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Fidelity Scorecard: Evaluation of a Caregiver-delivered Symptom Management Intervention

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Abstract

Aim—To evaluate and quantify intervention fidelity of a symptom management protocol through implementation of a scorecard, using an exemplar study of caregiver-delivered reflexology for breast cancer patients.

Background—Studies on caregiver-delivered symptom management interventions seldom include adequate information on protocol fidelity, contributing to potentially suboptimal provision of the therapeutic intervention, hindering reproducibility and generalizability of the results.

Design—Fidelity assessment of a 4-week intervention protocol in a randomized controlled trial (RCT) with data collection between 2012 - 2016.

Methods—The National Institutes of Health Behavior Change Consortium (NIH-BCC) conceptual model for intervention fidelity guided the study. The five NIH-BCC fidelity elements are: 1) dose; 2) provider training; 3) intervention delivery; 4) intervention receipt; and 5) enactment. To illustrate the elements, an intervention protocol was deconstructed and each element quantified using a newly developed fidelity scorecard.

Results—Mean scores and frequency distributions were derived for the scorecard elements. For dose, the mean number of sessions was 4.4, 96% used the correct intervention duration and 29% had 4 weeks with at least 1 session. Provider training was achieved at 80% of the maximum score,

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1. substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data;
2. drafting the article or revising it critically for important intellectual content.

* http://www.icmje.org/recommendations/

intervention delivery was 96%, intervention receipt was 99% and enactment indicated moderate adoption at 3.8 sessions per patient. The sample mean score was 15.4 out of 16, indicating high overall fidelity.

Conclusion—Research findings that include description of how fidelity is both addressed and evaluated are necessary for clinical translation. Clinicians can confidently recommend symptom management strategies to patients and caregivers when fidelity standards are explicitly reported and measured.

Keywords

Nursing; intervention fidelity; fidelity scorecard; protocol standardization; symptom management; caregiver involvement; reflexology; advanced breast cancer

INTRODUCTION

A key contributor to the rigor of randomized clinical trials (RCT) is the standardized implementation of the intervention protocol. This is commonly referred to as intervention fidelity and reflects the extent to which an intervention is delivered as prescribed (Bellg et al., 2004, Calsyn, 2000, Radziewicz et al., 2009, Wyatt et al., 2010, Wyatt et al., 2015). Protocols must include clear and sufficiently detailed descriptions of interventions with an associated way for determining adherence. Intervention fidelity is critical to accurate delivery of symptom management interventions and as reinforced by Chan et al. (2012), complex interventions must be monitored closely to assure the expected outcomes. For patients with cancer, such interventions are increasingly becoming the responsibility of unpaid lay caregivers in the home (Stenberg et al., 2010, Family Caregiver Alliance, 2006a, Family Caregiver Alliance, 2006b, Kissane and Bloch, 2002, Reinhard et al., 2012). The reality of this trend is demonstrated by the number of lay caregivers needed for the estimated 1.7 million patients expected to be diagnosed with cancer in the USA during 2016 (American Cancer Society, 2016). Lay caregivers are often family members, but the term is defined as someone who provides unpaid assistance to a patient with a chronic or disabling condition such as cancer (Family Caregiver Alliance, 2006a, Family Caregiver Alliance, 2006b) and is identified by the patient as their caregiver (Stenberg et al., 2010, Kissane and Bloch, 2002).

Background

Lay caregivers are often willing to support patients by delivering complementary and integrative health (CIH) therapies such as reflexology, but may lack essential training and thus can introduce inconsistencies that threaten intervention fidelity. Limited descriptions of protocol fidelity exist in the literature to aid replication of lay caregiver-delivered interventions; this becomes problematic for both translation and generalizability of findings. One attempt to address this issue is implementation of the National Institutes of Health Behavior Change Consortium (NIH-BCC) Treatment Fidelity Workgroup's (Bellg et al., 2004) fidelity elements. In this paper, a RCT intervention protocol will be deconstructed and the fidelity elements will be examined and quantified using a newly developed fidelity

scorecard. The exemplar RCT examined symptom management outcomes via lay caregiver-delivered reflexology for women with advanced breast cancer.

Conceptual Framework

The NIH-BCC (Bellg et al., 2004) intervention fidelity model guided the protocol deconstruction and the evaluation of fidelity using the scorecard. The five elements of intervention fidelity are: 1) dose; 2) provider training; 3) intervention delivery; 4) intervention receipt; and 5) skill enactment.

Key Concepts

Intervention fidelity—According to the NIH-BCC, the central design element in intervention studies is dose, including the number of sessions, length of each session and the interval between sessions (Bellg et al., 2004). Provider training, especially when using lay providers, requires initial training for skill attainment as a protocol standard (Radziewicz et al., 2009). Intervention delivery pertains to monitoring the consistent administration of the defined protocol (Bellg et al., 2004, Resnick et al., 2005). Intervention receipt is the determination of whether and to what extent the desired intervention has been delivered (Wyatt et al., 2010). Enactment of intervention skills pertains to performance (Bellg et al., 2004) resulting in assimilation into one's lifestyle (Resnick et al., 2005, Wyatt et al., 2015).

Review of Literature

Women facing breast cancer often turn to CIH therapies to manage symptoms and improve their health-related quality of life (HRQOL) (Boon et al., 2007). One CIH therapy that has promising efficacy in reducing symptoms for women with breast cancer is reflexology (McCullough et al., 2014, Wyatt et al., 2012), which is the use of pressure applied to reflexes located on the feet (International Institute of Reflexology, 2015). Many traditional cultures have promoted the manipulation of the feet to enhance the overall health of the body and the therapy has been called by different names. The Ingham Method of reflexology was used in this study. In 1938, Ingham experimented with multiple techniques of a pressure-point therapy known as Zone Therapy, which has similarities to acupressure. Ingham found that greater results were gained by applying alternating pressure rather than continuous pressure to each reflex of the foot. This led to the thumb-walking motion that is used today in the Ingham Method, providing intermittent pressure over each reflex (Watson and Voner, 2009). While the underlying mechanism of action is theoretical at this time, the most prominent premise is that stimulation of the reflexology points creates a neurochemical pathway from the peripheral nervous system through the central nervous system to connect with specific glands, organs and body parts (Stephenson and Dalton, 2003, Stephenson et al., 2007). The protocol used in the current study was developed by a certified reflexologist with 30 years of patient practice, much of which occurred with cancer patients. Nine key reflexes from the Ingham Method were selected for this protocol. A full protocol description can be found in a previous publication (Flynn et al., 2011). The protocol has been tested and established in completed large-scale studies (Kozachik et al., 2006, Wyatt et al., 2007, Wyatt et al., 2012).

While trained reflexologists have typically delivered reflexology, the availability of lay caregivers may be an important resource for providing this successful therapy. Involvement

of lay caregivers, such as friends or family members can provide access to the therapy in the home, an environment safer for patients who are vulnerable to infections due to suppressed immunity and cancer-related fatigue (National Cancer Institute, 2015). Only a few studies have tested reflexology interventions for cancer patients delivered by lay caregivers. Briefly, Kohara et al. (2004) used a lay caregiver (aromatherapist), to deliver a bundled intervention consisting of aromatherapy and reflexology-like foot sessions to hospitalized patients with terminal cancer and found a decrease in fatigue. Similarly, Quattrin et al. (2006) and Stephenson et al. (Stephenson et al., 2007) used lay caregivers to provide reflexology-like foot sessions to hospitalized cancer patients, both studies reported lowered anxiety. Finally, Wyatt et al. (2012) compared reflexology delivered by a reflexologist to lay foot manipulation delivered by research staff and conventional care among advanced breast cancer patients, with significant improvements in dyspnea, fatigue and physical functioning. This review focuses on one therapy and exemplifies how lay caregivers are becoming more engaged in provision of cancer care.

Although caregiver-delivered interventions can now incorporate the NIH-BCC model as a framework for inclusion of fidelity elements, few studies have explicitly operationalized these parameters. Inclusion of the fidelity elements in nurse-designed interventions remains a challenging gap in the science. The need for greater use of the fidelity elements is applicable to both research and practice and the addition of assigning scores for caregiver-delivered interventions provides the added benefit of quantifying evidence to assure a therapeutic level of the intervention is delivered.

THE EXEMPLAR STUDY

The exemplar study used to demonstrate inclusion of the NIH-BCC elements of fidelity was a RCT where lay caregivers deliver a symptom management intervention, reflexology (Wyatt et al., 2011-2016). This report makes a novel contribution to the state-of-the-science with the development of a scorecard to calculate individual participant and group measures of fidelity. Use of the scorecard provides an objective index for assessing the degree of adherence to the fidelity elements and can be adapted to other therapies. The scores can be used to determine acceptable performance and where adjustments are needed to ensure therapeutic delivery and generalizable findings.

Aims

The aims of this study were: 1) To examine how intervention fidelity was incorporated into lay caregiver-delivered reflexology for breast cancer patients through deconstruction of an intervention protocol; and 2) To analyze attainment of each fidelity element by lay caregivers, based on values obtained using a fidelity scorecard.

Design

The exemplar RCT (Wyatt et al., 2011-2016) involved patient and lay caregiver participation over 11 weeks. Consented patients and their caregivers were randomized to either reflexology or attention control groups. The protocol for the reflexology group called for patients to receive a minimum of one weekly session provided by their lay caregiver for four

consecutive weeks; whereas, the attention control group received no reflexology sessions; both groups received usual care. This was a regional study that enrolled patients from seven medical oncology clinics in the Midwestern USA; all reflexology sessions were delivered in the patients' homes. The primary outcome was symptom severity.

Ethical Considerations

The investigators' university granted Institutional Review Board (IRB) approval for the study in June 2011. Additionally, all recruitment sites, addressing the protection of human subjects and ethical research practices, granted approval.

METHODS

Sample

The sample included patients and their lay caregivers (hereafter referred to as caregivers) enrolled as dyads. Patient inclusion criteria were: 1) age 21 or older; 2) diagnosis of stage III or IV breast cancer; 3) able to perform basic activities of daily living; 4) receiving chemotherapy or hormonal therapy; 5) able to speak and understand English; 6) access to a telephone; 7) able to hear normal conversation; 8) cognitively oriented to time, place and person (determined by recruiter); and 9) have a caregiver willing to participate in the study. Patient exclusion criteria were: 1) documented diagnosis of major mental illness verified by the recruiter; 2) nursing home residency; 3) bedridden; 4) currently receiving regular reflexology; or 5) diagnoses of deep vein thrombosis or painful foot neuropathy.

The caregiver inclusion criteria were: 1) friend or family member identified by the patient; 2) age 18 or older; 3) able and willing to provide the 30-minute protocol for 4 consecutive weeks; 4) able to speak and understand English; 5) have access to a telephone; 6) able to hear normal conversation; and 7) cognitively oriented to time, place and person (determined by recruiter). The caregiver exclusion criterion was unwilling or unable to perform a return demonstration of the protocol with 90% accuracy according to training procedures.

Data collection

For the RCT, outcome data were collected at baseline, study week 5 (post 4-week intervention) and week 11 from both groups of patients and from those caregivers in both groups who agreed to provide data (the outcome data are presented elsewhere). This report, however, focuses only on data for the reflexology group of the RCT. Fidelity data were collected during intervention weeks 1-4, at which time patients were telephoned for symptom assessments and to derive information on the number of sessions actually delivered.

Measures

The new 'Intervention Fidelity Scorecard: Reflexology' (Figure 1) uses a novel approach to quantifying and monitoring the five fidelity elements in the protocol. Rigor was achieved through definition of each element in the reflexology intervention protocol. A procedure was devised with assistance from a statistical expert to calculate fidelity scores for each defined element as well as a total fidelity score for each participant and for the sample as a whole.

The points attained for each element contributed to an overall fidelity score for each participant ranging from 0 to 16. The fidelity elements and associated findings from the RCT follow.

Dose—The established 9-reflex protocol was used with all participants (Kozachik et al., 2006, Wyatt et al., 2007, Wyatt et al., 2012). The fidelity scorecard allowed for determination of dose relative to symptom outcomes through separate measures for each of the three distinct parts: number; frequency; and session duration. The number of sessions included in the protocol was established in previous research (Wyatt et al., 2012). In cases where sessions were missed, data regarding the reason for the missing session were obtained. As with other CIH therapies, it was not feasible or advisable to limit use of reflexology to only one session weekly. Thus, it was understood that the caregiver could provide extra sessions allowing patients the benefit of receiving more sessions when desired, such as when they experienced symptoms.

Second, frequency was defined as the interval between sessions, providing structure and allowance for acceptable variance in the design. The allowance of 5-9 days between sessions was established which helped overcome challenges of weekly scheduling for both the patient and caregiver (Wyatt et al., 2012). Frequency data was obtained during weekly calls to caregivers reporting the number of sessions delivered each week during weeks 1-4. Frequency was scored using the number of weeks with at least one session of reflexology. A score ranging from 0 to 4 was assigned corresponding with each week of the 4-week protocol. A value of 0 was assigned if no sessions were reported; a value of 1 if 1 session was reported and values of 2 and 3 respectively when 2 or 3 sessions were reported. A value of 4 was assigned when the full protocol dose of 4 or more sessions was reported for the four-week period.

Third, duration was the time spent stimulating reflexes on each foot using a clock or timer to achieve consistency. The protocol used approximately 3 minutes per reflex, with a total of 30 minutes to treat both feet. The duration of reflexology sessions was observed during the second home visit by the reflexologist and reflected in the evaluation of each step on the ‘Encounter Form’ (Figure 2). For the fidelity scorecard, a value of 1 was assigned for intervention duration if a score of 90% or higher was recorded by the reflexologist indicating the proper session duration of 30 minutes was observed which included approximately 3 minutes per reflex; a value of 0 was assigned if a score of less than 90% was recorded.

Provider Training—The study reflexologists were assigned to dyads to provide the in-home caregiver training. The reflexologist trained the caregivers by demonstrating the ‘thumb walking’ motion of reflexology over the specific reflexes on the caregiver’s feet. The reflexologist worked with the caregiver through instruction and return demonstration until accuracy was attained for technique. The caregiver then delivered session one to the patient with the reflexologist observing. A written guide of instructions for locating and stimulating reflexes with picture diagrams was used for training and given to the caregiver for reference. Provider training was measured during the first visit by the reflexologist and recorded on the ‘Encounter Form.’ A value of 0 was assigned if a score of less than 90% was recorded; a value of 1 was assigned if a score of 90% or higher was recorded, indicating adequate

caregiver application of the reflexology protocol. To summarize, this fidelity component measured the accuracy of the caregiver's technique.

Intervention Delivery—Intervention delivery monitored the ongoing accuracy of weekly home-based sessions after completion of training. The study reflexologist made a follow-up visit approximately one week after the initial visit. During this session, the caregiver delivered the intervention to the patient as the study reflexologist observed. The study reflexologist provided quality assurance by addressing adjustments where needed. Contact information was provided so that the study reflexologist could promptly answer future questions. Intervention delivery was measured during the second visit by the reflexologist and recorded on the 'Encounter Form.' A value of 0 was assigned if a score of less than 90% was recorded; a value of 1 was assigned for intervention delivery if a score of 90% or higher was recorded indicating correct caregiver demonstration of the reflexology protocol.

Provider Intervention Training Receipt—Intervention receipt was achieved when the caregivers completed two satisfactory training sessions. The reflexologists documented receipt of the training sessions on the 'Encounter Form.' When scoring intervention receipt, if no reflexology training was received, a value of 0 was assigned; a value of 1 was assigned if one training session was received; and a value of 2 was assigned if the caregiver received both reflexology trainings. This fidelity component measured the number of training sessions the caregiver received from the reflexologist.

Enactment—Enactment of intervention skills was assessed through obtaining one appraisal at week 11 of sustained reflexology delivery six weeks after the intervention period (between study weeks 5 and 11) when reflexology sessions were no longer required. This provided a short-term measure of whether the intervention had been incorporated into the dyad's lifestyle. On the scorecard, if no sessions of reflexology were reported between weeks 5 and 11, a value of 0 was assigned; if 1 to 2 sessions were reported, a value of 1 was assigned; if 3 to 4 sessions were reported, a value of 2 was assigned; and if at least 5 sessions were reported, a value of 3 was assigned.

Data Analysis

Summary scores for each fidelity element and an overall fidelity score were computed for the reflexology group. Descriptive statistics for variables of interest included frequency distributions, measures of central tendency, skewness and variability. SAS version 9.4 was used for analysis.

RESULTS

The RCT enrolled 79 patient-caregiver dyads randomized to the reflexology group who have completed the 11-week study (Wyatt et al., 2011-2016). The majority (59%) of dyads were married or living together. The characteristics of reflexology group patients are presented in Table 1. Analyses of fidelity data using the fidelity scorecard are summarized in Table 2. A report of the attainment for each of the five fidelity elements follows.

Fidelity Elements

Each of the three components of dose was measured individually. Analysis of the number of sessions revealed a majority (60%) of patients received 3 or more sessions over the four-week protocol period, with a mean of 4.4 sessions. However, even though the mean was greater than 4, these sessions were not always uniformly spread over the four weeks. Only 29% of patients received at least one session of reflexology each week as indicated by the interval component of dose: the mean number of weeks with at least one session was 2.8. The majority of caregivers (76%) achieved a minimum of 90% for session duration. The variation observed among the components of dose indicates the importance of all three components in intervention monitoring.

Eighty% of caregivers achieved a score of at least 90% for provider training, reflecting a high level of attainment in the intervention protocol. The majority of caregivers (96%) achieved at least 90% proficiency in correct delivery of reflexology, demonstrating high attainment of intervention delivery. The caregivers also demonstrated a high level of intervention receipt by completing both reflexology training sessions (99%, mean of 1.99 out of 2). While most patients received reflexology at least one time after the protocol period (65%), 35% received no sessions after completing the initial 4-week intervention period. The mean number of reflexology sessions reported between completion of the intervention protocol and week 11 was 3.8 per patient, indicating that enactment of the intervention was moderately adopted among participants.

Fidelity Total

The individual elements reported on the, ‘Intervention Fidelity Scorecard: Reflexology’ allow for a total fidelity score to be compiled for each participant and the overall sample. The total fidelity score is a summation of all element scores with a range of zero to 16. The sample mean total score was 11.99 of 16, indicating high fidelity and assurance that the intervention was delivered as planned.

DISCUSSION

Evaluation of the exemplar RCT demonstrates how fidelity can be assessed in a caregiver-delivered symptom management intervention using a scorecard based on the five NIH-BCC elements (Bellg et al., 2004). While no thresholds have been established to categorize values obtained for the total fidelity score, the mean for this group of participants was very high. However, the variation in mean values for the elements of fidelity demonstrates the important contribution of each element. For example, while 60% of patients received at least four sessions over the 4-week period, only 29% had at least one session during each of the four weeks, indicating that the sessions were not distributed in the same manner (mean number of weeks with at least one session 2.8). This finding, combined with group scores for each of the elements of fidelity, provides a perspective on caregiver-delivered symptom management interventions not previously considered.

Evaluation of overall fidelity was not reported by the four comparative studies of reflexology delivered by a lay caregiver (Stephenson et al., 2007, Quattrin, 2006, Kohara et al., 2004,

Wyatt et al., 2012). However, some of the studies did mention one or more of the five fidelity elements. Three of four comparable studies that used lay caregivers mentioned the three dose components (Kohara et al., 2004, Quattrin, 2006, Stephenson et al., 2007); although only one addressed a standardized dose, used a training manual and stated adequate detail for replication (Wyatt et al., 2012). Provider training was addressed in the four contrasted studies, but revealed little detail on content or verification of provider skill retention (Kohara et al., 2004, Quattrin, 2006, Stephenson et al., 2007, Wyatt et al., 2012). Intervention delivery was described in only one of the studies (Wyatt et al., 2012). Receipt was mentioned in two of the four studies (Wyatt et al., 2012, Stephenson et al., 2007). Finally, enactment is ideally measured over a period of time sufficient to determine the integration of the intervention into lifestyle routines but is frequently a challenge due to limitations in long-term follow-up (Bellg et al., 2004). None of the comparison studies provided measures of enactment beyond six weeks, which was the same timeframe used in the exemplar study, preventing determination of long-term integration of the therapy into a lifestyle routine.

It is important to note that the fidelity elements may have been omitted from previous publications, while actually present in the protocols. However, none attempted to incorporate a systematic method for evaluating fidelity. Only recently have investigators been encouraged to become more conscientious about rigorous reporting, potentially influencing the lack of consistency and gaps in the five NIH-BCC fidelity elements across comparable studies. Such consistency in complex multi-site intervention studies is critical to achieving the expected outcomes (Chan et al., 2012).

LIMITATIONS

While the total score for the scorecard is available, it suffers from the same limitations as total scores for other concepts. For example, a low score on dose added to a high score on provider training produce a moderate total fidelity score. For this reason, in addition to the total score, the scorecard provides separate scores for each fidelity element. Depending on the purpose of the study relevant elements can be used. Further, the fidelity scorecard produces an index and not a scale score; therefore, psychometric approaches to determination of validity and reliability are not applicable.

CONCLUSION

In the present era of heightened lay caregiver involvement, maintaining intervention fidelity becomes more challenging when testing delivery of interventions for symptom management. Research protocols that incorporate established fidelity elements provide standardization to support the consistent and effective delivery of symptom management interventions using lay caregivers. One mechanism for detailed evaluation of intervention fidelity is the use of a scorecard to examine each element. Clinicians can confidently translate caregiver-delivered symptom management therapies into practice when they are based on strong fidelity protocols and proven efficacy for specific patient groups.

This methodology example advances knowledge by serving as a model for examining fidelity in nurse-designed symptom management interventions. Future research that expands using measures of intervention fidelity like the exemplar scorecard hold potential for evaluating the degree that a therapeutic protocol is delivered. Such innovation enhances the likelihood of both generalizable findings and the translation to practice of lay caregiver-delivered interventions for patients.

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References

AMERICAN CANCER SOCIETY. Cancer Facts & Figures 2016. Atlanta: American Cancer Society; 2016.

BELLG AJ, BORRELLI B, RESNICK B, HECHT J, MINICUCCI DS, ORY M, OGEDEGBE G, ORWIG D, ERNST D, CZAJKOWSKI S. TREATMENT FIDELITY WORKGROUP OF THE, N. I. H. B. C. C. Enhancing treatment fidelity in health behavior change studies: best practices and recommendations from the NIH Behavior Change Consortium. Health Psychol. 2004; 23:443–51. [PubMed: 15367063]

BOON HS, OLATUNDE F, ZICK SM. Trends in complementary/alternative medicine use by breast cancer survivors: comparing survey data from 1998 and 2005. BMC Womens Health. 2007; 7:4. [PubMed: 17397542]

CALSYN RJ. A checklist for critiquing treatment fidelity studies. Ment Health Serv Res. 2000; 2:107–13. [PubMed: 11256717]

CHAN CWH, RICHARDSON A, RICHARDSON J. Evaluating a complex intervention: A process evaluation of a psycho-education program for lung cancer patients receiving palliative radiotherapy. Contemporary Nurse. 2012; 40:234–244. [PubMed: 22554216]

FAMILY CAREGIVER ALLIANCE. Caregiver Assessment: Principles, Guidelines and Strategies for Change. 2006a; 1

FAMILY CAREGIVER ALLIANCE. Caregiver Assessment: Voices and Views from the Field. 2006b; 2

FLYNN LL, BUSH TR, SIKORSKII A, MUKHERJEE R, WYATT G. Understanding the role of stimulation in reflexology: Development and testing of a robotic device. European Journal of Cancer Care. 2011; 20:686–696. [PubMed: 21771134]

INTERNATIONAL INSTITUTE OF REFLEXOLOGY. Facts About Reflexology. 2015. [Online]. Available: http://www.reflexology-usa.net/ [Accessed]

KISSANE, D., BLOCH, S. Family focused grief therapy. Oxford University Press; 2002.

KOHARA H, MIYAUCHI T, SUEHIRO Y, UEOKA H, TAKEYAMA H, MORITA T. Combined modality treatment of aromatherapy, footsoak and reflexology relieves fatigue in patients with cancer. J Palliat Med. 2004; 7:791–6. [PubMed: 15684846]

KOZACHIK S, WYATT GK, GIVEN CW, GIVEN B. Patterns of Use of Complementary Therapies Among Cancer Patients and Their Family Caregivers. Cancer Nursing. 2006; 29:84–94. [PubMed: 16565617]

MCCULLOUGH JE, LIDDLE SD, SINCLAIR M, CLOSE C, HUGHES CM. The physiological and biochemical outcomes associated with a reflexology treatment: a systematic review. Evid Based Complement Alternat Med. 2014; 2014 502123.

NATIONAL CANCER INSTITUTE. Adjuvant and Neoadjuvant Therapy for Breast Cancer. Washington, D.C: 2015.

QUATTRIN R, ZANINI A, BUCHINI S, TURELLO D, ANNUNZIATA M, VIDOTTI C, COLOMBATTI A, BRUSAFERRO S. Use of a reflexology foot massage to reduce anxiety in

hospitalized cancer patients in chemotherapy treatment: methodology and outcomes. Journal of Nursing Management. 2006; 14:96–105. [PubMed: 16487421]

RADZIEWICZ RM, ROSE JH, BOWMAN KF, BERILA RA, O'TOOLE EE, GIVEN B. Establishing treatment fidelity in a coping and communication support telephone intervention for aging patients with advanced cancer and their family caregivers. Cancer Nurs. 2009; 32:193–202. [PubMed: 19295420]

REINHARD S, LEVINE C, SAMIS S. Home alone: Family caregivers providing complex chronic care. American Association of Retired Persons. 2012

RESNICK B, INGUITO P, ORWIG D, YAHIRO JY, HAWKES W, WERNER M, ZIMMERMAN S, MAGAZINER J. Treatment fidelity in behavior change research: a case example. Nurs Res. 2005; 54:139–43. [PubMed: 15778656]

STENBERG U, RULAND CM, MIASKOWSKI C. Review of the literature on the effects of caring for a patient with cancer. Psychooncology. 2010; 19:1013–25. [PubMed: 20014159]

STEPHENSON N, DALTON J. Using reflexology for pain management. J Holist Nurs. 2003; 21:179–191. [PubMed: 12794960]

STEPHENSON N, SWANSON M, DALTON J, KEEFE FJ, ENGELKE M. Partner-delivered reflexology: Effects on cancer pain and anxiety. Oncology Nursing Forum. 2007; 34:127–132. [PubMed: 17562639]

WATSON, S., VONER, V. Practical Reflexology: Interpretation and Techniques. New York: McGraw-Hill Companies, Incorporated; 2009.

WYATT G, FRAMBES D, HARRIS R, ARNEDT J, MURPHY S, ZICK S. Self-administered acupressure for persistent cancer-related fatigue: fidelity considerations. Altern Ther Health Med. 2015; 21:18–23.

WYATT G, SIKORSKII A, HOLMSTROM A, LUO Z. Home Based Symptom Management via Reflexology for Advanced Breast Cancer Patients. National Institutes of Health, National Cancer Institute grant # R01CA157459-01. 2011-2016

WYATT G, SIKORSKII A, RAHBAR M, VICTORSON D, YOU M. Health-related quality of life outcomes: A reflexology trial with patients with advanced-stage breast cancer. Oncology Nursing Forum. 2012; 39:568–577. [PubMed: 23107851]

WYATT G, SIKORSKII A, RAHBAR MH, VICTORSON D, ADAMS L. Intervention fidelity: aspects of complementary and alternative medicine research. Cancer Nurs. 2010; 33:331–42. [PubMed: 20467309]

WYATT G, SIKORSKII A, SIDDIQI A, GIVEN CW. Feasibility of a reflexology and guided imagery intervention during chemotherapy: results of a quasi-experimental study. Oncology Nursing Forum. 2007; 34:635–42. [PubMed: 17573322]

Summary Statement

Why is this research needed?

- The responsibility of providing symptom management interventions for cancer patients is increasingly shifting to lay caregivers in the home.
- There is a significant gap in the science that addresses protocol fidelity to support rigor and reproducibility for lay caregiver-delivered interventions.
- In publications reporting on efficacy of lay caregiver-delivered interventions, fidelity is seldom addressed.

What are the key findings?

- The elements of intervention fidelity can be incorporated into lay caregiver-delivered symptom management interventions in the home.
- A fidelity scorecard is a feasible and useful instrument for evaluating intervention fidelity.

How should the findings be used to influence policy/practice/research/education?

- Research protocols must incorporate fidelity elements to establish the consistent and effective delivery of symptom management interventions delivered by lay caregivers.
- The exemplar RCT serves as a model to examine fidelity of a caregiver-delivered intervention demonstrating measurable scoring of the fidelity elements.
- Evaluation of evidence based symptom management interventions moves research closer to translation and the ability to influence policy.
- Maintaining intervention fidelity is necessary for rigor and reproducibility in establishing the evidence base for interventions in research and practice.

Intervention Fidelity Scorecard: Reflexology

Fidelity Element*	**Measure**		**Scoring**	
	Data Source	Variable Description		Points
1. Dose **Number** of sessions over weeks 1-4	Weekly calls to patients	4 week total number of sessions	≥ 4 = 4 points 3 = 3 points 2 = 2 points 1 = 1 point 0 = 0 points	(range 0 – 4)
Frequency is the interval between sessions:	Weekly calls to patients	Number of weeks with at least one session	4 weeks = 4 points 3 weeks = 3 points 2 weeks = 2 points 1 week = 1 point 0 weeks = 0 points	(range 0 – 4)
Duration of each session	Reflexologist "Encounter Form" visit #2	Session duration of 30 minutes	Evaluation ≥ 90% = 1; < 90% =0	(range 0 – 1)
2. Provider Training: Caregiver achievement of intervention accuracy during training session with reflexologist: ≥ 90%	Reflexologist "Encounter Form" visit #1	Training	≥ 90% = 1; < 90% =0	(range 0 – 1)
3. Intervention Delivery Accuracy Caregiver demonstration of accuracy in delivery of reflexology protocol to patient: ≥ 90%	Reflexologist "Encounter Form" visit #2	Demonstration of delivery of reflexology	≥ 90% = 1; < 90% =0	(range 0 – 1)
4. Provider Intervention Training Receipt Caregiver receives training and verification of retained skills in administration of reflexology protocol during 2 visits with reflexologist	Reflexologist "Encounter Forms" Visits #1 & 2	Number of visits with reflexologist	2 visits = 2 points 1 visit = 1 point 0 visits = 0 points	(range 0 – 2)
5. Enactment Number of sessions completed during weeks 5-11	Wave 3 Patient Interview "Debriefing Tool"	Number of sessions during weeks 5-11	≥ 5 sessions = 3 points 3-4 sessions = 2 points 1-2 sessions = 1 point 0 sessions = 0 points	(range 0 – 3)
Total:				(range 0 – 16)

*(Bellg et al., 2004)

Figure 1.
Intervention Fidelity Scorecard

EVALUATION: 5% for each step is based on accuracy of location and pressure for each reflex, and 5% for minimum time spent on each reflex.

Beginning	_____ **out of 10**
Step 1	_____ **out of 10**
Step 2	_____ **out of 10**
Step 3	_____ **out of 10**
Step 4	_____ **out of 10**
Step 5	_____ **out of 10**
Step 6	_____ **out of 10**
Step 7	_____ **out of 10**
Step 8	_____ **out of 10**
Step 9	_____ **out of 10**

Total: _____

(Must be at least 90)

Figure 2.
Encounter Form

Table 1

Patient Characteristics

	N = 79
Age	Mean (St. Dev.)
	58.2 (11)
	N (%)
Race	
White	66 (84)
Black or African American	9 (11)
Asian	2 (3)
American Indian/Native Alaskan	1 (1)
Not Available	1 (1)
Ethnicity	
Hispanic or Latino	2 (3)
Not Hispanic or Latino	76 (96)
Refused	1 (1)
Marital Status	
Never Married	7 (9)
Married or Living with Partner	56 (71)
Divorced/Separated	12 (15)
Widowed	4 (5)
Employment	
Full Time	18 (22)
Part Time	8 (10)
Not Employed	10 (13)
Retired	29 (37)
Homemaker	3 (4)
Disabled	9 (11)
Not Reported	2 (3)
Disease Metastasis	
Non-Metastatic	28 (40)
Metastatic	41 (60)
Disease Recurrence	
Not Recurrent	45 (66)
Recurrent	23 (34)
Caregiver Relationship to Patient	
Spouse/Partner	47 (59)
Parent/Step Parent	2 (3)
Sister/Step Sister Brother/Step Brother	3 (4)
Daughter In Law/Son In Law	2 (3)

	N = 79
Aunt/Uncle	2 (3)
Daughter/Step Daughter Son/Step Son	15 (19)
Friend	5 (5)
Other	3 (4)

Table 2

Fidelity Summary Measures N= 79

Fidelity Element	Measure	N %	Mean FidelityScore (S.D.)
Dose: Number of sessions completed over 4 weeks	At least 4 sessions	47 (60%)	3.27 (1.03)
	3 sessions	13 (16%)	
	2 sessions	13 (16%)	
	1 session	5 (6%)	
	0 sessions	1 (1%)	
Dose: Duration of each session	30 minutes	76 (96%)	0.96 (0.19)
	Not 30 minutes	3 (4%)	
Dose: Interval between sessions (number of weeks with at least one session)	4 weeks	23 (29%)	2.75 (1.04)
	3 weeks	25 (32%)	
	2 weeks	21 (27%)	
	1 week	9 (11%)	
	0 weeks	1 (1%)	
Provider Training: Accuracy 90% during reflexologist visit #1	≥ 90%	63 (80%)	0.80 (0.40)
	< 90%	16 (20%)	
Intervention Delivery: Accuracy ≥ 90% during reflexologist visit #2	≥ 90%	76 (96%)	0.96 (0.19)
	< 90%	3 (4%)	
Intervention Receipt: Caregiver visits with reflexologist	2 visits	78 (99%)	1.99 (0.11)
	1 visit	1 (1%)	
	0 visits	0 (0%)	
Enactment: Sessions completed during weeks 5-11	≥ 5 sessions	19 (24%)	1.25 (1.18)
	3-4 sessions	10 (13%)	
	1-2 sessions	22 (28%)	
	0 sessions	28 (35%)	
Total Fidelity Score			11.99 (2.67)