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Dawn Frambes
Calvin University

Rebecca Lehto
Michigan State University

Alla Sikorskii
The University of Arizona

Irena Tesnjak
Michigan State University

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RESEARCH METHODOLOGY: EMPIRICAL RESEARCH – METHODOLOGY

Fidelity scorecard: evaluation of a caregiver-delivered symptom management intervention

Dawn Frambes , Rebecca Lehto, Alla Sikorskii, Irena Tesnjak, Barbara Given & Gwen Wyatt

Accepted for publication 11 January 2017

Correspondence to D. Frambes:
e-mail: dawn.frambes@calvin.edu

Dawn Frambes PhD RN
Assistant Professor
Department of Nursing, Calvin College,
Grand Rapids, MI, USA

Rebecca Lehto PhD RN
Associate Professor
College of Nursing, Michigan State
University, East Lansing, MI, USA

Alla Sikorskii PhD
Professor
College of Nursing, University of Arizona,
Tucson, AR, USA

Irena Tesnjak MS
PhD candidate
Department of Statistics and Probability,
Michigan State University, East Lansing,
MI, USA

Barbara Given PhD FAAN RN
University Distinguished Professor
College of Nursing, Michigan State
University, East Lansing, MI, USA

Gwen Wyatt PhD FAAN RN
Professor
College of Nursing, Michigan State
University, East Lansing, MI, USA

FRAMBES D., LEHTO R., SIKORSKII A., TESNJAK I., GIVEN B. & WYATT G. (2017) Fidelity scorecard: evaluation of a caregiver-delivered symptom management intervention. *Journal of Advanced Nursing* 73(8), 2012–2021. doi: 10.1111/jan.13266

Abstract

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

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 Behaviour 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 one session. Provider training was achieved at 80% of the maximum score, 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 the 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: advanced breast cancer, caregiver involvement, fidelity scorecard, intervention fidelity, nursing, protocol standardization, reflexology, symptom management

Why is this research needed?

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

the responsibility of unpaid lay caregivers in the home (Kissane & Bloch 2002, Family Caregiver Alliance, 2006a, 2006b, Stenberg *et al.* 2010, 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, 2006b) and is identified by the patient as their caregiver (Kissane & Bloch 2002, Stenberg *et al.* 2010).

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 Behaviour 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.

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 (Calsyn 2000, Bellg *et al.* 2004, Radziewicz *et al.* 2009, Wyatt *et al.* 2010, 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

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 (Wyatt *et al.* 2012, McCullough *et al.* 2014), 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 & 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 & 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 people with breast cancer. 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, 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 because of the suppressed immunity and cancer-related fatigue (National Cancer Institute, 2015). Only a few studies have tested reflexology interventions for people with breast cancer 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.* (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 people with advanced breast cancer, 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 the 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 people with breast cancer through deconstruction of an intervention protocol; and (2) To analyse 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 the 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 participants 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' (Table 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 and 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 0-16. 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, 2012). The fidelity scorecard allowed for determination of dose relative to the 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 about the reason for the missing session were obtained. As with other

Table 1 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)

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 0–4 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 1). For the fidelity scorecard, a value of 1 was assigned for intervention duration if a score of 90% or higher was recorded by the

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 1 Encounter form.

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

In this study, the 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 the 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 the 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 2.

Table 2 Patient characteristics.

	N = 79
Age	Mean (SD) 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	3 (4)
Brother/step brother	
Daughter in law/son in law	2 (3)
Aunt/uncle	2 (3)
Daughter/step daughter	15 (19)
Son/step son	
Friend	5 (5)
Other	3 (4)

Analyses of fidelity data using the fidelity scorecard are summarized in Table 3. 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 the patients received 4 or more sessions

Table 3 Fidelity summary measures *N* = 79.

Fidelity element	Measure	N (%)	Mean fidelity score (SD)
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)

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 the 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 the 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 the 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 the patients received at least four sessions over the 4-week period, only 29% of the patients 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 *et al.* 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 *et al.* 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 *et al.* 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 (Stephenson *et al.* 2007, Wyatt *et al.* 2012). 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 because of the 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.

Funding

This work is supported by funding from a grant entitled: *Home-based Symptom Management via Reflexology for Advanced Breast Cancer Patients* from the National Cancer Institute (Grant Number 1 R01CA 157459).

Conflict of interest

No conflict of interest has been declared by the authors.

Author contributions

All authors have agreed on the final version and meet at least one of the following criteria (recommended by the ICMJE [<http://www.icmje.org/recommendations/>]):

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

References

American Cancer Society (2016) *Cancer Facts & Figures 2016*. American Cancer Society, Atlanta.

Bellg A.J., Borrelli B., Resnick B., Hecht J., Minicucci D.S., Ory M., Ogedegbe G., Orwig D., Ernst D. & Czajkowski S. & Treatment Fidelity Workgroup of the N. I. H. B. C. C. (2004) Enhancing treatment fidelity in health behavior change studies: best practices and recommendations from the NIH Behavior Change Consortium. *Health Psychology* 23, 443–451.

Boon H.S., Olatunde F. & Zick S.M. (2007) Trends in complementary/alternative medicine use by breast cancer survivors: comparing survey data from 1998 and 2005. *BMC Womens Health* 7, 4.

Calsyn R.J. (2000) A checklist for critiquing treatment fidelity studies. *Ment Health Serv Res* 2, 107–113.

Chan C.W.H., Richardson A. & Richardson J. (2012) Evaluating a complex intervention: a process evaluation of a psycho-education program for lung cancer patients receiving palliative radiotherapy. *Contemporary Nurse* 40, 234–244.

Family Caregiver Alliance (2006a) *Caregiver assessment: principles, guidelines and strategies for change*. 1.

Family Caregiver Alliance (2006b) *Caregiver assessment: voices and views from the field*. 2.

Flynn L.L., Bush T.R., Sikorskii A., Mukherjee R. & Wyatt G. (2011) Understanding the role of stimulation in reflexology: development and testing of a robotic device. *European Journal of Cancer Care* 20, 686–696.

International Institute Of Reflexology 2015 *Facts about reflexology* [Online]. Retrieved from <http://www.reflexology-usa.net/> on 4 April 2016.

Kissane D. & Bloch S. (2002) *Family Focused Grief Therapy*. Open University Press, Buckingham, UK.

Kohara H., Miyauchi T., Suehiro Y., Ueoka H., Takeyama H. & Morita T. (2004) Combined modality treatment of aromatherapy, footsoak and reflexology relieves fatigue in patients with cancer. *Journal of Palliative Medicine* 7, 791–796.

Kozachik S., Wyatt G.K., Given C.W. & Given B. (2006) Patterns of Use of Complementary Therapies Among Cancer Patients and Their Family Caregivers. *Cancer Nursing* 29, 84–94.

McCullough J.E., Liddle S.D., Sinclair M., Close C. & Hughes C.M. (2014) The physiological and biochemical outcomes associated with a reflexology treatment: a systematic review. *Evidence-Based Complementary and Alternative Medicine: eCAM* 2014, 502123.

National Cancer Institute (2015) *Adjuvant and Neoadjuvant Therapy for Breast Cancer*. National Cancer Institute, Washington, D.C.

Quattrin R., Zanini A., Buchini S., Turello D., Annunziata M., Vidotti C., Colombatti A. & Brusaferrero S. (2006) Use of a reflexology foot massage to reduce anxiety in hospitalized cancer patients in chemotherapy treatment: methodology and outcomes. *Journal of Nursing Management* 14, 96–105.

Radziewicz R.M., Rose J.H., Bowman K.F., Berila R.A., O'Toole E.E. & Given B. (2009) Establishing treatment fidelity in a coping and communication support telephone intervention for aging patients with advanced cancer and their family caregivers. *Cancer Nursing* 32, 193–202.

Reinhard S., Levine C. & Samis S. (2012) *Home Alone: Family Caregivers Providing Complex Chronic Care*. American Association of Retired Persons, Washington, DC.

Resnick B., Inguito P., Orwig D., Yahiro J.Y., Hawkes W., Werner M., Zimmerman S. & Magaziner J. (2005) Treatment fidelity in behavior change research: a case example. *Nursing Research* 54, 139–143.

Stenberg U., Ruland C.M. & Miaskowski C. (2010) Review of the literature on the effects of caring for a patient with cancer. *Psychooncology* 19, 1013–1025.

Stephenson N. & Dalton J. (2003) Using reflexology for pain management. *J Holist Nurs* 21, 179–191.

Stephenson N., Swanson M., Dalton J., Keefe F.J. & Engelke M. (2007) Partner-delivered reflexology: effects on cancer pain and anxiety. *Oncology Nursing Forum* 34, 127–132.

Watson S. & Voner V. (2009) *Practical Reflexology: Interpretation and Techniques* McGraw-Hill Companies, Incorporated, New York.

Wyatt G., Sikorskii A., Siddiqi A. & Given C.W. (2007) Feasibility of a reflexology and guided imagery intervention during

- chemotherapy: results of a quasi-experimental study. *Oncology Nursing Forum* 34, 635–642.
- Wyatt G., Sikorskii A., Rahbar M.H., Victorson D. & Adams L. (2010) Intervention fidelity: aspects of complementary and alternative medicine research. *Cancer Nursing* 33, 331–342.
- Wyatt G., Sikorskii A., Holmstrom A. & Luo Z. (2011-2016) *Home Based Symptom Management via Reflexology for Advanced Breast Cancer Patients*. National Institutes of Health, National Cancer Institute grant # R01CA157459-01, Bethesda, MD.
- Wyatt G., Sikorskii A., Rahbar M., Victorson D. & You M. (2012) Health-related quality of life outcomes: a reflexology trial with patients with advanced-stage breast cancer. *Oncology Nursing Forum* 39, 568–577.
- Wyatt G., Frambes D., Harris R., Arnedt J., Murphy S. & Zick S. (2015) Self-administered acupressure for persistent cancer-related fatigue: fidelity considerations. *Alternative Therapies in Health and Medicine* 21, 18–23.

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