = 181)	130 (71.8%)
Hormone therapy (n = 182)	118 (64.8%)
Targeted therapy (Herceptin, n = 118)	9 (7.6%)
Demographics	**Mean ± SD**
Months since cancer	63.68 ± 52.23
Age, y	58.68 ± 10.04

Table 2. Demographic Characteristics of Acupressure Educators (n = 17)

Demographics	n (%)
Gender	
Male	2 (11.8%)
Female	15 (88.2%)
Occupation	10 (58.8%)
Nurse	
Physician's assistant	1 (5.9%)
Nonnurse educator	6 (35.3%)
Trained by Licensed Acupuncturist	17 (100%)

Data Collection

In the ongoing study, participants log the frequency of the self-administered acupressure sessions and their fatigue levels. Data are collected for 10 weeks via a combination of in-person visits and telephone calls and include demographics, self-efficacy, quality of life, and symptoms, particularly fatigue. A competency checklist is used at each training and retraining of both acupressure educators and participants, and it is referred to as the Acupressure Fidelity Form. Telephone symptom assessments of fatigue are made to both the attention control and acupressure groups at study weeks 2 through 5 to assess fatigue. The 2 intervention groups are also asked about any adverse events and/or problems with acupoint locations.

RESULTS

Descriptive statistics were used to calculate demographic, disease, and treatment results using SPSS statistical software, version 10.0 (SPSS Inc, Chicago, IL, USA).

Results Objective 1

Describe how the intervention dose is measured. There is slight variation between the 2 intervention protocols used in the ongoing study. One protocol has 9 acupoints and the other 10, so the total duration of a full session is 27 or 30 minutes. Acupoints are stimulated daily for 3 minutes each.

Results Objective 2

Discuss intervention training. Intervention training consists of a structured 2-step program: (1) the coprincipal investigator, who is an acupuncturist, trains the acupressure educators in the acupoint protocols; and (2) the acupressure educators train participants in the protocol they are randomized to.

Educator Training. The coprincipal investigator, who is certified in acupuncture, trained all study acupressure educators during the startup phase of the study. The training included a written description of the acupoint locations and a digital video disc (DVD) of a person performing administration of the acupoints. The acupuncturist demonstrated the points, followed by a return demonstration on their own body allowing for assessment of the correct location of the acupoints. The educator demonstrated the correct pressure and simulation motion for 1 point on the acupuncturist. Each study acupressure educator was scored by the acupuncturist on their demonstration and achieved ≥95% on the Acupressure Fidelity Form to begin and continue training participants. All study acupressure educators received refresher training when the acupuncturist made site visits following the first 2 participants for each educator and biannually thereafter. This training assures continued adherence and consistency in the training techniques. For acupoint details, see the Zick et al[8] publication.

Participant Training. The study educators meet with each participant individually. The educator demonstrates each acupoint on his/her own body and then on the participant. The depth of pressure and stimulation motion is demonstrated over each point. Following the demonstration, a self-administered return demonstration is performed by the participant. Adhesive colored dots are placed on the participant to reinforce the acupoint locations for the first 2 to 3 days. The educator works with the participant through instruction and return demonstration of the 9 or 10 points until ≥95% accuracy is attained for location, pressure, and technique. The number of acupoints correctly located and the adequacy of stimulating the acupoints are recorded on the Acupressure Fidelity Form. Participants are corrected and asked to relocate acupoints as needed. A written instruction manual is used during the training and left with the participant for reference. This manual consists of instructions for locating and stimulating each point with picture diagrams. Participants also receive a DVD of a person performing the acupoints specific to the protocol for their randomization group.

Results Objective 3

Explain how fidelity is maintained during self-administration of the intervention. Daily acupressure sessions are expected to be self-administered following training. Participants have a follow-up visit with the educator approximately 3 weeks after the initial training to evaluate technique. During this visit, the participant demonstrates the acupressure intervention while the educator observes. The participant's retention of the skills and ability to perform the intervention are evaluated with a goal of maintaining 95% accuracy on the Acupressure Fidelity Form during the follow-up visit. The educator provides feedback by making needed adjustments in the technique. Participants log their acupressure sessions. Although no further technique visits are scheduled, the written manual used during the training stays with the participant. Contact information is also provided in case questions arise during the intervention period.

Results Objective 4

Describe intervention receipt. Receipt is measured by the number of acupressure sessions self-administered each week of the intervention (ie, those which are recorded by the

participant in their log). During the 6-week protocol period, women are requested to self-administer 42 sessions. Attrition rates can also reflect receipt by indicating the number of participants that complete the entire protocol. These data will be tabulated at the end of the ongoing study, providing a measure of the receipt component.

Results Objective 5

Describe intervention enactment. Enactment is the final component and involves the long-term integration of a behavior change into daily routines.[1] The ongoing study continues to follow women through their last data contact to assess if the behavior change is maintained between the end of the protocol at weeks 6 and 10.

DISCUSSION

Ideally, each of the 5 components of the guidelines put forth by the NIH-BCC Workgroup would be included in any study expecting behavioral change from participants. Both the Molassiotis et al[16] study and the ongoing study outlined clear dose parameters. The dose component contributes to fidelity by standardizing the number, duration, and frequency of sessions. It is necessary to establish a dose that allows for improvement in outcomes, within a timeframe that is practical for participants.

The ongoing study incorporates a 2-step training plan where the expert acupuncturist trained the study educators, who in turn trained all the participants. Molassiotis et al[16] also used 1 acupuncturist, but in contrast, this 1 person conducted all of the participants' training. Although a standard performance level was recorded on the Acupressure Fidelity Form in the ongoing study, Molassiotis et al[16] did not mention the use of an established standard. To evaluate delivery, the ongoing study incorporates periodic evaluation and coaching for the acupressure educators and participants, and accuracy is again recorded on the Acupressure Fidelity Form.

Receipt was monitored in both the ongoing and Molassiotis et al[16] studies by the number of sessions completed as recorded in a log by the participants and by investigator records of study attrition. Molassiotis et al[16] required completion of 14 daily sessions in 2 weeks by participants, whereas the current study requires 42 daily sessions in 6 weeks. The ongoing study addresses the recommendation by Molassiotis et al[16] that a larger-scale investigation of this intervention be conducted for PCRF.

Enactment beyond the timeframe of the study was not possible in either the Molassiotis et al[16] or the ongoing study. However, the ongoing study assesses short-term enactment at week 10, which is 4 weeks after participants complete the acupressure protocol. Although that assessment provides an early measure of enactment between weeks 6 and 10, a longer interval would be more accurate in assuring a permanent behavior change. This lack of long-term evaluation to assess a permanent behavior change can be seen as a limitation, but such a study would be resource intensive and is often not feasible in the absence of ongoing funding.

CONCLUSIONS

Research protocols that address intervention fidelity can provide results that support internal and external validity. Clinicians should consider recommending complementary interventions that have incorporated fidelity components into their efficacy testing. As more attention is focused on participants' behavior changes required for intervention fidelity among CAM studies, a standard can be set for assuring consistency across studies. The NIH-BCC Workgroup guidelines now provide investigators with a strong foundation for looking at components of behavioral change when a self-administered intervention is used, including dose, training, delivery, receipt, and enactment.

By drawing on the available guidelines that serve different purposes, such as CONSORT, STRICTA, and the NIH-BCC Workgroup when designing and reporting CAM studies, the science will be strengthened by standardized interventions whether self-administered or provided by experts. Such standardization can contribute to the creation of evidence-based CAM therapies that can be incorporated into practice guidelines. Further, clinicians will be able to use CAM in practice with confidence for symptom management, when it is based on proven efficacy and a standardized protocol for a specific population of patients.

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AUTHOR DISCLOSURE STATEMENT

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