EXAMINING RELATIONSHIPS BETWEEN CAREGIVING ACTIVITIES AND
CAREGIVER HEALTH OUTCOMES

By

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PUBLIC ABSTRACT

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Background

It is estimated that over 43 million friends or family members in the United States (U.S.) provided care for individuals with health-related support needs in 2015. Caregivers of cancer patients frequently seek ways to support patients, becoming involved in complex cancer-related care activities.

Aims

The aims of this research were:

1. To determine the state of the science regarding care activities performed by friend/family caregivers of cancer patients;

2. To examine inclusion of the elements of intervention fidelity within a research study of reflexology delivered by caregivers to breast cancer patients;

3. To analyze caregiver data for the effects of providing a symptom management intervention for breast cancer patients on caregivers' psychological, physical, and social health;

4. To expand knowledge about the effects of caregiving by looking at relationships between providing reflexology and caregiver health outcomes.

Methods

Three papers address the research aims: 1) "Health Outcomes of Informal Caregivers of Cancer Patients: A Literature Review"; 2) "Fidelity Scorecard: Evaluation of a Caregiver-delivered

Symptom Management Intervention"; and 3) "Caregiver Health Outcomes: The Effects of Providing Reflexology for Symptom-Management for Women with Advanced Breast Cancer".

Findings

Literature published during the past six years revealed interventions that helped caregivers of cancer patients succeed and cope in their role. What was not clear was which specific care activities caregivers performed to help patients with cancer and the impact this had on the caregivers' health.

Examining the National Institutes for Health Behavior Change Consortium elements of intervention fidelity in training informal caregivers to deliver reflexology to patients with breast cancer resulted in creation of a scorecard to measure intervention fidelity, a new contribution to science. An assessment of caregiver health outcomes resulted in finding that depressive symptoms differed between caregivers who provided reflexology and those who did not. The nature of the difference was dependent on the caregiver's relationship to the patient, with adult children who provided reflexology to a parent experiencing more depressive symptoms than those who did not provide reflexology. Friends of the patient who provided reflexology reported lower levels of depressive symptoms than friends who did not provide reflexology.

Fatigue was found to decrease over time for all caregivers, with caregivers who provided reflexology reporting lower levels of fatigue than caregivers who did not provide reflexology. Also, delivery of more sessions of reflexology was associated with reports of lower levels of caregiver fatigue.

ABSTRACT

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Background

It is estimated that over 43 million friends or family members in the United States provide care

for individuals with health-related support needs (American Association of Retired Persons

Public Policy Institute & National Alliance for Caregiving, 2015). Caregivers of cancer patients

frequently seek ways to provide supportive care for the patients' disease and treatment-related

symptoms, becoming involved in complex care activities.

Aims

The aims of this research were to: 1) synthesize the state of the science relative to care activities

performed by informal caregivers for cancer patients through a review of literature; 2) examine

application and achievement of the elements of intervention fidelity within a research protocol

for reflexology delivered by informal caregivers to advanced breast cancer patients; 3) analyze

caregiver data for the effects of providing a care activity consisting of delivery of a symptom

management intervention for breast cancer patients on caregiver psychological, physical, and

social health outcomes; and 4) advance nursing science on the effects of informal caregiving by

evaluating relationships between performance of a specific symptom management care activity

and caregiver health outcomes, providing a level of detail not currently available in the literature.

Methods

A three manuscript dissertation was completed, with each manuscript having its own

methodology and results.

Results

1) The body of literature revealed a gap regarding the specific care activities performed by informal caregivers on behalf of patients with cancer, and the associated impact on the caregivers' health outcomes. 2) Examining the National Institutes for Health Behavior Change Consortium elements of intervention fidelity in the protocol used to train informal caregivers to deliver reflexology to patients with breast cancer resulted in a scorecard for rating intervention fidelity. 3) The nature of the association between delivery of reflexology and caregiver depressive symptoms differed based on the relationship of the caregiver and the patient, with adult children caring for a parent experiencing significantly higher levels of depressive symptoms than control caregivers, and friends of the patient who provided reflexology reporting significantly lower levels of depressive symptoms. The physical health outcome of fatigue was found to decrease over time for all caregivers, but caregivers who provided reflexology reported significantly lower levels of fatigue than controls. Further, delivery of more sessions of reflexology was associated with significantly lower levels of reported fatigue.

This dissertation is dedicated to my parents and late grandparents who provided me with the first examples of family caregiving.

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The foundations for my successful completion of this program are many, each contributing vital support. I am indebted to my family, friends, colleagues, and the excellent faculty and staff of the Michigan State University College of Nursing for their contributions to my achievement of this personal and professional goal. All have provided combinations of encouragement, patience, guidance, mentoring, and belief in my abilities that got me through the joyous and hard days.

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owe them so much and hope I can at least partially support them as they have supported me.

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KEY TO ABBREVIATIONS

CAM: Complementary Alternative Medicine

CIH: Complementary and Integrative Health

LME: Linear Mixed Effects

LS: Least square

NIH-BCC: National Institutes of Health Behavior Change Consortium

PRISMA: Preferred Reporting Items for Systematic reviews and Meta-Analyses

RCT: Randomized control trial

SD: Standard deviation

SE: Standard error

U.S.:   United States of America

CHAPTER 1

Introduction

Background

It is estimated that over 43 million friends or family members in the United States (U.S.) became the informal caregiver for individuals with health-related support needs in 2015 (American Association of Retired Persons Public Policy Institute & National Alliance for Caregiving, 2015). With 1.6 million people in the U.S. predicted to be diagnosed with cancer in 2015 (American Cancer Society, 2015), caregivers of cancer patients comprised a large segment of this group. Caregivers of cancer patients are frequently involved in complex cancer-related care activities (Fletcher, Miaskowski, Given, & Schumacher, 2012) and frequently seek ways to provide supportive care for the patients' disease and treatment-related symptoms. However, they are often not prepared for the care activities required of them (B. Given, Given, & Sherwood, 2012; National Alliance for Caregiving, 2016).

Advanced breast cancer represents nearly 15% of all cancers projected to be diagnosed during 2016 (National Cancer Institute, 2016a). Breast cancer is the leading cancer among women in the U.S., with 246,600 cases of invasive disease expected to be diagnosed during 2016 (National Cancer Institute, 2016b). Symptom management interventions delivered by informal caregivers at home can improve health-related quality of life for patients with advanced cancer (Belgacem et al., 2013). However, the activities of patient care performed to support cancer patients, such as symptom management interventions, may impact the caregivers' psychological, physical, and social health (American Cancer Society, 2011; Jayani & Hurria, 2012; National Alliance for Caregiving, 2016; Stenberg, Ruland, & Miaskowski, 2010; Tsigaroppoulos et al.,

2009). Changes in these caregiver outcomes may in turn affect their capacity to provide care for cancer patients.

A randomized control trial (RCT) examining caregiver-delivered reflexology as a symptom management intervention for women with advanced breast cancer was the source of data for this research (Wyatt, Sikorskii, Holmstrom, & Luo, 2011-2016). Secondary analyses of data from this study were performed to examine intervention fidelity and caregiver health outcomes and are reported in this dissertation.

The purpose of this research is to examine the health outcomes of informal caregivers who support cancer patients by performing care activities in the home setting during medical treatment. The population of caregivers is considered first broadly with regard to the types of activities performed for patients with varying types of cancer. The population focus then narrows to a specific group of friend/family caregivers who provide a symptom management intervention within the parent RCT for women undergoing treatment for advanced breast cancer.

The scientific contribution of this research expands what is known about the inclusion of informal caregivers in the delivery of symptom management interventions for cancer patients in three ways: 1) synthesis of the available evidence and identification of gaps related to the activities performed for cancer patients by informal caregivers while considering the caregivers' health outcomes; 2) evaluation of the inclusion and achievement of intervention fidelity relative to an informal caregiver-delivered symptom management intervention for patients with advanced breast cancer; and 3) analysis of caregiver data within a RCT for evidence of relationships between provision of a protocol-driven intervention to manage cancer patient symptoms and the impact on caregiver health outcomes.

Aims

The aims of this research were to:

1. Determine the state of the science relative to care activities performed and the health outcomes of informal caregivers for cancer patients through a review of literature;

2. Examine application of the elements of intervention fidelity within a research protocol for a symptom management care activity delivered by informal caregivers to advanced breast cancer patients;

3. Analyze caregiver data for the effects of providing a care activity (intervention) for symptom management among advanced breast cancer patients on caregiver psychological, physical, and social health outcomes; and

4. Contribute knowledge on the effects of informal caregiving by evaluating relationships between performance of a specific symptom management care activity (intervention) and caregiver health outcomes, in order to design ways to enhance caregiver preparation for these tasks while preserving their own health.

Conceptual Model

The Organizing Framework for Caregiver Interventions (Van Houtven, Voils, & Weinberger, 2011) provided a foundation to address the aims of this research (Figure 1). The framework consists of five components: 1) caregiver and care recipient baseline characteristics; 2) caregiver interventions; 3) caregiver activities; 4) caregiver outcomes; and 5) care recipient outcomes. The framework components influence each other beginning with the baseline characteristics of the caregiver and care recipient (patient), which should inform the nature of interventions for caregivers. Caregiver interventions potentially change caregiver activities, which impact caregiver and care recipient outcomes. Caregiver and care recipient outcomes have a reciprocal effect on the caregivers' performance of caregiver activities as well as the other member of the caregiver-patient dyad's outcomes (Van Houtven et al., 2011). Van Houtven et

al.'s (2011) framework is not specific to patient condition or caregiver interventions, and can be applied to a variety of caregiver-patient situations. While the original model suggests various caregiver activities and outcomes, as well as patient outcomes, they have not been included in Figure 1. This study uses the model as a foundation and tailors the elements to the population of breast cancer patients and a unique intervention involving caregivers.

The Organizing Framework for Caregiver Interventions (Van Houtven et al., 2011) was adapted to guide this research. The adapted model will be referred to as the Caregiver Outcomes Model (Figure 2), (Frambes, Given, Lehto, Sikorskii, & Wyatt, 2016); it has five main components: 1) supportive interventions for caregivers of cancer patients; 2) care activities performed by caregivers on behalf of cancer patients; 3) caregiver outcomes associated with psychological, physical, and social health; 4) characteristics of caregivers; and 5) characteristics of patients.

The model asserts that supportive care interventions for caregivers directly influence the caregivers' performance of one or more care activities for a patient with cancer. Within the model, solid arrows represent paths of direct influence; the dashed arrow represents a potential moderating effect. Interventions to support caregivers should be selected to directly impact the care activities performed on behalf of patients with cancer. Care activities performed by caregivers directly influence outcomes of both the caregiver and the patient with regard to psychological, physical, and social health outcomes. Characteristics of the caregiver directly influence the choice of supportive interventions and/or the activities they perform on behalf of cancer patients. The dashed arrow connecting caregiver and patient characteristics to the connection between care activities performed for the patient on caregiver and patient outcomes

represents a potential moderating effect. A detailed discussion of the model's components

follows.

Supportive interventions for caregivers. The model components begin with an

examination of the supportive interventions for caregivers. Feasibility and efficacy of supportive

interventions for caregivers of cancer patients is reported in the literature (Applebaum &

Breitbart, 2013; Northouse, Katapodi, Song, Zhang, & Mood, 2010; Waldron, Janke, Bechtel,

Ramirez, & Cohen, 2013). Northouse et al. (2010) categorized supportive interventions for

caregivers of patients with cancer as targeting the following areas: a) psychoeducation to

develop knowledge/skills related to the patient's cancer diagnosis; b) skill development to

promote the caregivers' coping, communication, and problem-solving behaviors; and c)

counseling for reactions to caring for a cancer patient. Supportive intervention strategies for the

caregivers of cancer patients tested within the past six years (2009-2016) include cognitive-

behavioral therapy (Badger et al., 2011; Boele et al., 2013; Heinrichs et al., 2012; Hendrix,

Landerman, & Abernethy, 2011; Hultgren, Turrisi, Mallett, Ackerman, & Robinson, 2016;

McLean, Walton, Rodin, Esplen, & Jones, 2013; Meyers et al., 2011; Northouse et al., 2013;

Sherwood et al., 2012; Ward et al., 2009); facilitating communication with providers (Chih et al.,

2013; DuBenske et al., 2014); and caregiver self-care (McLean et al., 2013). One area not

evident in the intervention literature was psychomotor skill development enabling caregivers to

provide hands-on symptom management interventions. This component has been added to

Figure 2 for this dissertation.

Care activities performed on behalf of cancer patients. As posited in the Caregiver

Outcomes Model, supportive interventions for caregivers should lead to support for performance

of patient care activities (Van Houtven et al., 2011). Effective interventions promote the

caregivers' development of skills for managing cancer symptoms and comorbid conditions, communicating with the patient, family, and providers, participating in decision-making and problem-solving, accessing community resources, and navigating the health system (B. Given et al., 2012). A synthesis of the literature produced the following five major categories of care activities.

Managing cancer symptoms and comorbidities. The first category of care activities involves maintaining the stability of chronic conditions and addressing and/or avoiding acute changes related to cancer symptoms and comorbidities. People with cancer have similar types of comorbidities, but generally have more co-occurring conditions than those without cancer (Edwards et al., 2014), requiring additional knowledge and skill of caregivers.

Skilled activities commonly performed by health care personnel, who have been prepared through formal education, constitute a group of medical or nursing activities that caregivers are often required to perform (Reinhard, Levine, & Samis, 2012; Van Houtven et al., 2011). These care activities are especially challenging when needed, because informal caregivers usually lack the training and experience of health professionals (Schumacher, Stewart, Archbold, Dodd, & Dibble, 2000). When caregivers must rely on trial and error in their efforts to perform care activities, the quality and contribution to patient outcomes is uncertain (B. Given et al., 2012). The extent that the elements of fidelity established by the National Institutes of Health Behavior Change Consortium (Bellg et al., 2004) are integrated within this group of activities present key considerations relative to safety, consistency, and potentially patient outcomes. Additionally, determining the achievement of fidelity where informal caregivers provide an intervention for helping the patient with symptom management provides knowledge regarding the consistency of the caregiver's experience in providing the care activity. The elements of fidelity are discussed

in detail in Chapter 3 and applied to a specific caregiver-delivered care activity for breast cancer patients.

Based on the work of Fletcher et al. (2012), Reinhard et al. (2012), and Given et al. (2012), the following are examples of managing cancer symptoms and comorbid conditions during the cancer trajectory:

- Obtaining and administering complex cancer medications administered orally, via injections, intravenous infusions, infusion ports, and the use of infusion pumps.

- Recognition and management of cancer treatment side effects and symptoms such as nausea, vomiting, diarrhea, fatigue, weakness, pain, and development of infections.

- Assistance with mobility and the use of assistive devices including maneuvering environmental barriers or identifying barrier-free access for cancer or comorbidity related mobility impairment.

- Management of patient behaviors such as agitation and restlessness and emotional responses to cancer such as anxiety through use of medication and complementary practices. Also included are management of behaviors related to comorbidities such as dementia.

- Nutritional support through preparation of altered texture foods, preparation of special diets to promote caloric intake in small volumes, and management of anorexia related to cancer, it's treatment, or comorbid conditions affecting nutrition.

- Wound and skin care involving the application of topical medications or dressings, care and protection of catheter insertion sites, prevention of skin breakdown, and managing wound drainage associated with cancer treatments or comorbid conditions affecting skin integrity.

- Management of altered elimination functions including constipation and diarrhea, incontinence, urinary and fecal drainage catheters, and application of ostomy appliances which may be associated with either cancer or comorbidities.

- Use of monitoring devices such as meters for measuring blood pressure, blood sugar, and oxygen saturation related to comorbid conditions such as hypertension, diabetes, or lung disease.

- Operation of medical equipment including oxygen, ventilators, tube feedings, peripherally inserted central catheters (PICC lines) and dialysis (B. Given et al., 2012).

As with cancer-related care activities, specific knowledge and psychomotor skills are necessary to prevent worsening of any existing comorbid conditions in addition to the cancer (B. Given et al., 2012), as will be addressed in Chapter 3. This is achieved through knowing the expected normal course of the patient's disease trajectory and taking action to prevent exacerbations. The effects of comorbid conditions such as diabetes, heart failure, and chronic lung disease on the treatment of cancer represent another set of care activities that may be necessary during care for cancer.

Communication with the patient, family, and health providers. Caregivers frequently communicate about cancer and comorbidity care among providers and other family members regarding care and treatment issues and on behalf of the patient when he/she is not able to communicate (Bevan & Pecchioni, 2008; B. Given et al., 2012). Speaking on behalf of the patient, caregivers must frequently relate information to providers about the patient's symptoms and responses to treatments and the care activities performed by the caregiver; consequently, they also receive information from providers on behalf of the patient. These dialogues require a

"cancer literacy" (Bevan & Pecchioni, 2008) for caregivers to effectively communicate. Development of familiarity and comfort with the health and cancer-specific terminology used is important as caregivers assist the patient with decision-making.

Decision-making/problem-solving. Patients and their caregivers face many decision points during the cancer trajectory related to treatment options, nutrition, pain and other symptom management, and promoting comfort versus curative treatment. For example, when managing the patient's pain, caregivers must decide whether the frequency and intensity the patient is experiencing are normal, problem-solve among options available, and decide when to report their observations to the patient's health provider. Furthermore, caregivers must know which provider to contact for problems and questions as patients generally have multiple specialty providers in addition to their primary care provider.

Accessing community resources. Identifying and using available community resources, such as for patient and family support during the cancer trajectory, is another type of care activity (Fletcher et al., 2012). Examples include patient and family support groups, resources for patient wigs/head coverings and specialty garments, and caregiver respite services. Determining the suitability and knowing how and when to access available community resources are common care activities.

Navigating the health system. Caregivers interact with primary and specialty care providers by organizing office, diagnostic, and treatment appointments, providing transportation, and obtaining medication and supplies (Fletcher et al., 2012; B. Given et al., 2012) which require consideration of timing, distance, and patient tolerance of travel. Management of insurance benefits, (including health, long-term-care, and "cancer" insurance programs), and obtaining pre-authorization from insurance programs for treatments and services are performed by caregivers.

Navigating the health system throughout the cancer trajectory is an important care activity for patients with cancer, but can be time consuming and unfamiliar to caregivers.

There is a wide range of the type and complexity of care activities performed by informal friend and family caregivers of patients with cancer. It is important to examine the expected outcomes of performing care activities on caregivers to understand their experiences and needs, and to sustain them for the patients who rely upon them.

Caregiver outcomes. Performing care activities has the potential to impact caregivers negatively or positively with regard to psychological, physical, and social health, and other outcomes (American Cancer Society, 2011; Feinberg & Houser, 2012; Jayani & Hurria, 2012; National Alliance for Caregiving & American Association of Retired Persons, 2009; Stenberg et al., 2010; Tsigaroppoulos et al., 2009; Van Houtven et al., 2011). Examples of caregiver outcomes include depression, anxiety, stability of chronic conditions, and changes in social interactions (B. Given et al., 2012). The Organizing Framework for Caregiver Interventions (Van Houtven et al., 2011) asserts the direct relationship between the care activities performed by caregivers and the impact on the caregivers' health in the dimensions of psychological, physical and social health with the associated use of health services and economic impacts. The negative effects on the health of caregivers not only impacts them as individuals, but also have the potential to limit their capacity to carry on over time, which could ultimately affect quality of care for patients (Van Houtven et al., 2011).

Patient outcomes. Caregivers perform care activities for patients with cancer in an effort to positively influence the psychological, physical and social health outcomes experienced by the patient. While this is an important component of the overall Caregiver Outcome Model, the focus of this research is primarily on outcomes of the caregivers.

Caregiver characteristics. In the context of a cancer diagnosis, characteristics of the caregiver provide essential background information for supportive interventions for caregivers (Van Houtven et al., 2011). Characteristics of the caregiver including demographics (age, sex, and race/ethnicity), relationship to the patient, employment, level of education achieved, health status (conceptualized as comorbid conditions), distance between the caregiver's and patient's residences, and amount of caregiving experience in weeks, months, or years must be considered with regard to their influence on the performance of care activities.

Patient characteristics. Characteristics of the patient also contribute to selection of interventions to support the caregiver and the type and amount of care activities required by the patient. The patient's cancer diagnosis and treatment are key considerations in examining health outcomes of both caregivers and the patients. Further, characteristics associated with both the caregiver and patient may moderate the effects of providing care activities on caregiver and/or patient outcomes. The scope of this research focuses on the caregivers' role and health outcomes. While patient outcomes are important and an integral component of the model, they will not be addressed.

When analyzing the effects of caring for a patient with cancer on the caregiver's health outcomes, it is clear that a combination of factors related to the patient and caregiver contribute to variations in caregiving circumstances. Consideration of each factor within the context of each patient-caregiver pair provides the most comprehensive view of caregiving.

The Caregiver Outcomes Model provides a framework to examine caregiving by including supportive interventions for caregivers; care activities performed by caregivers; and the influence of characteristics of the caregiver and patient on the health outcomes of both. However, as depicted in Figure 2, caregiving literature contains minimal discussion of how

interventions for caregivers are linked to care activities performed, particularly with regard to navigation of the health system. Another gap is also evident among interventions for caregivers addressing psychomotor skills necessary for performing symptom management care activities for cancer patients. These areas will be addressed throughout the following chapters as the Caregiver Outcomes Model guides examination of caregivers for patients with breast cancer.

Review of Literature

The role of informal caregivers of cancer patients has been addressed in the literature from the perspective of several concepts related to the outcomes of the caregiving experience. Caregiver outcomes have been examined in conjunction with provision of supportive interventions for caregivers, the type and amount of care activities performed by caregivers, and characteristics of the patient such as demographic factors and cancer type. Characteristics of caregivers have also been reported such as demographic factors, relationship to the patient, employment, and cultural group identity. Literature examined for this research includes definition and prevalence of informal caregiving in the context of a patient with a cancer diagnosis, and reports of supportive intervention research protocols for caregivers of cancer patients.

Cancer. Patients with cancer have improved rates of survival from past generations due to earlier diagnosis and more effective treatment options (Hazelwood, Koeck, Wallner, Anderson, & Mayer, 2012). These advances in cancer detection and treatment contribute to a growing number of aging adults with cancer who often have comorbid conditions that present challenges in cancer treatment as well as management of the other diseases (B. Given & Given, 2009). Breast cancer incidence and survival rates are consistent with these patterns, with the number of cases diagnosed stabilizing and the number of deaths declining over the past 20 years

(American Cancer Society, 2016b). While there is wide variation in the amount and type of assistance patients require during cancer treatment, the importance of informal caregivers is well documented (Applebaum & Breitbart, 2013; B. Given et al., 2012; Jayani & Hurria, 2012; Lambert, Girgis, Lecathelinais, & Stacey, 2013). Nursing has a key role in educating caregivers about disease, treatment, and care activities to support patients with cancer.

Caregiving. Caregivers of cancer patients have been reported to spend an average of 9 hours per day in the caregiving role (American Association of Retired Persons Public Policy Institute & National Alliance for Caregiving, 2015); when distant metastasis was present, caregivers provided even more support (van Ryn et al., 2011). The literature addresses positive (Jervis, Boland, & Fichenscher, 2010; Y. Kim, Baker, & Spillers, 2007; Y Kim, Carver, Schulz, Lucette, & Cannady, 2013; Roth et al., 2013) and negative (Bevans & Sternberg, 2012; Blum & Sherman, 2010; Girgis et al., 2013; National Alliance for Caregiving & American Association of Retired Persons, 2009; Northouse et al., 2013; Stenberg et al., 2010) outcomes of routine caregiving activities. Research relative to caregivers' performing specific activities, such as delivery of a symptom management intervention, is minimal but suggests several alternatives: 1) adding the delivery of psychomotor symptom management interventions to existing caregiving activities may increase caregiver burden and distress (Feinberg & Houser, 2012; B. Given et al., 2012; B. Given, Given, Sikorskii, et al., 2006; 2009; Reinhard et al., 2012; Van Houtven et al., 2011); and 2) caregiver outcomes may improve in conjunction with patient outcomes as a result of symptom reductions (Belgacem et al., 2013; Hazelwood et al., 2012).

Although caregivers of cancer patients are identified as a group who perform a variety of care activities and whose health outcomes differ from non-caregiving peers, research examining potential relationships between these two aspects of caregiving is not evident in the literature.

Studies have focused on interventions delivered to caregivers and patients (B. Given, Given, Sikorskii, et al., 2006; Hopkinson, Brown, Okamoto, & Addington-Hall, 2012; Langford & Miaskowski, 2012), and factors that may moderate the intervention effects, such as age, sex, ethnicity, and employment (B. Given et al., 2012; Hodges, Humphris, & Macfarlane, 2005; Jayani & Hurria, 2012; Jervis et al., 2010; Pitceathly & Maguire, 2003; Stenberg et al., 2010; Thomas, Morris, & Harman, 2002). Care activities performed by caregivers have been identified as a broad range of functions associated with patient needs (Fletcher et al., 2012; B. Given et al., 2012; Reinhard et al., 2012), but generally not in relationship to the outcomes caregivers experience. The role of nursing in preparing caregivers to support patients with cancer serves to maintain the capacity of caregivers as an integral component of the patients' care team.

Intervention fidelity. As informal caregivers of cancer patients become increasingly responsible for providing symptom management interventions in the home setting (Family Caregiver Alliance, 2006a, 2006b; Kissane & Bloch, 2002; Reinhard et al., 2012; Stenberg et al., 2010), fidelity must be considered to promote consistency and reproducibility. The importance of incorporating the fidelity standards established by the National Institute for Health-Behavior Change Consortium (NIH-BCC) (Bellg et al., 2004) has been demonstrated within health provider-delivered interventions with caregivers of cancer patients (Radziewicz et al., 2009), but are equally important to informal caregiver-delivered protocols. Studies utilizing lay caregivers to deliver interventions comparable to the one being tested among breast cancer patients by Wyatt et al., (2011-2016) do not demonstrate full inclusion of the fidelity elements (Kohara et al., 2004; Quattrin, 2006; N. L. Stephenson, Swanson, Dalton, Keefe, & Engelke, 2007; Wyatt, Sikorskii, Rahbar, Victorson, & You, 2012). The resulting gap in knowledge of the extent that intervention fidelity was achieved in these studies presents questions regarding the consistent

delivery of the intervention by informal caregivers, and therefore the interpretation of results. Knowledge generated by research that includes the elements of intervention fidelity in caregiver delivered symptom management interventions will provide needed information on this component of cancer care.

Caregiver outcomes. Examining outcomes provides an opportunity to look at the relationships between those outcomes experienced by informal caregivers and the care activities they perform on behalf of cancer patients. Informed by the existing literature, the following research contributes to an identified gap in science by analyzing the effects of delivering a symptom management intervention to breast cancer patients on caregiver health outcomes.

Within each of the following papers, a synthesis of literature describes the state of the science for: 1) care activities performed by caregivers of patients with cancer and caregiver health outcomes; 2) intervention fidelity application to reflexology RCTs; and 3) caregiver health outcomes in conjunction with delivery of reflexology as a symptom management intervention.

Examining recent caregiving literature provides a foundation for determining the extent that relationships between providing care activities and caregiver health outcomes have been addressed. Inclusion of intervention fidelity in caregiver-delivered intervention research is limited; intentional incorporation and measurement within a RCT provides knowledge regarding feasibility and fidelity achievement when caregivers deliver a symptom management intervention. Using a conceptual model to guide analyses of the relationships between a caregiver-delivered intervention, the influence of caregiver and patient characteristics, and the caregivers' health outcomes provides a unique view of relationships among the model components. The culmination of these research activities will provide a perspective important to

nursing by contributing expanded knowledge about the informal caregivers' experience of supporting patients with cancer and caregiver health outcomes.

Methods

Examining relationships among caregiver characteristics, care activities performed by caregivers of cancer patients, and caregiver health outcomes are achieved through integrating three research activities. First, a review of caregiving literature provides a foundation for the state of science examining caregiver health outcomes as they relate to performing care activities for cancer patients. Caregivers perform care activities for cancer patients with varying experience and preparation. Thus it is imperative, particularly in research studies, that appraisal of intervention fidelity elements is performed in conjunction with caregiver delivery of specific symptom-management interventions for patients. A critical appraisal of achievement of fidelity within a study of a caregiver-delivered intervention provides an indicator of reliability for the analysis of associated caregiver health outcomes. The degree of caregiver success in achieving fidelity within the confines of a RCT provides insights regarding the homogeneity of the caregiving experience, and therefore interpretation of results. Finally, this research reports an analysis of outcomes among caregivers who deliver protocol-driven reflexology to breast cancer patients in terms of psychological, physical, and social health. The methods for establishing each of these research components are now presented.

Review of caregiving literature. Chapter 2 is a literature review of caregiver interventions published between January 2009 and July 2016. This paper establishes the state of the science regarding connections between care activities performed by caregivers of cancer patients and caregiver health outcomes. The paper utilizes the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) statement (Liberati et al., 2009) and is

formatted for submission to the Western Journal of Nursing Research for publication consideration.

Intervention fidelity methods. Chapter 3 is a deconstruction of the R01 research protocol for the elements of intervention fidelity established by the National Institutes of Health Behavior Change Consortium (Bellg et al., 2004). This paper critically evaluates the fidelity of the intervention from which caregiver data will be analyzed. The paper is formatted for submission to the Journal of Advanced Nursing for publication consideration.

Analysis of caregiver outcomes data. Chapter 4 is a data analysis of caregiver outcomes in conjunction with a caregiver-delivered reflexology intervention for patient symptom management from a parent RCT (Wyatt et al., 2011-2016) guided by the Caregiver Outcomes Model. The report of findings is formatted for submission to Oncology Nursing Forum for publication consideration.

Outcomes

This research contributes the following knowledge to the science relative to informal caregivers of cancer patients:

1.   Results of a review of literature published between 2009 and 2016 relative to associations between care activities performed by informal caregivers for cancer patients and caregiver outcomes. This synthesis of recently published quantitative research is reported in Chapter 2 and establishes the current state of science and identified gaps;

2.   Application of the elements of intervention fidelity within a research protocol for a caregiver-delivered symptom management intervention for breast cancer patients. Measurement of intervention fidelity via a scorecard, an approach not previously used for validating the results of caregiver delivered interventions, is illustrated in Chapter 3; and

3.   Results of an analysis of caregiver data examining the effects of providing a symptom

management intervention for breast cancer patients on caregiver psychological, physical,

and social health outcomes. Chapter 4 reports the findings and provides an assessment of

outcomes upon which to plan future interventions for informal caregivers of cancer

patients, while noting methods to maintain their own health while caregiving.

This research contributes to the scientific knowledge of relationships between performing

a specific symptom management intervention, promoting and measuring intervention fidelity in

caregiver delivered interventions, and caregiver health outcomes. The findings can be applied to

research for development of supportive caregiver interventions and has the potential of

application among other caregiving populations. Chapter 5 summarizes the findings of these

three research outcomes and synthesizes the conclusions as they contribute to future nursing

research, practice, and health policy.

CHAPTER 2

Health Outcomes of Informal Caregivers of Cancer Patients:
A Literature Review

Abstract

Family and friends are important resources for patients during cancer treatment. Informal caregivers are often responsible for helping patients manage cancer-related and comorbid conditions via accessing community resources, health system navigation, communication about treatment options, and participation in the treatment plan. While the effects of caregiving demands on caregiver health have been reported, limited research has examined care activities performed by caregivers in relation to reported caregiver health outcomes.

A review of randomized controlled trials published between 2009 and 2016 indexed in PubMed, CINAHL, Cochrane, and PsychInfo databases was completed utilizing the Preferred Reporting Items for Systematic reviews and Meta-analyses. The Caregiver Outcomes Model guided data extraction pertaining to care activities and health outcomes for caregivers of cancer patients.

Fourteen articles were reviewed with gaps identified regarding the relationships between care activities performed for cancer patients, caregiver characteristics, and caregivers' health outcomes.

Introduction

Informal caregivers of cancer patients are family members or friends identified by individuals with cancer as their primary source of care and support (National Alliance for Caregiving, 2016; Stenberg et al., 2010). Cancer patients globally are cared for by family and friends who are recognized not only as an important resource, but also as a potentially vulnerable population with needs directly associated with their caregiving role (American Association of Retired Persons, 2016; National Alliance for Caregiving, 2016; World Health Organization, 2015). Although caregivers often have a limited skill set to prepare them for activities required in the caregiving role (B. Given, Given, Sikorksii, et al., 2006), relationships between the activities performed to care for patients with cancer, and the impact on caregiver outcomes have not been explicitly evaluated. Specifically, a variety of caregiver outcomes have been reported but not in conjunction with types or quantities of care activities performed. Based on these observations, a review of the recent literature was conducted to summarize the available evidence regarding relationships among activities performed to care for cancer patients, caregiver characteristics, and health outcomes of caregivers.

The effects of caring for patients with cancer. More than 1.6 million new cases of cancer are expected to be diagnosed in the U.S. during 2016 (American Cancer Society, 2016a). Friend or family caregivers provide multiple types of care activities during a patient's cancer treatment and recovery (National Alliance for Caregiving, 2016) including symptom management (Kozachik, Wyatt, Given, & Given, 2006; N. L. Stephenson et al., 2007). Care provision also includes complex activities such as communicating with health providers and translating information to the patient regarding treatment, providing emotional support, and assisting with insurance and financial matters (Fletcher et al., 2012).

The effects of informal caregiving on physical, psychological, and social aspects of caregiver health suggest both positive and negative outcomes (Jayani & Hurria, 2012; Jervis et al., 2010; Y. Kim & Given, 2008; Pitceathly & Maguire, 2003). Interventions supporting cancer caregivers have been tested and summarized in recent reviews (Applebaum & Breitbart, 2013; Northouse, Katapodi, Schafenacker, & Weiss, 2012; Waldron et al., 2013). The scope of these reviews focused on caregiver characteristics and: 1) intervention type (Applebaum & Breitbart, 2013); 2) caregiver and/or patient outcomes (Applebaum & Breitbart, 2013; Northouse et al., 2012; Waldron et al., 2013); 3) the impact of care activities associated with the caregiver's relationship to the patient and primary versus secondary caregiving roles on caregiver outcomes (Lund, Ross, Petersen, & Groenvold, 2014); and 4) evaluation of measures of caregiver outcomes (Prue, Santin, & Porter, 2015).

Two systematic reviews (Applebaum & Breitbart, 2013; Waldron et al., 2013) and one meta-analysis (Northouse et al., 2010) synthesized intervention research focused on supporting caregivers of cancer patients from 1947 to 2011. While the scope of these studies is broad with regard to the type and effectiveness of interventions to support caregivers, the impact of performing care activities on their health outcomes is not explicit and therefore cannot be extracted. Further, past reviews covered the literature published over lengthy time periods leading to heterogeneity in patient and caregiver outcomes. This is especially noteworthy in regards to changes that have occurred in diagnosis and treatment regimens (Applebaum & Breitbart, 2013; Northouse et al., 2010).

The purpose of this review was to analyze recent (2009 – 2016) caregiving literature for evidence of relationships between the care activities performed by caregivers of cancer patients, caregiver characteristics and resulting caregiver outcomes. Such a review expands the scope of

what is known in several ways: 1) updates caregiving literature; 2) focuses on specific activities that caregivers perform for cancer patients in conjunction with interventions to support caregivers; and 3) identifies caregiver characteristics that may be associated with specific care activities and/or caregiver outcomes.

Methods

Design. A review of literature was completed using the overarching framework of the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) statement (Liberati et al., 2009). PRISMA consists of four broad elements in the selection of publications: identification, screening, eligibility, and inclusion (Figure 3). Only the subcomponents of PRISMA applicable to this review are included.

In addition to PRISMA, a conceptual model was adapted to guide this review from Van Houtven, Voils, and Weinberger's Organizing Framework for Caregiver Interventions (2011) (Figure 2). For the purposes of this literature review, the modified model is referred to as the Caregiver Outcomes Model. This adapted model identifies relationships among the following concepts as experienced by caregivers of patients with cancer: 1) supportive interventions for caregivers as they care for patients with cancer; 2) care activities performed on behalf of cancer patients; 3) caregiver outcomes; 4) characteristics of caregivers; and 5) characteristics of patients with cancer. Starting at the left of Figure 2 (Van Houtven et al., 2011), supportive interventions for caregivers are scientifically validated protocols from randomized controlled trials (RCTs) designed to improve either the caregivers' ability to perform care, or their personal responses to caring for a patient with cancer. Moving to the right in Figure 2, care activities performed for cancer patients include actions taken by caregivers for the purpose of improving the patients' response to disease or treatment. Viewing the lower box in Figure 2, caregiver and patient characteristics should be considered in the design of supportive interventions for caregivers and

may influence the performance of care activities by caregivers. Furthermore, they may moderate the effects of performing care activities on caregiver outcomes. Finally, on the far right, caregiver outcomes refer to effects of caregiving on psychological, physical, and social health. While patient characteristics and health outcomes are a part of the model, they are not the focus of this review, but are included to illustrate the full potential of the model.

Search methods. The four components of the PRISMA framework were employed in the search and review process. Figure 3 represents the identification, screening, eligibility, and inclusion of articles reviewed.

Identification. A search of the CINAHL, Cochrane Library, PubMed, and PsycINFO databases for articles published internationally in English between January 1, 2009 and July 31, 2016 was completed. The time frame was selected for two reasons: 1) to identify articles that had not been included in previous systematic reviews and meta-analyses, and 2) to examine and update types of activities provided by caregivers to maintain currency and to minimize differences in the cancer trajectory related to changing treatment options. Articles reporting caregiver intervention studies focusing on supporting either care delivery or the response to providing care and identifying at least one care activity performed by caregivers of adult cancer patients were retained for review. Keywords and MeSH terms included "family, caregiver, cancer, neoplasm, patient, spouse, partner, couple, and caregiver intervention." The term "caregiver outcome" was not included in the search strategy because using this term did not result in identification of additional articles. Inclusion criteria limited selection to RCTs testing supportive interventions for informal caregivers of cancer patients with a minimum of one control group condition.

Studies dedicated solely to palliative care were excluded due to the unique conditions

associated with end-of-life caregiving.   Further, reports of research proposals, pilot studies, or

articles not reporting data were excluded. Studies focusing on patient diagnoses other than

cancer were also excluded to preserve similarity of context in which care activities were

performed.

Screening and eligibility. Titles of 447 articles retrieved from the initial database search

were examined with 420 retained for evaluation of eligibility after removal of duplicates.

Examination of article abstracts by two authors resulted in 47 articles for full review. Following

elimination of articles that included pilot studies, non-randomized trials, and other exclusion

criteria, 14 articles were retained with dual consensus (Figure 3).

Inclusion. The review summary for the 14 articles is presented in Table 1 with

description of the supportive interventions, measurements where available, outcomes, and data

collection time points. For the 14 retained articles, three procedural steps were then taken: 1)

assessment for risk of bias; 2) data abstraction at two levels; and 3) a synthesis of the model

variables abstracted.

Risk of bias. Risk of bias was assessed using the Cochrane Collaboration's tool

(Higgins, Altman, & Sterne, 2011) as a guideline. Categories of bias assessed were: 1) selection

bias related to how participants were allocated to intervention or control groups, methods used

for randomization, and assessment of equality of groups at baseline; 2) performance bias

associated with blinding of participants, personnel performing data collection, and quality

assurance procedures; 3) detection bias relative to measurement of exposure to the intervention,

consideration of the effects of variables not measured, and power considerations; 4) attrition bias

related to missing data handling and reporting of the number of participants, timing, and reasons

for not completing the full intervention or follow-up measurements; and 5) selective outcome reporting.

Data abstraction. A two level abstraction was used. First, one author completed data abstraction, with subsequent review by a second author. Data were abstracted from each article regarding the supportive intervention delivered to caregivers, care activities performed by caregivers on behalf of patients with cancer, characteristics of the caregivers and patients comprising the population sample, and caregiver outcomes. The research design, including inclusion and exclusion criteria, the number of groups, and randomization procedures, were noted for each supportive intervention. The type and setting of supportive interventions delivered to either caregivers solely, or to both caregivers and patients were recorded. Intervention objectives were examined to determine whether the intended outcome was to help caregivers perform care activities, or to directly influence caregiver outcomes without regard to performance of care activities.

Data were organized from each article according to the conceptual model into categories for analysis as follows: 1) supportive interventions for caregivers; 2) care activities performed on behalf of cancer patients; 3) caregiver characteristics; and 4) caregiver outcomes with associated measures.

Synthesis of model variables abstracted. Integrating the Caregiver Outcomes Model, distinct categories were established for supportive interventions for caregivers, care activities, caregiver outcomes, and caregiver characteristics based on the literature and professional experience. A detailed description of how the variables in each category were defined follows, as well as a narrative synthesis of findings for each variable and associated measure (Table 1).

Supportive interventions for caregivers. Guided by the Caregiver Outcomes Model (Figure 2) and intervention types identified by Northouse et al. (2010), supportive interventions were categorized as: 1) psychoeducation relative to the patient's disease; 2) skill development for coping, communication, and problem-solving; and 3) counseling for reactions to caring for a patient with cancer. Interventions were sorted into these three categories by the authors based on the descriptions provided because they were not identified in the articles in terms of the established categories.

Care activities performed on behalf of the cancer patient. Care activities performed by caregivers were identified and classified by the authors into four categories: 1) managing cancer symptoms and comorbidities; 2) communication with the patient, family and health providers; 3) decision making and problem solving; and 4) accessing community resources. Each article was examined for identification of care activities within the background research, intervention design, and results reported. Caregiver performance measures with pre- and post- intervention values were examined when available. Final classification of care activities was agreed upon by consensus of the authors.

Caregiver outcomes. Caregiver outcomes were categorized as pertaining to psychological, physical, or social health as reported in each article with other types of outcomes also noted (Fletcher et al., 2012; Van Houtven et al., 2011).

Patient outcomes. While patient outcomes were not the focus of this review, several interventions were delivered to both patients and caregivers as opposed to the caregiver only (Badger et al., 2011; Heinrichs et al., 2012; McLean et al., 2013; Meyers et al., 2011; Northouse et al., 2013; Ward et al., 2009). In these cases, only caregiver outcomes were examined.

Caregiver characteristics. Demographic variables for caregivers included mean age, sex, race/ethnicity, and education level. Additionally, the caregiver's relationship to the patient, the distance between caregiver and patient residences, and prior caregiving experience reported by caregivers was extracted when available.

Patient characteristics. Demographic variables for patients included mean age, sex, and race/ethnicity. Cancer type, and stage of disease were also recorded. Patient characteristics were examined with regard to relationships with caregiver outcomes, and are not a focus of this review.

Results

Demographics (Table 1). A total of 2714 caregivers were represented in the 14 studies. The majority of caregivers were females with a mean age of 55 years; Caucasian; and with an average education level of "completion of some college." Patients were nearly equally distributed between male and female; the majority were Caucasian; and cancer diagnoses covered a wide range as shown in Table 1.

Risk of bias. Selection bias was low across the 14 studies, with documented procedures used for randomizing participants into intervention and control groups. Differences between groups with regard to either demographic variables or baseline outcome measures were reported in five studies (Boele et al., 2013; Heinrichs et al., 2012; Hendrix et al., 2011; McLean et al., 2013; Ward et al., 2009). Three studies described a change in the study design with a reduction in the number of groups in one study (DuBenske et al., 2014), the combining of two separate studies due to low enrollment in the second (Chih et al., 2013), expansion of inclusion criteria after study initiation in the third (Hultgren et al., 2016), and addition of an intervention delivery

method following study initiation (Hultgren et al., 2016). In all cases, the handling of data and assignment of participants were described.

Risk of performance bias was generally low across studies although blinding of participants or personnel was only reported in three studies (Heinrichs et al., 2012; Hendrix et al., 2016; McLean et al., 2013). Interventions were delivered in private settings such as patient or caregiver homes, hospital patient rooms, outpatient clinics, or via telephone reducing contamination risk. The use of different personnel for intervention versus control conditions was reported in all but one study (Hultgren et al., 2016). In one study (Boele et al., 2013) the personnel who recruited subjects appeared to have also provided usual care, which was not discussed with regard to potential for contamination of outcomes.

Detection bias was determined to be low across all studies, with reported values for the participants' exposure to the intervention for all study groups. Confounding variables were considered in two studies (Boele et al., 2013; DuBenske et al., 2014). Power analysis and effect sizes were reported in nine studies (Badger et al., 2011; Couper et al., 2015; DuBenske et al., 2014; Hendrix et al., 2011; McLean et al., 2013; Meyers et al., 2011; Northouse et al., 2013; Sherwood et al., 2012; Ward et al., 2009). Couper et al. (2015) identified a potential recruitment bias toward younger caregivers.

Attrition and retention rates were reported for all studies with eight studies reporting procedures for handling missing data (Boele et al., 2013; Couper et al., 2015; Hendrix et al., 2016; Hendrix et al., 2011; Hultgren et al., 2016; Meyers et al., 2011; Northouse et al., 2013; Sherwood et al., 2012). Selective outcome reporting was not detected in any of the 14 studies with all noting significant and non-significant findings.

Data abstraction. The 2-level abstraction was successful. All categories from the conceptual model were represented.

Synthesis of model variables abstracted. Using the Caregiver Outcomes Model (Figure 2) to guide the literature comparisons, all four components were evaluated. The model subheadings are used to outline this results section.

Supportive interventions for caregivers. Among the 14 articles reviewed, 1697 caregivers received a supportive intervention for themselves while caring for a cancer patient. An additional 1017 caregivers participated in the studies through receipt of usual care or a comparison attention control intervention.

According to the Caregiver Outcomes Model, the interventions in each study supported caregivers in performance of care activities for the cancer patient or the caregiver's response to care delivery. The particular interventions were not the focus of the review, but were an important mechanism for identifying the care activities performed and health outcomes among each population of caregivers. The supportive intervention types identified in each article are presented in Table 2 and summarized as follows:

Psychoeducation relative to the patient's disease (Badger et al., 2011; Boele et al., 2013; Chih et al., 2013; DuBenske et al., 2014; Heinrichs et al., 2012; Hendrix et al., 2016; Hendrix et al., 2011; Hultgren et al., 2016; McLean et al., 2013; Northouse et al., 2013; Sherwood et al., 2012; Ward et al., 2009);

Skill development for coping, communication, problem-solving, and psychomotor intervention delivery (Badger et al., 2011; Boele et al., 2013; Chih et al., 2013; Couper et al., 2015; DuBenske et al., 2014; Heinrichs et al., 2012; McLean et al., 2013; Meyers et al., 2011; Northouse et al., 2013; Sherwood et al., 2012; Ward et al., 2009); and

Counseling for reactions to caring for a patient with cancer (Badger et al., 2011; Couper et al., 2015; Heinrichs et al., 2012; Hendrix et al., 2016; McLean et al., 2013; Northouse et al., 2013). It was evident that most studies (Badger et al., 2011; Boele et al., 2013; Couper et al., 2015; Heinrichs et al., 2012; Hendrix et al., 2016; McLean et al., 2013; Northouse et al., 2013; Sherwood et al., 2012; Ward et al., 2009) utilized more than one of the intervention types in their protocols.

Care activities performed on behalf of cancer patients (Table 2). While care activities were identified, the caregiver participants in the reported studies did not always perform them (Table 2). The care activities described in each article are summarized below using the previously discussed classifications identified in the Caregiver Outcomes Model (Figure 2). Descriptions of the instruments used to measure care activities in the studies are located in Table 3 with psychometric properties when available.

Managing cancer symptoms and comorbidities. Twelve articles indicated that caregivers managed acute and chronic conditions for patients with cancer. Managing the patient's physical symptoms and behavior changes (Boele et al., 2013; Chih et al., 2013; Couper et al., 2015; Hendrix et al., 2016; Hendrix et al., 2011; McLean et al., 2013; Northouse et al., 2013; Sherwood et al., 2012), monitoring for treatment side effects (DuBenske et al., 2014), assessing for disease progression (Hultgren et al., 2016), providing emotional support (Heinrichs et al., 2012; Hultgren et al., 2016; Sherwood et al., 2012), and pain management (Ward et al., 2009) were examples given. Hendrix et al. (2011) referred to detailed activities such as maintenance of nutrition via tube feedings and caloric intake, management of elimination, prevention of infection, caring for infusion and drainage lines, wound care and other "medical" tasks. Only one article (Sherwood

et al., 2012) included quantification, such as frequencies or duration to evaluate the extent of care activities (Table 3).

Communication with the patient, family, and providers. Eleven articles identified communication with the patient, other family members, or health providers about the cancer patient's condition and treatment as a care activity performed by caregivers. Examples of communication activities included discussing the patient's disease with children (Boele et al., 2013), interacting with health providers concerning the patient's symptom experience (Chih et al., 2013; DuBenske et al., 2014; McLean et al., 2013), and discussing disease progression and treatment decisions with the patient (Badger et al., 2011; Couper et al., 2015; Heinrichs et al., 2012; Hultgren et al., 2016; Northouse et al., 2013; Sherwood et al., 2012; Ward et al., 2009). Three articles identified measures of communication. Heinrichs et al. (2012) examined communication quality between the patient and caregiver. Short-term increases in discussions with patients about treatment were noted among caregivers in the intervention group; however, detail of the quantity or frequency of such communications was not given. Two studies (Northouse et al., 2013; Sherwood et al., 2012) assessed illness-related communication between caregivers and patients with no significant change over time or between group differences among the caregivers in any study groups. While communication about the patients' condition was the most frequently identified and measured care activity among studies (Table 2), it was not quantified or described in a way that contributed to association with caregiver outcomes.

Decision-making/problem-solving. Five articles included reference to decision-making or problem-solving care activities. Medical treatment decisions and symptom management options were the primary topics cited as requiring caregiver input (Heinrichs et al., 2012; Sherwood et al., 2012) with widely varied experiences among caregivers (Meyers et al., 2011).

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Problem-solving styles used to manage patient symptoms, communicate with health providers and obtain assistance from others were examined by Meyers et al. (2011), but without measures of frequency or effectiveness that could be tied to caregiver outcomes (Table 2).

Accessing community resources. Two articles (Badger et al., 2011; DuBenske et al., 2014) included the identification and activation of resources outside the family and health care milieu as activities performed by cancer caregivers. These were caregiver access to diagnosis-specific and health promotion resources available from organizations such as the National Cancer Institute (Badger et al., 2011), and a specially designed web site for participants to facilitate access to disease information (DuBenske et al., 2014). None of the articles indicated using measures to evaluate this care activity. However, DuBenske et al. (2014) reported attempts to measure use of a web-based communication and information systems that comprised the caregiver intervention without success (Table 2).

Navigating the health system. None of the articles identified navigating the health system as a care activity. This category of care activities has been identified as an area that caregivers are often unfamiliar with and a source of stress (Fletcher et al., 2012)

Caregiver outcomes (Table 4). This review evaluated potential associations between the types of activities performed on behalf of cancer patients and informal caregiver psychological, physical, and social health outcomes. Measures of caregiver outcomes are summarized in Table 4. There were over 40 measures of caregiver outcomes used across articles, and most articles reported psychometric properties of the instruments. Caregiver outcomes were categorized according to the Caregiver Outcomes Model and are summarized below.

Caregiver psychological health outcomes. Psychological caregiver health outcomes included anxiety, coping, depression, distress, negative mood, self-esteem, stress, and caregiver

perception of the patient's illness and prognosis. In general, depression, negative mood, coping style, and self-esteem improved among caregivers who received any of the three identified intervention types. It was noted, however, that caregivers in some control conditions also experienced similar improvements. Sherwood et al. (2012) noted a significant positive intervention effect on caregiver self-esteem, but indicated the result could have been related to chance. Boele et al. (2013) reported a positive correlation between caregiver and patient mental functioning. Meyers et al. (2011) noted a decline in psychological well-being for both intervention and usual care groups of caregivers, while Hendrix et al. (2016) noted similar improvements in depression and anxiety for caregivers in both intervention and usual care groups over time.

Managing cancer symptoms and comorbidities was an identified care activity in six studies where caregiver psychological health measures improved among caregivers randomized to intervention groups (Boele et al., 2013; Couper et al., 2015; Heinrichs et al., 2012; Hendrix et al., 2011; Northouse et al., 2013). Improvements in caregiver psychological health outcomes were also noted in several studies where caregivers performed communication care activities (Badger et al., 2011; Chih et al., 2013; Couper et al., 2015; Heinrichs et al., 2012; Sherwood et al., 2012). Accessing community resources was an identified care activity in two studies that reported improvements in caregiver depression in intervention and control groups (Badger et al., 2011) and stronger well-being within the control group (DuBenske et al., 2014).

Caregiver physical health outcomes. Physical health outcomes examined among caregivers consisted of fatigue, sleep disorders, and illness. Badger et al. (2011) noted increased fatigue among caregivers in the intervention group and decreased fatigue in the attention control group over time. Chih et al. (2013) ascertained no significant difference between intervention

and control groups. Boele et al. (2013) assessed multiple components of caregiver physical health outcomes including physical functioning, pain, and vitality; outcome measures were, however not reported. Chih et al. (2013) and DuBenske et al. (2014) obtained measures of sleep disruption and physical health impacts with no significant change over time or between groups (Chih et al., 2013), and less burden over time when they received a supportive caregiver intervention (DuBenske et al., 2014). Care activities identified in studies where physical health outcomes were evaluated included managing cancer and comorbidities and communicating with the patient, health providers or family members (Boele et al., 2013; Chih et al., 2013; DuBenske et al., 2014), accessing community resources (DuBenske et al., 2014), and decision-making or problem-solving (Boele et al., 2013). The majority of physical health outcomes cannot be directly related to the performance of these noted care activities.

Caregiver social health outcomes. Reported aspects of caregivers' social health outcomes among the studies consisted of social well-being (Badger et al., 2011), disruption in lifestyle and work (DuBenske et al., 2014), family support (Badger et al., 2011), relationship function (Couper et al., 2015), relationship quality (Hultgren et al., 2016), marital satisfaction (McLean et al., 2013), and social quality of life (Northouse et al., 2013). While improvements were noted in relationship function among some caregivers who received an intervention (Couper et al., 2015), improvements in caregiver social well-being and marital satisfaction over time were not necessarily related to the interventions tested (Badger et al., 2011; McLean et al., 2013). DuBenske et al. (2014) reported no significant changes in disruptiveness for caregivers at either short or long term interval measurement points or associated with the intervention tested.

Care activities identified in studies reporting improvements in social health outcomes included management of cancer and comorbidities, accessing community resources,

communicating with the patient, family, or health providers, and decision-making or problem-solving (Badger et al., 2011; Couper et al., 2015; McLean et al., 2013). As with psychological and physical health outcomes, associations between performance of care activities and social health outcomes cannot be clearly identified.

Other caregiver outcomes. Caregiver outcomes that did not fit within the established categories of caregivers' psychological, physical, or social health were assessed in several articles. These outcomes included quality of life, mastery, accuracy of perceptions about the patient's illness, and self-efficacy and will be considered next.

Caregiver quality of life, (a multi-dimension outcome inclusive of psychological, physical and social health components), was a focus for four of the studies (Boele et al., 2013; Hendrix et al., 2011; Meyers et al., 2011; Northouse et al., 2013) and was measured with established quality of life instruments (Table 4). Caregivers of patients with mixed cancer types who received an intervention consisting of a combination of psychoeducation, skill development, and counseling demonstrated improved quality of life that was sustained over time (Northouse et al., 2013). A study testing an intervention consisting of cognitive-behavior therapy and psychoeducation for a group of caregivers who performed decision-making and/or problem-solving care activities for patients with brain cancer reported unchanged caregiver quality of life outcomes, while caregivers in the control group exhibited improved quality of life (Boele et al., 2013). Quality of life also remained unchanged among caregivers of patients with hematological malignancies who received training in care specific to the patient's condition prior to hospital discharge, while control group caregivers exhibited a steady increase in quality of life over time (Hendrix et al., 2011). Meyers et al. (2011) reported a decline in caregiver well-being (using a

quality of life instrument) within both intervention and control groups for a population of caregivers of patients with mixed types of cancers.

Caregiver mastery, defined as how caregivers perceived their ability to provide care to the patient, was assessed as an intervention outcome in two studies (Boele et al., 2013; Sherwood et al., 2012). Boele et al. (2013) reported increased mastery among caregivers who received an intervention of psychoeducation and cognitive behavioral therapy and decreased mastery among caregivers in the control group. Caregiver mastery was reported by Sherwood et al. (2012) with regard to associations with the patient's symptom severity, caregiver relationship to the patient, and duration of the patient's illness. Mastery was found to be higher in the presence of fewer patient symptoms, earlier in the care situation, and when caregivers were the patient's spouse (Sherwood et al., 2012).

Accuracy of caregivers' perceptions regarding patient symptoms, preparedness to care for the patient (Chih et al., 2013), and self-efficacy in the caregiver role (Hendrix et al., 2011) were also examined. According to the Caregiver Outcomes Model, these are directly associated with performance of care activities, which were identified as managing patient symptoms (Chih et al., 2013; Hendrix et al., 2011) and communication with health providers (Chih et al., 2013). These care activities were not described or measured in the two articles preventing interpretation as effects on caregiver outcomes.

Caregiver characteristics (Table 1). Caregiver characteristics extracted were age, sex, race/ethnicity, relationship to patient, education, distance between caregiver and patient residences and experience as a caregiver. Caregiver employment status and health status, characteristics included in the Caregiver Outcomes Model, were not abstracted due to lack of

availability consistency in reporting. Characteristics were synthesized as descriptive data since they were not treated as moderating variables.

Age, sex and race/ethnicity. The mean age of caregivers was 55 years with the majority of caregivers being female. Race was reported for caregivers in five studies with 76– 92% identified as white/Caucasian.

Relationship to patient. Most caregivers were spouses (60 – 83%) with two studies specifying that caregivers must be the patient's spouse/romantic partner to participate (Couper et al., 2015; McLean et al., 2013). Other caregivers were identified as a sibling, child, grandparent, aunt/uncle, or unrelated individual. Hultgren et al. (2016) required caregivers to have been in a committed relationship with the patient for at least 12 months as an eligibility criterion, but did not report the actual caregiving experience of participating caregivers.

Employment. Caregiver employment data was not abstracted from the articles due to infrequent reporting and variation in categories used among the studies.

Education. The average education level of the caregivers who participated in 10 of the 14 studies was "completion of some college," indicating they were more highly educated than the general population. This was true not only within studies completed in the U.S. (United States Census Bureau, 2015), but also for the studies completed in Australia, Germany, and the Netherlands (National Center for Education Statistics, 2015).

Health status. Caregiver health status represented by the presence of comorbid conditions could not be abstracted from the criteria-based literature reviewed.

Distance between caregiver and patient residence. Caregiver living arrangements were reported in only three studies, where 78% (DuBenske et al., 2014) and 100% (Couper et al., 2015; Hendrix et al., 2011) of the caregivers lived with the patient. Distances between

residences for caregivers and patients who did not reside in the same household were not reported.

Caregiving experience. Only one article reported the amount of previous caregiving experience among the caregivers which was an average of 19 months prior to enrollment in the study (Hendrix et al., 2016). While it was not explicitly stated in the article, the caregiving experience reported appeared to have been with the patient with whom the caregiver participated in the study.

Patient characteristics. Patient characteristics among the studies were similar to the caregivers where reported with mean patient ages ranging between 51 and 67 years. Samples consisted of varying proportions of male and female participants. Two studies consisted of all male patients with prostate cancer (Badger et al., 2011; Couper et al., 2015), and one study examined only women with breast and gynecological cancers (Heinrichs et al., 2012). The remaining studies consisted of multiple types of cancer diagnoses, with disease stages ranging from I through IV where stated.

In summary, each of the 14 articles contributed to identifying the current state of the science concerning associations between supportive interventions for caregivers, care activities performed on behalf of cancer patients, caregiver health outcomes, and characteristics of caregivers and patients. Supportive interventions for caregivers consisted of psychoeduction, for development of coping, communication, problem-solving, and psychomotor skills, and counseling. Most interventions for caregivers used a combination of at least two of the intervention types. Reported care activities performed by caregivers most often consisted of managing cancer symptoms and comorbidities, communication with the patient, family and providers, and decision-making and problem solving. Accessing community resources was

minimally reported and navigating the health system was not mentioned at all. Psychological, physical, and social caregiver health outcomes were reported using an array of measures with varied results among intervention and control samples. The age, sex, and race/ethnicity of caregivers were similar among most samples, comprised of mostly female Caucasian caregivers with a mean age of 55 years. Most caregivers were the patient's spouse or partner, and had some college education. Caregiver health status, employment, and experience in caregiving could not be determined from most of the articles.

Discussion

It was helpful to use guides such as the overarching 4-component PRIMSA statement and the conceptual model, the Caregiver Outcomes Model, to identify and evaluate the 14 articles that met the criteria for this review. It is acknowledged that a full systematic review would need to include all aspects of the PRISMA rather than the selected ones used to illustrate this review.

Research designs that intentionally incorporate each component of the Caregiver Outcomes Model can more precisely measure the associations between caregiver interventions, care activities performed by caregivers of patients with cancer, characteristics, and caregiver health outcomes. Understanding the potential relationships between performing care activities and caregiver outcomes can support clinicians in preparing caregivers in two ways. First, assessing the characteristics of the patient and caregiver early in the patient's disease trajectory can help anticipate the type and amount of care activities caregivers will need to perform. Second, the potential effects on caregiver health can be addressed by using a prevention focus to help caregivers both preserve and restore their health during caregiving.

Employing the Caregiver Outcomes Model, however, revealed that the established category of accessing community resources was minimally mentioned among this set of studies (Badger et al., 2011; DuBenske et al., 2014). Similarly, while previous research has indicated

that caregivers frequently coordinate the cancer patient's interactions with health providers over the course of the disease trajectory (Fletcher et al., 2012; National Alliance for Caregiving, 2016), this activity was not reported. Such findings would indicate that these care activities are not as prevalent or important as other categories, a conclusion that is counter intuitive to professional observations.

Supportive interventions for caregivers fit the categories established by Northouse (2010), focusing either on helping the caregiver in patient care delivery, or their responses to caregiving. Future research may point to additional categories as standards-of-care evolve and nursing interventions continue to emerge for symptom management.

While it is evident that caregivers perform multiple complex care activities for cancer patients, assessment of the impact of performing care activities is difficult to ascertain. In addition, the brief descriptions of care activities and their performance by caregivers in the study samples contributed to a lack of precision in evaluating the types and amounts of activities performed in conjunction with the reported outcomes.

In consideration of caregiver characteristics, the distribution of caregiver race was generally not representative of the known population of caregivers (National Alliance for Caregiving, 2016) with a disproportionately high number of Caucasian participants, where reported. This finding is consistent with previous research (Northouse et al., 2010) and must be considered in future studies. The caregivers' attained education level was also higher than the populations from which the samples were drawn, with many participants possessing "some college." Compensating for these deviations from population demographics in future research will provide a more representative view of caregivers.

No studies reported the distance between the caregiver and patient residences, and only one provided the amount of caregiving experience prior to assuming the role they were fulfilling when they participated in the studies. This information can be critical in determining the burden of caregiving, and the subsequent caregiver outcomes. Both these characteristics would add valuable data to future caregiver studies.

In terms of outcomes, the distinct impact of performing cancer-care activities to the caregivers' psychological, physical, and social health is not clearly reflected in most caregiver intervention literature. This fact, minimal reporting of outcome variables presented a challenge to abstracting meaningful data across studies. In future work, considering the type and amount of care activities during the testing of interventions in conjunction with caregiver health outcomes may help determine: 1) the impact of specific activities; and 2) allow for more robust analysis of intervention effects on outcomes and caregivers' ability to perform care activities.

Measurement variability was also found in reported caregiver outcomes with regard to intervention effects. This variety of instruments presents a challenge in consistently defining and measuring outcomes. This may be indicative of the challenges of measuring this area of health, or of the missing assessment of quantifiable care activities performed by the caregivers. For example, some authors reported perception of the patient's symptom distress (Chih et al., 2013) and communication with health providers (DuBenske et al., 2014) as caregiver outcome measures; these however, may have been more suitably considered as measures of care activity performance. On the positive side, the measures identified in the 14 studies had acceptable internal consistency, where reported, but not all articles indicated whether the instruments used had been psychometrically established for use with caregivers of patients with cancer. Clearly more work is needed in the area of measurement of cancer caregiver outcomes.

In summary, this review has provided a timely update on of the caregiving literature, brought focus to specific activities that caregivers perform for cancer patients in conjunction with interventions to support caregivers, and identified caregiver characteristics that may be associated with specific care activities and/or caregiver outcomes. Knowing what caregivers can expect to do and experience as they perform care activities for a cancer patient not only contributes to positive caregiver health outcomes, but also ultimately supports their ability to care for a friend or family member.

CHAPTER 3

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

Abstract

Title

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

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 and 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,

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.

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., 2015; Wyatt, Sikorskii, Rahbar,

Victorson, & Adams, 2010). 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 (Family Caregiver Alliance, 2006a, 2006b; Kissane & Bloch,

2002; Reinhard et al., 2012; Stenberg et al., 2010). The reality of this trend is demonstrated by

the number of lay caregivers needed for the estimated 1.6 million patients expected to be

diagnosed with cancer in the United States (U.S.) during 2016 (American Cancer Society,

2016a). 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 approach 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) provider intervention training receipt; and 5) skill enactment.

According to the NIH-BCC, the central design element in intervention studies is <u>dose</u>, including the number of sessions, length of each session, and the interval between sessions (Bellg et al., 2004). <u>Provider training</u>, especially when using lay providers, requires initial training for skill attainment as a protocol standard (Radziewicz et al., 2009). <u>Intervention delivery</u> pertains to monitoring the consistent administration of the defined protocol (Bellg et al., 2004; Resnick et al., 2005). <u>Provider intervention training receipt</u> is the determination of whether and to what extent the desired intervention has been delivered (Wyatt et al., 2010). <u>Enactment</u> 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, Olatunde, & Zick, 2007). One CIH therapy that has promising efficacy in reducing symptoms for women with breast cancer is reflexology (McCullough, Liddle, Sinclair, Close, & Hughes, 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 & 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 (N. Stephenson, Dalton, J., 2003; N. L. 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, Bush, Sikorskii, Mukherjee, & Wyatt, 2011). The protocol has been tested and established in completed large-scale studies (Kozachik et al., 2006).

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, 2015a). 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. (2007) utilized 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 utilized 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 U.S.; 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 4) uses a novel approach to quantifying and monitoring the five fidelity elements within the protocol. Rigor was achieved through definition of each element within 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., 2012; Wyatt, Sikorskii, Siddiqi, & Given, 2007). 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 within the design. The allowance of 5 to 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 utilized 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 percent 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 percent 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 percent was recorded; a value of 1 was assigned if a score of 90 percent 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 percent was recorded; a value of 1 was assigned for intervention delivery if a score of 90 percent or higher was recorded indicating correct caregiver demonstration of the reflexology protocol.

Provider intervention training receipt. Provider intervention training 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 5. Analyses of fidelity data using the fidelity scorecard are summarized in Table 6. A

report of the attainment for each of the five fidelity elements follows.

Fidelity elements. Each of the three components of dose were 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 percent of caregivers achieved a score of at least 90% for provider training,

reflecting a high level of attainment within 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 provider

intervention training 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 11.98 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 within 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 (Kohara et al., 2004; Quattrin, 2006; N. L. Stephenson et al., 2007; 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; N. L. 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; N. L. Stephenson et al., 2007; Wyatt et al., 2012). Intervention delivery was described in only one of the studies (Wyatt et al., 2012). Provider intervention training receipt was mentioned in two of the four studies (N. L. 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 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.

Conclusions

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 utilizing 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 within 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.

CHAPTER 4

Caregiver Reported Health Outcomes: The Effects of Providing Reflexology for Symptom Management to Women with Advanced Breast Cancer

Abstract

Purpose/Objectives

To determine the effects of delivering reflexology on health outcomes of informal caregivers, and to explore whether these effects are moderated by caregiver and/or patient characteristics such as age, sex, employment and baseline comorbidity.

Design

Two-group, randomized clinical trial.

Setting

Eight oncology clinics in the Midwestern United States.

Sample

Convenience sample of 180 informal caregivers of patients with advanced breast cancer.

Methods

Following baseline telephone interview, caregivers were randomized to either provide reflexology to the care recipient over a four-week period or attention control. Data were collected at baseline, and at weeks 5 and 11. Repeated measures of caregiver health outcomes at weeks 5 and 11 were analyzed using linear mixed effects models in relation to study group for all participants and to the number of delivered reflexology sessions in the intervention group.

Main Research Variables

Psychological, physical, and social health outcomes, and personal characteristics.

Findings

Reduction in caregiver fatigue in the reflexology group compared to control occurred at both weeks 5 (p = 0.02) and 11 (p = 0.05). No significant differences were found between groups for other caregiver outcomes. Delivery of more reflexology sessions was associated with lower caregiver fatigue, but not significantly (p = 0.09). Friend caregivers reported lower depression over time in the reflexology group compared to control (p=.06).

Conclusions

Fatigue was lessened among caregivers of patients with breast cancer who provided reflexology for symptom management. Patient-caregiver relationship may have an impact on psychological health outcomes.

Implications for Nursing

As the health care system increasingly relies on caregivers to deliver symptom management interventions in the home environment, the effects of providing care on caregiver psychological and physical health need to be evaluated.

Knowledge Translation

1) Inclusion of informal caregivers in patient symptom management; 2) The impact of providing symptom management interventions on caregiver health; and 3) The importance of caregiver relationship to the patient in relation to caregiver psychological health outcomes.

Key Words

Informal caregivers, cancer, symptom management intervention, caregiver health outcomes, reflexology.

Introduction

The number of caregivers supporting cancer patients is growing with estimates of at least 2.8 million in 2015 (National Alliance for Caregiving, 2016). Friend or family caregivers are individuals identified by the patient (Stenberg et al., 2010) who provide unpaid assistance with chronic or disabling conditions such as cancer (American Cancer Society, 2011; Family Caregiver Alliance, 2006b; National Alliance for Caregiving, 2016). Engaging informal caregivers to provide symptom management supports patients with serious conditions (Reinhard, Given, Petlick, & Bemis, 2008). However, the time and type of activities devoted to caregiving impact caregivers' psychological, physical, and social health outcomes (Bevans & Sternberg, 2012; Girgis et al., 2013; B. Given et al., 2012; Northouse et al., 2013; Weiss et al., 2016). Integrative therapies (also known as complementary and alternative medicine, or CAM) provide options for cancer symptom management when used in conjunction with standard medical care (National Cancer Institute, 2015b). Reflexology, the application of pressure on specific reflexes located in the hands and feet, is an integrative therapy which has been tested with breast cancer patients for symptom management (Wyatt et al., 2012). The purpose of this paper is to report the findings of examination of the psychological, physical, and social health outcomes in informal caregivers who provided reflexology to patients with breast cancer to support symptom management (Wyatt et al., 2011-2016).

Literature Review

Studies indicate that health may be impacted by caregiving (Bradley et al., 2009; Gaston-Johansson, Lachica, Fall-Dickson, & Kennedy, 2004; Grov, Dahl, Moum, & Fossa, 2005; Lambert et al., 2013; Northouse et al., 2013; Pitceathly & Maguire, 2003). A systematic review by Stenberg et al. (2010) identified pain, insomnia, and fatigue as the most prevalent physical

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problems, and depression and anxiety as the most prevalent emotional problems among caregivers of cancer patients. Compared to age- and sex-matched controls, caregivers of patients at end of life had higher levels of anxiety, (Grov et al., 2005) depression, and sleep dysfunction (Cora, Partiico, Manafo, & Palomba, 2012). Social health is also influenced as more time is devoted to caregiving activities and diminished in other aspects of daily life (B. Given et al., 2012; Stenberg et al., 2010; Van Houtven et al., 2011). Caregiver characteristics such as age, sex, race/ethnicity, spiritual preference, marital status, relationship to patient, employment, and health status are important considerations when evaluating caregivers with differing health outcomes (Van Houtven et al., 2011). The personal relationship of the informal caregiver to the patient adds a dimension to the role that makes it uniquely different from professional patient-caregiver relationships. Such personal relationships may contribute to similar distress levels for both the patient and caregiver (Badger et al., 2011; Hodges et al., 2005; Northouse et al., 2013). For example, physical and psychological responses to a cancer diagnosis dually impacts the patient and the caregiving spouse (Litzelman, Green, & Yabroff, 2016).

In contrast to research that provides knowledge of the combined effects of caring for a patient with cancer, less is known about how supportive interventions delivered by patients' caregivers impact caregiver health outcomes (Hopkinson et al., 2012). This report informs the science for supporting caregivers while they support the patients as an integral part of the cancer care team.

Conceptual Model

Adapted from VanHoutven et al. (2011), the Caregiver Outcomes Model guided analysis of health outcomes for caregivers providing reflexology for symptom management to breast cancer patients. Caregiver delivery of this type of symptom management intervention is

particularly significant because it provides a sustainable family-care option that does not rely on external interventionists and is not limited to the study protocol period.

The adapted model, operationalized in Figure 6, integrates the care activities performed on behalf of cancer patients, characteristics of caregivers who care for patients with cancer, and caregiver outcomes associated with psychological, physical, and social health (Frambes, Given, et al., 2016).

Purpose/Objectives

The study purpose was to determine the effects of delivering reflexology on caregiver psychological, physical, and social health outcomes, and to determine if the effects of intervention delivery on caregiver outcomes were moderated by caregiver and/or patient baseline characteristics including age, sex, employment and comorbidity (Figure 6). The aims and associated research questions for this analysis were:

Aim 1. To determine the effects of delivering reflexology on caregiver psychological, physical, and social health outcomes at weeks 5 and 11.

Research Questions:

1. What is the difference in caregiver health outcomes for those caregivers randomized to deliver the reflexology intervention versus control caregivers at study weeks 5 and 11?

2. Among caregivers randomized to deliver the reflexology sessions, what is the relationship between the number of sessions delivered and caregiver health outcomes at study weeks 5 and 11?

Aim 2. To determine if the effects of intervention delivery (care activity) on caregiver health outcomes at weeks 5 and 11 are moderated by caregiver and/or patient baseline characteristics: 1) patient and caregiver age; 2) caregiver sex; 3) caregiver relationship to

patient; 4) caregiver employment; 5) caregiver education; and 6) caregiver health status (comorbid conditions)?

Methods

     Design. The sample of caregivers for this study were participants in a two-group RCT, *"Home Based Symptom Management via Reflexology for Advanced Breast Cancer Patients"* (R01 CA157459). Informal friend/family caregivers were chosen by women with advanced breast cancer and trained by study staff to deliver a 4-week reflexology protocol to the patient. Caregivers provided data regarding their psychological, physical, and social health, and delivery of reflexology to the patient (Wyatt et al., 2011-2016).

     Institutional review board approval for ethical treatment and protection of human subjects was received from the investigators' university and all recruitment sites. Signed informed consent was obtained from all participants. Data were stored on a secure study server at the investigators' university; access to data was restricted by password protection.

     The main trial findings on the primary outcome of patient symptom severity are reported elsewhere (Wyatt et al., 2016). Briefly, a significant reduction in patient symptoms was observed over time in the reflexology group compared to controls.

     Setting and participants. Caregivers and patients were recruited as dyads from eight cancer centers in the Midwestern United States. Inclusion criteria for patients were: 1) age 21 years 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 conversation; 8) cognitively oriented to time, place, and person (determined by recruiter); and 9) had 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 years or older; 3) able and willing to provide the 30-minute protocol for 4 consecutive weeks; 4) able to speak and understand English; 5) access to a telephone; 6) able to hear conversation; and 7) cognitively oriented to time, place, and person (determined by recruiter). The caregiver exclusion criteria were unwillingness or being unable to perform a return demonstration of the protocol with 90% accuracy according to training procedures (Wyatt et al., 2011-2016). Training of caregivers was completed in a location convenient for the caregiver with all sessions of reflexology provided in the patient's home.

Intervention. The research protocol specified that caregivers deliver a minimum of one session of reflexology per week to the patient for four consecutive weeks, with additional sessions if desired by the patient and caregiver. A caregiver control group contributed comparison data. Following the 4-week protocol period, caregivers could continue delivering reflexology sessions.

Data collection. Trained staff collected all caregiver data via telephone three times at baseline, and study weeks 5 and 11. Each contact took approximately 30-45 minutes to complete and consisted of questions pertaining to the caregivers' psychological, physical, and social health. Additionally, demographic data were obtained during the first contact. Data were also collected from patients on the same schedule. If a caregiver or patient could not complete an entire call at one time, the interviewer stopped and scheduled the remainder for the next day. Caregivers who provided reflexology to patients were also called weekly during the 4-week

intervention period to obtain fidelity data regarding the number of sessions provided to the

patient. Each call took approximately 10 minutes to complete (Wyatt et al., 2011-2016).

Measures. Measures and timing of their administration are summarized in Figure 7.

Specific care activity: number of sessions delivered. Information about the number of

reflexology sessions provided weekly during the intervention period was obtained from

caregivers' self report during weekly phone calls initiated by study personnel. The number of

reflexology sessions provided by the caregiver during the six weeks after the intervention period

when reflexology sessions were not required was obtained from patients in the reflexology group

during exit interview at study week 11. A single question: "Have you had any additional

reflexology sessions by your friend or family home provider (who took part in this study) since

your second interview 6 weeks ago?" provided this measure (Wyatt et al., 2011-2016).

Characteristics. Demographic data derived from caregivers included: age; sex;

race/ethnicity; marital status (reported as single, married/partnered, widowed, or divorced);

relationship to patient with breast cancer; and employment status (Wyatt et al., 2011-2016).

Caregiver comorbidity was measured using the Bayliss Instrument which identifies the presence

of 21 common chronic conditions and associated ratings of resultant limitations on daily

activities (Bayliss, Ellis, & Steiner, 2009).

Caregiver health outcomes. The Patient Reported Outcomes Measurement Information

System (PROMIS) Profile-29 (2010) was used to obtain psychological, physical, and social

health data. The items that make up the PROMIS instruments were developed and tested for use

with the general United States population with funding support from the National Institutes of

Health (2010). The PROMIS-29 is a collection of short forms, each containing four items from

seven primary PROMIS domains (depression, anxiety, physical function, fatigue, sleep

disturbance, satisfaction with participation in social roles, and pain interference) rated on a Likert-type scale, and a single-item rating pain severity scale scored 0-10 (PROMIS, 2010).

Psychological health. Short forms for anxiety (4 items) and depression (4 items) were used to measure psychological health (PROMIS, 2010). Anxiety items have the respondent rate frequency of feeling fearful, difficulties focusing, worry, and uneasiness during the past seven days. Similarly, the depression items include perceptions of worthlessness, helplessness, depression, and hopelessness over the past seven day period. Both forms use a 0-4 scale for each item with higher values representing higher frequency. Cronbach's alphas were 0.90 for anxiety and 0.91 for depression.

Physical health. Short forms for fatigue (4 items), pain severity (1 item, 0-10 scale), physical function (4 items), and sleep disruption (4 items) were used to assess physical health (PROMIS, 2010). Fatigue items reflect extent of fatigue during the past seven days. Cronbach's alpha for the fatigue form was 0.90. The pain severity item represents pain experienced during the past seven days ranging from no pain (0) to the worst imaginable pain (10). Physical function items consist of four items rated on a scale from 0-4 with larger values representing higher levels of difficulty experienced during the past seven days. Physical function items reflect the respondent's ability to complete chores, use stairs, walk, and run errands or shop over the past seven days. Cronbach's alpha for the physical function short form was 0.91. The sleep disruption items have the respondent rate quality, nature, problems with sleep, and difficulties falling asleep with larger values indicating better sleep quality. Cronbach's alpha for sleep disruption was 0.84.

Social health. Social health (4 items) has the respondent rate satisfaction with participation in social roles including the amount and ability to work, ability to complete

personal and household duties, and satisfaction with ability to perform daily routine over the past seven days. Higher values on the 0-4 scale reflect higher levels of satisfaction. Cronbach's alpha for satisfaction with participation in social roles was 0.92.

The pain interference short form consists of items indicative of the amount of interference from pain relative to performance of daily activities, work around the home, ability to participate in social activities, and enjoyment of life (PROMIS, 2010). Higher values on the 0-4 scale indicate higher levels of interference from pain over the past seven-day period. Cronbach's alpha for pain interference was 0.93.

Data analysis. Since all caregiver outcomes were specified a priori, primary analyses of research questions 1 and 2 used 0.05 level of significance for two-sided tests. The findings for the exploratory analysis of research question 3 were given lower strength of interpretations ($p \leq$ 0.10) and were considered hypothesis-generating for future research. SAS 9.4 was used for data analyses.

Baseline comparison of study groups and attrition. Baseline comparisons for caregivers in the reflexology and control groups were performed using t-tests and chi-square tests for caregiver characteristics, potential moderators and outcome variables.

Attrition analyses. Data from participants were analyzed as randomized, using intention-to-treat principle. Attrition rates and reasons were compared to determine that the lack of differences between groups at baseline was not affected by attrition.

Primary analyses.

Aim 1 analyses. The analyses for Aim 1 examined the effects of providing reflexology on the caregiver's psychological, physical, and social health outcomes at weeks 5 and 11 as measured by the PROMIS instruments (Figure 7). Each health outcome was analyzed separately

using the linear mixed effects (LME) model that generalizes classical analysis of repeated measures and allows for data missing at random, time-varying covariates, and structured covariance matrix. Group assignment (reflexology or control), caregiver health outcomes at baseline, time (5 or 11 weeks) and time by group interaction were entered as explanatory variables. The least square (LS) means at each time point were output from the model, and a test of their difference by study group yielded a formal test of significance for the hypotheses associated with research question 1. For research question 2, only data from reflexology group caregivers were analyzed to determine the relationship between the number of sessions provided and caregiver health outcomes at weeks 5 and 11. The group assignment variable was not applicable in this analysis; instead, the number of reflexology sessions delivered over the 4-week intervention period and during weeks 5-11 was the variable of interest in the LME models. The test for its significance yielded a formal test of significance of the relationship between the number of sessions provided and caregiver health outcomes at weeks 5 and 11.

Aim 2 analyses. Moderating effects of caregiver and patient characteristics (age, sex, race, relationship to the patient, employment, and comorbidities) on the effects of providing the reflexology intervention and caregiver health outcomes at weeks 5 and 11 were explored by including group by potential moderator interaction term (one at a time) in the LME model that also included baseline value of the caregiver health outcome, time (week 5 or 11), potential moderator and study group.

Results

A total of 256 caregivers consented to participate in the study with an eligible breast cancer patient; a number of eligible patients did not participate due to lack of an available/willing caregiver, a finding reported elsewhere by Holmstrom et al. (2016). All 256 caregivers were

randomized to either reflexology or control groups in the parent trial; of the 256, 180 (70%) agreed to provide data about their own health outcomes and were included in this secondary analysis (Figure 8). No differences existed between the reflexology and control group caregivers at baseline with regard to demographic characteristics (Table 7) or caregiver outcome variables (Table 8). There were no differences in attrition by study group (data not shown).

Baseline characteristics of caregivers (Table 7). There were more male than female caregivers in this sample (56%); this is attributed directly to the exclusive patient diagnosis of female breast cancer and the majority of caregivers being spouses or partners. The average age of caregivers was 54 years; most were employed at least part-time, and had some college education. The sample was comprised primarily of white, non-Hispanic or Latino caregivers, consistent with the demographic make-up of the geographic locations served by the participating Midwestern oncology clinics.

Caregiver outcomes at Weeks 5 and 11, between study groups (Aim 1, Research Question 1) (Table 9). The LS means of caregiver health outcomes and their standard errors (SE) for the reflexology and control groups at weeks 5 and 11 are presented in Table 9. In this Table, lower LS mean values at each time point represent the presence of less of the construct (outcome). For example, improvement in fatigue was reported as a significantly lower LS mean for reflexology caregivers than the control group at both weeks 5 ($p = 0.02$) and 11 ($p = 0.05$). No differences were noted between groups at weeks 5 or 11 on anxiety, depression, pain severity, physical function, sleep disturbance, satisfaction with participation in social roles, or pain interference.

Association of increasing number of sessions delivered on caregiver outcomes (Aim 1, Research Question 2) (Table 10). The association between the increasing number of

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reflexology sessions delivered and caregiver outcomes is reported as a model coefficient, representing change over time. The negative notation in the model coefficients indicate that caregivers reported less of the outcome as more sessions of reflexology were provided for all but pain severity. For example, the negative sign in front of fatigue indicated that fatigue was reported at lower levels as caregivers provided more sessions; even though this association did not reach statistical significance (p = .09). While other outcomes also had a negative model coefficient, none of them approached significance including anxiety, depression, physical function, sleep disturbance, satisfaction with participation in social roles, or pain interference.

Moderation of the effect of reflexology delivery on caregiver health outcomes by caregiver and/or patient characteristics (Aim 2). The sex of the caregiver may moderate the effect of reflexology delivery on physical functioning. In the reflexology group, female caregivers had better physical functioning than males: time-averaged LS means of 53.97 (SE 0.71) versus 52.28 (SE 0.63) respectively (p=.07). Such difference did not exist among the control caregivers.

Another potential moderator is patient-caregiver relationship that modified the effects of reflexology delivery on caregiver depressive symptoms. A difference existed between the reflexology and control group caregivers with regard to relationship to the patient and mean depression scores. Caregivers who were friends of the breast cancer patient reported lower levels of depressive symptoms in the reflexology group as compared to the control group: time-averaged LS means of 42.97 (SE 2.05) versus 46.84 (SE 1.51), respectively (p = 0.06).

Caregiver comorbidity is another potential moderator with the p-value of 0.08 $(F(1,135)=3.03)$ for the interaction between each study group and the number of comorbid conditions. In the control group, the number of comorbid conditions was negatively associated

with the satisfaction of participation in social roles (slope of -0.72, SE=0.30); in other words, a higher number of comorbid conditions was associated with lower satisfaction in social roles. On the other hand, in the reflexology group the slope did not indicate this negative effect between a higher number of comorbidities and satisfaction with participation in social roles (0.05 (SE 0.48).

Discussion

The sample of caregivers in this study had a similar demographic profile to that of caregivers of cancer patients recently reported by the National Alliance for Caregiving (2016) with regard to caregiver sex, age, and relationship to the patient. Several differences were noted. More than 80% of the caregivers in the current study identified as white, non-Hispanic or Latino as compared with the reported 66% of caregivers in the U.S (National Alliance for Caregiving, 2016). This sample was also more highly educated than most caregivers in the U.S. with approximately 50% possessing a college degree in comparison with 40% nationally (National Alliance for Caregiving, 2016). Demographic characteristics similar to those of this study sample were also noted in a recent review of caregiver intervention literature (Frambes, 2016).

In a recently published study by Weiss et al. (2016), caregivers of cancer patients described experiences of mental fatigue manifested as difficulty concentrating, remembering, and irritability. This group of caregivers indicated that fatigue did not interfere with providing care for the patient, but did impact their self-care.

The findings of the current study indicate that caregivers who provided reflexology to a friend/family member with breast cancer experienced lower levels of fatigue at weeks 5 and 11 than caregivers in the control group. Additionally, caregivers who delivered more sessions of reflexology tended to report lower levels of fatigue. In contrast, fatigue levels of caregivers of cancer patients have been reported to increase over time (Alumutairi, Lodhayani, Alonazi, &

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Vinluan, 2016; Y. Kim, Spillers, & Hall, 2010), but types and extent of care activities performed by caregivers were not reported. The current study enriches the available evidence on caregiver fatigue in relation to a specific type of assistance provide to the patient such as the delivery of reflexology for symptom management, and the impact of the number of sessions provided.

The difference in physical function noted between female caregivers who provided reflexology and those in the control group indicates that the additional task of delivery of an intervention does not adversely affect, and even may be positive.

The lack of negative effects of comorbidity on satisfaction with participation in social roles in the reflexology group in contrast to the control group suggests a similar conclusion of positive effects of caregiver's a meaningful involvement in the patient care. While moderator analyses were exploratory and this finding could be due to chance alone, examination of the associations among caregiver characteristics such as sex, comorbidity and physical functioning in future studies could provide further insights.

The findings of lower levels of depressive symptoms reported among friends who provided reflexology than controls underscores the importance of patient-caregiver relationship as a factor in explaining caregiver health. Northouse et al. (2012) investigated the psychological responses of family caregivers to the patient's cancer diagnosis, finding that a reciprocal relationship existed between the patient and caregiver's distress. Even though this study did not demonstrate any associations with various family members and the patient, the majority of the available literature does focus on familial relationships. Kim et al (2007) found that adult daughters caring for a parent with cancer experienced the highest levels of caregiving stress associated with their roles among caregivers with various family-type relationships to the patient. The findings of the current study add further information regarding the influence of relationship

on caregiver outcomes in the context of a specific caregiver-delivered intervention. The number and frequency of contacts between caregivers and patients beyond the reflexology sessions were not measured in the current study except with regard to the number of reflexology sessions provided. Investigating this additional aspect of the relationship could provide further information on the nature of the relationship between delivering reflexology versus the number of contacts with the patient.

Limitations. The results of this study are generalizable only to caregivers of women with breast cancer who satisfy the inclusion criteria. While efforts to obtain a diverse sample of caregivers were made, the diversity of the sample was limited to the populations served by the participating sites, and the resulting sample of caregivers demonstrated under representation of minority and less than college educated participants. The communication between caregivers and patient dyads beyond the delivery of reflexology in the intervention group was not measured, nor were the number of non-reflexology session contacts between caregivers and patients in the reflexology group. While randomization equalizes the influences of other factors, this information could be useful in assessing caregiver outcomes.

Implications for Nursing

Caregivers provide vital support to patients with breast cancer undergoing treatment. While the relationship between the nurse and caregiver is not as well defined as the relationship with the patient, a holistic nursing approach incorporates the patient's support systems in the plan of care. Considering the caregivers' health outcomes in relation to providing symptom management for the patient is an important nursing function. Supporting caregiver health promotes sustainability of their caregiving abilities.

This study expands the knowledge regarding the vulnerability of caregivers of cancer patients and the influence of intervention delivery on the caregiver outcome of fatigue. The between group results found that fatigue was lower for the reflexology caregivers. Further, within group findings indicated a trend toward lower fatigue among caregivers who delivered more reflexology sessions. Due to this trend in the data, there is a potential for clinical significance as clinicians encourage delivery of symptom management interventions. Delivery of interventions for the patient may hold promise for reducing caregiver fatigue. These findings associated with caregiver fatigue improvements raise questions for future research and practice.

Since friends who delivered reflexology were less susceptible to depressive symptoms than those friends who did not, clinicians can encourage patients looking for an intervention partner to consider friends. This has the potential for reducing the burden on family while widening the support system. Further, from a practice standpoint, it appears clinicians do not need to be concerned about the number of comorbid conditions caregivers have in relation to providing symptom management interventions. The number of caregiver comorbids did not negatively impact the satisfaction with participation in social roles; in fact, it was enhanced over the control group.

Conclusions

Further research examining associations between performing specific care activities is warranted to determine if the findings of the study are applicable to other care. The current study found that fatigue experienced by caregivers of patients with breast cancer may be reduced with the delivery of reflexology for patient symptom management. The findings suggest that caregivers who provide reflexology for a patient with breast cancer may experience health benefits relative to fatigue and depression through their meaningful involvement in patient's

symptom management. Examination of this relationship among caregiver populations who care for patients with other types of cancers could provide further insight into the generalizability of these findings.

The potential for association between fatigue and depression should be examined in conjunction with the caregiver's relationship to the patient based on the common coexistence of fatigue and depression. Expanding the types of cancer diagnoses examined relative to the relationship of the caregiver to the patient would provide further information among caregivers of patients with cancer and further evaluate the generalizability of the study findings.

CHAPTER 5

Conclusion

This dissertation research provides evidence regarding the topic of health outcomes of caregivers of patients with cancer. The importance of expanding knowledge in this area is clear with regard to the continued prevalence of cancer and increasing reliance on informal caregivers to perform complex care activities previously reserved for health professionals.

Aim 1: State of the Science for Care Activities Performed by Informal Caregivers of Patients with Cancer

The importance of supporting informal caregivers of patients with cancer is evident based on the continued prevalence of cancer in the United States (National Cancer Institute, 2016b) and globally (World Health Organization, 2015), and the numbers of caregivers who support these patients (National Alliance for Caregiving, 2016). Literature published during the past six years demonstrates evaluation of supportive interventions to help caregivers succeed and cope in this role with varying results (Frambes, Given, et al., 2016). What is not clear from this body of literature, however, is examination of which care activities caregivers performed on behalf of patients with cancer (Table 2), and any associated impact on the caregivers' health outcomes. Application of a conceptual framework adapted from VanHoutven et al. (2011) in a review of this recent literature revealed this gap and opportunity for further research (Frambes, 2016). Further research is needed that investigates all of the relationships represented in the Caregiver Outcomes Model to develop knowledge and translation to practice that will benefit caregivers and the patients they support.

Aim 2: Application of Elements of Fidelity to a Caregiver-Delivered Intervention

Examining reflexology delivered by informal caregivers to patients with breast cancer provided insights regarding the complexity and importance of incorporating and measuring intervention fidelity in this context. Caregivers are required with increasing frequency to participate in complex care activities to support patients with cancer, but there is little evidence of the fidelity elements established by the NIH-BCC (Bellg et al., 2004) in intervention protocols for caregiver-delivered reflexology (Frambes, Lehto, et al., 2016). Including intervention fidelity is important for accurate and consistent intervention delivery to patients, thus supporting efficacy and safety. Integrating intervention fidelity also promotes validity of findings through uniform intervention provision.

Studying how each element of fidelity was integrated in the protocol for training informal caregivers to deliver reflexology to patients with breast cancer resulted in two conclusions: 1) a scorecard can be used to assess the attainment of the elements of intervention fidelity within caregiver delivered interventions; and 2) consistent caregiver delivery of reflexology can be fostered and measured through inclusion of the elements of intervention fidelity. These findings support use of data obtained from these caregivers regarding their experience in consistently delivering the intervention to examine associations with caregiver health outcomes (Frambes, Sikorskii, Wyatt, Lehto, & Given, 2016).

Aim 3: Analysis of Caregiver Health Outcomes

Psychological health outcomes. Depression has been identified as one of the psychological health concerns associated with caring for a friend or family member with cancer (Jayani & Hurria, 2012; National Alliance for Caregiving, 2016; Stenberg et al., 2010) and further research is needed to explore contributing factors. Recent intervention studies have

included efforts address the experience of depression among caregivers of cancer patients with varied results (Frambes, Given, et al., 2016). Findings from this research suggest a positive correlation among the sample caregivers between depressive symptoms and providing reflexology to a parent (mother, step mother) with breast cancer. Caregivers who provided reflexology to a parent reported higher levels of depressive symptoms than caregivers of parents in the control group. This finding suggests that the parent-child relationship had a negative moderating effect on the caregivers' psychological health relative to depressive symptoms. One factor that could have contributed to this is the unknown frequency and nature of interactions that occurred between the caregiver and patient outside of the reflexology sessions. There could be a correlation between non-reflexology interactions that contributed to the caregivers' depressive symptoms, such as fewer overall interactions resulting in lower levels of caregiver depressive symptoms, which should be examined in future research.

A negative correlation between providing reflexology and reported depression was found where the caregiver was a friend of the patient. Caregivers who delivered reflexology to a friend with breast cancer tended to report lower levels of depression than their peers who did not provide the intervention. A hypothesis generated from this finding is friends experienced satisfaction from providing a symptom management intervention for the patient that resulted in a fewer depressive symptoms than friends who did not. Additionally, as with the adult child caregivers, further information regarding the number and frequency of interactions could provide more information regarding the nature of this finding.

Physical health outcomes. Fatigue was considered as a component of physical health in this analysis based on the Caregiver Outcomes Model. Findings indicated that fatigue experienced by caregivers may decrease over time, and may also be influenced positively by the

caregiver's involvement in providing reflexology to the patient. Additionally, findings indicated that the number of sessions of reflexology provided to the patient might have been a factor in caregivers' fatigue, with delivering more sessions associated with reports of lower fatigue levels (Frambes, Sikorskii, et al., 2016). While fatigue has been identified as an outcome associated with caregiving (B Given & Sherwood, 2006), it has not been consistently evaluated as an outcome among recent caregiver intervention literature. Among 14 articles published within the past six years evaluating the effectiveness of supportive interventions for caregivers of cancer patients, only one study reported an outcome measure of fatigue among caregivers of patients with prostate cancer (Badger et al., 2011). Findings from that study indicated that caregivers who received a supportive intervention experienced increased fatigue over time than caregivers who did not receive the intervention. The context of Badger et al.'s (2011) findings are considerably different from the current study in that no defined or measured care activities were reported as performed by caregivers. One hypothesis is that in the absence of knowing what care activities were performed by caregivers, the knowledge and communication facilitated by the intervention could have stimulated caregivers to perform care activities that contributed to fatigue.

Social health outcomes. Using the Caregiver Outcomes Model to guide this research revealed the complexity and challenges of defining and measuring social health outcomes. The recent literature examined for evidence of caregiver health outcomes among studies testing supportive interventions for caregivers of cancer patients used an array of measures of social health (Frambes, Given, et al., 2016). The resulting heterogeneous representation of social health outcomes illustrated the opportunity for further definition and selection of measures for use with caregivers of patients with cancer.

This research did not reveal detectable relationships between providing reflexology for symptom management to patients with breast cancer and caregivers social health outcomes. Because of the diversity of the concepts and associated measures of social health outcomes encountered, comparison of findings with existing literature was inconclusive. In general, however, previous studies where caregivers performed care activities involving communication with and about the patient, or decision-making/problem-solving, reported improved social health outcomes in the presence of a supportive intervention (Frambes, Given, et al., 2016). Further examination of the association between care activities and social health outcomes that uses defined outcome measures in conjunction with the categories of care activities contained in the Caregiver Outcomes Model is warranted to develop further knowledge.

Research Implications and Next Steps: Aim 4

The approach employed in completing the research presented in the preceding chapters contributes to the science concerning the inclusion of informal caregivers in the delivery of symptom management interventions for cancer patients in three ways by: 1) identifying gaps in intervention literature pertaining to examining care activities performed as they related to the health outcomes experienced by caregivers; 2) creating and applying a measure of the elements of intervention fidelity to determine attainment within a caregiver-delivered symptom management intervention; and 3) analyzing caregiver data within a RCT for evidence of relationships between providing a protocol-driven care activity (reflexology) for breast cancer patients and caregiver psychological, physical, and social health outcomes. It further expands knowledge regarding the improved outcomes of depression and fatigue among the population of caregivers who delivered reflexology as a symptom management intervention.

Nursing research. This research provides a perspective and process for expanding knowledge regarding the health outcomes of caregivers who are the friends and family of patients with cancer. A conceptual model was adapted which includes the components and associated relationships necessary to examine the caregivers' health outcomes. The Caregiver Outcomes Model can be used to inform nursing research that proposes to influence or test any of the model's components and relationships. Using this approach promotes inclusion of the essential components for research design and measurement to advance the science pertaining to the health outcomes of caregivers.

Influence on policy. The importance of informal caregivers in the treatment and recovery of patients with cancer is recognized in the U.S. and globally. Policy that supports the provision of care activities by these caregivers, however, is not prevalent or well known among the general and health provider populations. A noted exception is the inclusion of informal caregivers in planning for a patient's cancer treatment and recovery, which has been identified and acted upon through advocacy initiatives by the American Association of Retired Persons (AARP) (American Association of Retired Persons, 2016). While the majority of states in the U.S. have responded by passing or introducing legislation that assures the identification and inclusion of caregivers when a patient is hospitalized, these actions do not promote support for the care activities caregivers will be called upon to complete. The current research serves to inform policy makers on the responsibilities caregivers of patients with cancer take on and the potential impacts on their health as a result of caregiving. As a result, this research holds potential to increase awareness of the identity of these caregivers as a group who share an established need for consideration of the effects of caregiving on their health outcomes.

Policy that guides research utilizing informal caregivers to provide interventions for cancer patients needs to include the elements of intervention fidelity in research design requirements. This will promote the most consistent and high quality intervention delivery.

Because informal caregivers of patients with cancer may experience differing health outcomes associated with their relationship to the patient and involvement in providing symptom management interventions, policy concerning patient care planning needs to include assessment of the caregiver as well. Using information about caregivers' identified characteristics that may increase their vulnerability to negative health outcomes will promote preservation of their ability to perform as a designated part of the health care team.

Practice implications. This research has demonstrated that intervention fidelity is an important component of caregiver delivered symptom management interventions. The scorecard developed and implemented in this research can be adapted for use in a variety of practice settings to promote consistency and evaluation of the effectiveness of caregiver delivered interventions. Additionally, it serves as a mechanism for the achievement of quality and safety in care activities performed by caregivers.

Fatigue, depression, and the caregiver's relationship to a patient with cancer are factors that may influence their health outcomes, and ultimately, ability to provide care for the patient over time. Based on this knowledge, health team members working with patients with cancer diagnoses should include consideration of the caregiver's relationship to the patient. Caregivers who are the patient's child should be assessed for depressive symptoms and provided with resources to prevent depression. Health team members should also keep in mind that caregivers do not necessarily experience increased fatigue from providing a symptom management intervention, but may experience lessened fatigue as a result of supporting the patient in this

way. Educating nurses and other health professionals about including support of the caregiver's health as part of planning the patient's care promotes sustaining caregivers as a vital component of the care team.

Conclusion

This research has accomplished the established dissertation aims to: 1) synthesize the state of the science relative to care activities performed by informal caregivers for cancer patients through a review of literature; 2) examine application and achievement of the elements of intervention fidelity within a research protocol for reflexology delivered by informal caregivers to advanced breast cancer patients; 3) analyze caregiver data for the effects of providing a care activity consisting of delivery of a symptom management intervention for breast cancer patients on caregiver psychological, physical, and social health outcomes; and 4) advance nursing science on the effects of informal caregiving by evaluating relationships between performance of a specific symptom management care activity and caregiver health outcomes. Each of the three manuscripts prepared for this dissertation makes a contribution to science in terms of the caregiving literature, intervention fidelity, and caregiver outcomes. It also has inspired questions related to caregiving that can be addressed with further research to add knowledge and translation to practice regarding caregiving.

APPENDICES

APPENDIX A

Tables

Table 1. Literature Review Summary

Study	Caregiver & Patient Characteristics (NG – not given)	Care Activities Performed on Behalf of Cancer Patients		Supportive Intervention for Caregivers	Caregiver Outcomes	
		Category	Measures (instrument)		Measures (instrument)	Results
Badger, et al. (2011). 2-group RCT with repeated measures over 8 weeks.	71 caregiver-patient dyads (prostate cancer) Mean age: 61 years Sex: 93% female Race: NG Relation to pt.: 83% spouse Distance to pt. home: NG Experience caregiving: NG Education: 81% with some college Minority: NG Patient Dx: Prostate Cancer Patient mean age: 67 years Patient sex: 100% male Patient dx. stage: I: 16% II: 9% III: 11% IV: 11%	b,d* No specific activities noted. Indirectly identified: -Informational needs related to disease (b). - Communication as component of interpersonal functioning with patient. (d)	No measures identified.	1,2, 3** 4 sessions delivered over 8 weeks. Telephone interpersonal counseling and health education delivered by RN or social worker with psychology and oncology expertise. Control: 4 sessions delivered over 8 weeks. Health education control delivered by research assistant, not identified as a health professional.	Psychological well-being: - Depression (CES-D) - Affect (PANAS) - Stress (PSS) Physical well-being: - Fatigue (MFI) Social well-being: - (Social Well-Being Scale) - Family support (PSS-FA)	-Improved caregiver depression scores similar over time in intervention group & control group. - Increased fatigue in intervention caregivers; decreased fatigue in control caregivers over time. -Improved caregiver psychological, and social well-being in control group with stronger magnitude than intervention
Boele, et al., (2013). 2-group RCT with repeated measures over 8 months.	56 caregiver-patient dyads (brain cancer – high-grade glioma) Mean age: 51 years Sex: 74% female Race: NG Relation to pt.: NG Distance to pt. home: NG Experience caregiving: NG Education: 61% "high" Minority: NG Patient Dx.: Brain cancer: high grade glioma Patient mean age: 53 years Patient sex: 71% male	a,d,e* Assisting with patient's symptoms, epilepsy, end-of-life care (a) Indirectly identified: -Ability to successfully perform activities of providing care	No measures identified.	1,3** 6 sessions (maximum) delivered over 12 weeks. Cognitive-behavioral therapy and psychoeducation delivered by psychologist. Control: Usual care.	Health-related quality of life: (SF-36) - Physical functioning - Role functioning (physical problems) - Role functioning (emotional problems) - Pain -Vitality - Social functioning	-Caregiver and patient mental function positively correlated. -Caregiver mental health improved in intervention group. -Health-related quality of life unchanged in intervention caregivers; declined in control

Table 1. (cont'd)

Study	Caregiver & Patient Characteristics (NG – not given)	Care Activities Performed on Behalf of Cancer Patients		Supportive Intervention for Caregivers	Caregiver Outcomes	
		Category	Measures (instrument)		Measures (instrument)	Results
	Patient race: NG Patient dx. stage: I: 0% II: 0% III: 26% intervention: 36% control IV: 74% intervention: 64% control	as a portion of definition of "mastery" (a) -Contact with patient and others. (d) -What and how to tell children (d,e)			- Mental health - General health perception Caregiver Mastery: (Caregiver Mastery Scale)	caregivers. -Mastery positively correlated with patient symptoms but not tumor type. - Mastery increased in intervention caregivers; declined in control caregivers.
Chih, et al., (2013). Pooled analysis of two RCT's with repeated measures over 12 months.	217 caregiver-patient dyads (breast, prostate, or lung cancer) Mean age: 56 years Sex: 63% female Race: 93% white Relation to pt.: 70% spouse Distance to pt. home: NG Experience caregiving: NG Education: most with some college Minority: NG Patient Dx.: Lung, breast or prostate cancer Patient mean age: 63 years Patient sex: 56% female Patient race: NG Patient dx. stage: Breast: metastatic or recurrence Prostate: hormone refractory or metastatic Lung: Stages IIIA, IIIB, or IV	a,d* Managing patient symptoms (a) Timely communication with health providers about patient symptoms (d)	No measures identified. Note: Caregiver perceived symptom distress measure was not used as a measure of caregiver activity performance of determination of the patient's symptom burden, but rather for a demographic descriptor of the patient's condition.	2** 12 months access to Internet-based communication system for weekly caregiver reporting and provider notification of: patient symptoms, caregiver needs, questions to be addressed at next provider visit, caregiver burden, and caregiver preparedness. Source of information, interaction with peers, and tailored feedback. Control: Weekly caregiver reporting to Internet-based system with no provider notification of reporting.	Caregiver characteristics: - Comfort with use of Internet - Caregiver-perceived patient symptom distress (modified ESAS) Caregiver preparedness: (Preparedness scale of Family Care Inventory) Caregiver physical burden: (Physical Burden Scale of Caregiver Burden Inventory) Caregiver negative mood: - Sub set of negative mood	-Caregivers completing 6- and 12-month post-tests reported lower patient symptom distress at baseline. -No between group differences for caregiver preparedness or physical burden. -Caregiver negative mood negatively correlated with provider notification of weekly reports.

Table 1. (cont'd)

Study	Caregiver & Patient Characteristics (NG – not given)	Care Activities Performed on Behalf of Cancer Patients		Supportive Intervention for Caregivers	Caregiver Outcomes	
		Category	Measures (instrument)		Measures (instrument)	Results
					items (SV-POMS)	
Couper, et al., (2015) 2-group RCT; random block assignment. Repeated measures over 9 months.	62 caregiver-patient dyads (prostate cancer) Mean age: 61 years Sex: 100% female Race: NG Relation to pt.: 100% married or partnered. Distance to pt. home: 100% live with patient Experience caregiving: NG Education: 97% with education beyond high school Minority: NG Patient Dx.: Prostate cancer Patient mean age: 65 years Patient sex: 100% male Patient dx. stage: I: 36% II: 32% III: 19% Missing: 13%	a,d* Communication with patient about cancer-related concerns (d). Indirectly Identified: Physical symptom management (a)	No measures identified. Note: Relationship Function subscale for expressiveness not used as a measure of communication as a care activity; used as an outcome measure of couple support.	2,3** 6 sessions of 80-90 minutes of supportive, existential, and cognitive therapy delivered by mental health professionals with experience working with cancer. Control: Usual care and generic booklet of prostate cancer information.	Relationship function: (Family Relationship Index) Coping: (Brief COPE) Cancer-specific distress: (Impact of Events Scale-Revised) Mental health: (Mental Health Inventory)	- Younger partners in treatment group with better psychological well-being (less cancer-specific distress, avoidance, intrusive thoughts, and hyperarousal) at T1; maintained at T2 for same age group. - All treatment group partners with greater use of problem-focused coping strategies and relationship outcomes (cohesion, conflict resolution, and relational function). - Deterioration of relationship outcomes in control group over time. - General mental health of participants not impacted by treatment;

Table 1. (cont'd)

Study	Caregiver & Patient Characteristics (NG – not given)	Care Activities Performed on Behalf of Cancer Patients		Supportive Intervention for Caregivers	Caregiver Outcomes	
		Category	Measures (instrument)		Measures (instrument)	Results
						comparable with general aging population cancer patients and caregivers. - Limited to non-high stress couples. - Recruitment bias toward younger couples.
DuBenske, et al., (2014). 2-group RCT with stratification for race, study site, and caregiver relationship to patient. Repeated measures over maximum of 24 months.	246 caregiver-patient dyads (lung cancer) Mean age: 56 years Sex: 68% female Race: NG Relation to pt.: 72% spouse Distance to pt. home: 78% live with patient Experience caregiving: NG Education: 53% with Associate degree or higher Minority: NG Patient Dx.: Lung cancer Patient mean age: NG Patient sex: NG Patient race: NG Patient dx. stage: NG; life expectancy of at least 4 months	a,b,d* Patient symptom monitoring (a) Leveraging support networks (b) Communication with the health care system (d)	No measures identified. Note: Caregiver access to the CHESS system was a quantitative outcome measure of use of the system and not used to measure the activities caregivers performed.	2** Up to 24 months access to Internet-based communication system for optional weekly caregiver reporting and provider notification of: patient symptoms, caregiver needs, questions to be addressed at next provider visit, caregiver burden, and caregiver preparedness. Source of information, interaction with peers, and tailored feedback. Control: Access to internet-based list of cancer and palliative care web sites.	Disruptiveness: (CQOLC Disruptiveness subscale) Burden: (CQOLC Burden subscale) Negative mood: (SV-POMS) Use of CHESS system: Passworded login to system noted as most reliable.	-No between group differences in disruptiveness for caregivers. -Caregivers in intervention group with less burden and negative mood than control; may indicate outlet for reporting of patient symptoms has positive effect on caregiver.
Heinrichs et al., (2012). 2-group RCT.	72 caregiver-patient dyads (breast or gynecological cancer) Mean age: 53 years	a,d,e* Emotional and instrumental	Communication: (Partnership Questionnaire Communication	1,2,3** 4 120-minute sessions of psychosocial counseling	Psychosocial distress: (Fear of Progression Questionnaire)	-Short-term intervention effects recognized versus control group for

Table 1. (cont'd)

Study	Caregiver & Patient Characteristics (NG – not given)	Care Activities Performed on Behalf of Cancer Patients		Supportive Intervention for Caregivers	Caregiver Outcomes	
		Category	Measures (instrument)		Measures (instrument)	Results
Repeated measures over 16 months.	Sex: 100% male Race: NG Relation to pt.: 82% spouse Distance to pt. home: NG Experience caregiving: Required to be in committed relationship for at least 12 months; otherwise not given Education: 50% "high"; 30% "low" Minority: NG Patient Dx.: Breast or gynecological cancer Patient mean age: 52 years Patient sex: 100% female Patient race: NG Patient dx. stage: I or II: 83%; all within 4 weeks of diagnosis	support to the patient (a) Key discussions concerning treatment options (a,e)	subscale) Results: Intervention group with increase in communication quality from pre-test to post-test, followed by declines at 1st and 2nd follow-ups. Control group with decline between pre-test and post-test, which persisted to 1st follow-up, but improved at 2nd follow up.	over 16 months; instruction in dyadic relationship skills delivered by a therapist. Couple-based, delivered in caregiver/patient home. Control: 1 120-minute session of listening to caregiver concerns; written information provided with no counseling or instruction in dyadic skills. Delivered by a therapist.	Benefit finding: (Posttraumatic Growth Inventory) Relationship satisfaction: (Quality of Marriage Index – modified for consideration of non-married partners) Dyadic Coping: (Dyadic Coping Inventory)	psychological health outcomes. -Dyadic relationship skills sustained in intervention group, but decreased in control. -All improvements diminished over time (12 months) for caregivers in both groups.

Hendrix et al., (2011).
 	
2-group RCT.
 	
Repeated measures over 4 weeks.
	120 caregiver-patient dyads (hematological malignancy)
	Age Group 1: 88% ≥ 46 years
	    Group 2: 82% ≥ 46 years
	Sex Group 1: 80% female
	    Group 2: 87% female
	Race: 80% white
	Relation to pt. Group 1: 83% spouse
	    Group 2: 70% spouse
	Distance to pt. home: 100% living with patient
	Experience caregiving: NG
		a*
		
		Health management, medical tasks, symptom management (a)
			No measures identified.
			
			Note: Self efficacy - (Lorig's self-efficacy scale – modified to address training components of intervention) Serves as measure of caregiver perceived ability, not
				1**
				
				1-2 sessions; 2-3 hours each.
				
				Caregiver training: -infection prevention -pain control -nutrition -elimination; tailored to caregiver needs
				
				Delivered by nurses.
				
				Provided in hospital prior to patient's discharge.
					Caregiver well-being: - (HADS) - (CQOLC)	-Intervention group with increased self-efficacy – sustained for up to 4 weeks post discharge.
						
						-Decreased short-term anxiety & depression for immediate effect (up to 1 week after training).
						
						-Intervention group QOL unchanged;

Table 1. (cont'd)

Study	Caregiver & Patient Characteristics (NG – not given)	Care Activities Performed on Behalf of Cancer Patients		Supportive Intervention for Caregivers	Caregiver Outcomes	
		Category	Measures (instrument)		Measures (instrument)	Results
	Education: 55% with at least some college Minority: NG Patient Dx.: Hematological malignancy Patient age Group 1: 78% ≥ 60 years Group 2: 76% ≥ 60 years Patient sex: Group 1: 72% male Group 2: 71% male Patient race: NG Patient dx. stage: NG		measure of actual performance of activities.	Written materials also provided. Control: 1-2 sessions Information provided about general health and community resources; tailored to caregiver needs Delivered by different nurse(s) than intervention.		control group QOL improvement over time. -Differences between intervention and control groups disappeared after 1 week post-training.
Hendrix et al., (2016) 2-group RCT Repeated measures over 4 weeks.	138 caregiver-patient dyads (no cancer type specified; presence of "cancer-related complications" requiring hospitalization) Mean age: 55 years Sex: 83% female Race: 77% white Relation to pt.: 67% spouse Distance to pt. home: NG Experience caregiving: 19 months Education: 70% with at least some college Minority: NG Patient Dx.: Cancer type not reported Patient mean age: 57 years Patient sex: 50% female Patient race: 76% white Patient dx. stage: Not given	a[*] Symptom management		1,3[**] 1 session (could be extended to 2 sessions at caregiver's request) lasting 1-2 hours. Teaching of 2 components using manualized training protocol. 1) Patient symptom management: - prevention of infection - management of fatigue - pain control - maintenance of nutrition - proper elimination 2) Caregiver stress management: - deep breathing - progressive muscle relaxation - pleasant imagery	Self-efficacy for managing patients' cancer symptoms: (Self-efficacy Scale for Cancer Caregivers) Caregiver stress: - Preparedness for caregiving: (Preparedness for Caregiving Scale) - Caregiver depression: (CES-D) - Caregiver anxiety: (POMS anxiety sub-scale) - Caregiver burden: (CRA)	Caregivers who received intervention initially with higher self-efficacy for managing patient's cancer symptoms and preparedness for caregiving than control; difference between intervention and control not sustained at 2 or 4 weeks post hospital discharge. No significant difference between intervention and control caregivers

Table 1. (cont'd)

Study	Caregiver & Patient Characteristics (NG – not given)	Care Activities Performed on Behalf of Cancer Patients		Supportive Intervention for Caregivers	Caregiver Outcomes	
		Category	Measures (instrument)		Measures (instrument)	Results
				Delivered at patient's bedside in hospital by study nurse. Handouts for patient-specific symptoms provided. Interactive discussion with patient participation encouraged. Control: 1 session lasting approximately 1 hour. Standardized training regarding local community resources, home health, hospice, palliative care, living will, and medical power of attorney. Delivered by social worker or nurse.	Health literacy: (REALM-R)	for depression or anxiety with improvements in both groups over time. Little change over time for caregiver burden for both groups.
Hultgren et al. (2016). 4-group RCT (began as 3; expanded to 4 after first 150 recruited. Repeated measures over 12 months.	494 caregiver-patient dyads (melanoma) Mean age: 55 years Sex: 57% female Race: NG Relation to pt.: cohabiting spouse or committed partner, or non-cohabiting friend, child, sibling, parent, or other relative. Distance to pt. home: NG Experience caregiving: Required to be in committed	a, d* Examination of patient's skin in areas the patient cannot self examine (a)	No measures identified. Note: A modified version of the Spouse Treatment Mediation Inventory was used to determine aspects of	1** Group 1: In Person:1 session; duration not given. 3 reinforcement sessions provided once every 4 months. Group 2: Workbook read by dyad in dermatology office and taken home. Group 3: Electronic tablet	Relationship quality: -(Dyadic Adjustment Scale) -Agreeability between patient and caregiver -Activities performed together -Happiness in relationship	-Statement that "all pairs" benefitted from the intervention; no caregiver data provided. - Measure of relationship quality reported only as a moderator for outcome of self skin examination

Table 1. (cont'd)

Study	Caregiver & Patient Characteristics (NG – not given)	Care Activities Performed on Behalf of Cancer Patients		Supportive Intervention for Caregivers	Caregiver Outcomes	
		Category	Measures (instrument)		Measures (instrument)	Results
	relationship for at least 12 months; otherwise not given Education: 90 % with at least some college Minority: NG Patient Dx.: Melanoma Patient mean age: 55 years Patient sex: 51% female Patient race: NG Patient dx. stage:0-IIB: at least 6 weeks post surgical treatment		caregiver support to the patient. Serves as a measure of caregiver motivation in making changes and belief that participating in skin exam would help caregiver. Did not measure the caregivers' performance of the skin examination activity.	version of intervention. Dyad training: - "ABCDE (Assess Border Color Diameter Evolution of pigmented lesions) rule" to assess moles during skin self examination using color picture examples. - Provision of ruler, lighted magnifying lens, laminated card with ABCDE rules. - Provision of a scorecard to record ABCDE rules. - Reinforcement visits consisted of dermatologist examination of patient's skin with caregiver identifying spots to be checked by the dermatologist and the reason for concern. Caregiver received "good job" feedback for correct identification of areas of concern. Delivered by dermatologist. Provided in dermatology clinic. Control: Usual care with no didactic training. Caregivers not invited to look at the patient's skin during visits		and not as a caregiver outcome measure.

Table 1. (cont'd)

Study	Caregiver & Patient Characteristics (NG – not given)	Care Activities Performed on Behalf of Cancer Patients		Supportive Intervention for Caregivers	Caregiver Outcomes	
		Category	Measures (instrument)		Measures (instrument)	Results
				with the dermatologist.		
McLean et al., (2013). 2-group RCT stratified by patient sex. Repeated measures over 3 months.	42 caregiver-patient dyads (romantic partners) (metastatic cancers) Mean age: 50 years Sex: 55% male Race: NG Relation to pt.: 100% romantic relationship Distance to pt. home: NG Experience caregiving: NG Education: 41% with at least some college Minority: NG Patient Dx.: Metastatic cancer; multiple types Patient mean age: 51 years Patient sex: 45% male Patient race: NG Patient dx. stage: NG - Mean 4 years since diagnosis	a,d,e* "Care-related tasks" (a, e) Communication about cancer with patient (d)	No measures identified. Note: Empathic behavior toward patient measured with Relationship-Focused Coping Scale could potentially serve as a measure of caregiver emotional support but identified as outcome measure.	1,2,3** 8 weekly 1-hour sessions delivered to couple by psychologist. Focus on communication, control of symptoms, & decision-making within couple (examples). Control: 2-8 sessions of usual care, comprised of approximately 2/3 social work sessions.	Marital Functioning: (Revised Dyadic Adjustment Scale) Psychosocial Outcomes: - Depression: (Beck Depression Scale) - Hopelessness: (Beck Hopelessness Scale) - Empathic Caregiving: (Relationship-Focused Coping Scale) * Question if patient outcome or care activity measure -Caregiver Burden: (Caregiver Burden Scale – demand and difficulty subscales)	Intervention group caregivers with improvement in marital function with retained effects over 3 months.
Meyers et al., (2011). 2-group RCT Repeat measures over 6 months.	441 caregiver-patient dyads (multiple cancer types) Mean age: 61 years Sex: 69% male Race: 85% White Relation to pt.: 70% spouse Distance to pt. home: NG Experience caregiving: NG Education: 66% with at least	e* Problem solving (e)	Problem solving: (Social Problem Solving Inventory) Results: No significant difference between	2** 3 sessions over 30 days of cognitive behavioral problem solving education in combination with written materials delivered by instructor (credentials not specified).	Quality of Life: (City of Hope Quality of Life Instrument Family Version)	-Decline of quality of life, psychological well-being, and social well-being over time in both groups; intervention group did not decline as

Table 1. (cont'd)

Study	Caregiver & Patient Characteristics (NG – not given)	Care Activities Performed on Behalf of Cancer Patients		Supportive Intervention for Caregivers	Caregiver Outcomes	
		Category	Measures (instrument)		Measures (instrument)	Results
	some college Minority: 23% Patient Dx.: Multiple types of cancer Patient mean age: 62 years Patient sex: 55% female Patient race: 88% White Patient dx. stage: NG; all "advanced"		intervention and control for problem solving (e).	Target: caregiver -quality of life. Control: Usual care.		rapidly as control group. -Results did not support that improvement in caregiver quality of life was related to improved problem solving skills.
Northouse et al., (2013). 3-group RCT Repeated measures over 6 months.	484 caregiver-patient dyads (breast, colorectal, lung, prostate cancer) Mean age: 57 years Sex: 56% female Race: 83% White Relation to pt.: 74% spouse Distance to pt. home: NG Experience caregiving: NG Education: mean 14.8 years Minority: 17% Patient Dx.: Breast, colorectal, lung, prostate Patient mean age: 60 years Patient sex: 61% female Patient race: NG Patient dx. stage: NG; all stage III or IV	a,d* Emotional care (a) Illness-related communication (d)	Illness-related communication: (Lewis Mutuality and Sensitivity Scale) Results: Communication unchanged in "high risk" caregivers in all groups (d).	1,2,3** Brief and Extended FOCUS information and support interventions delivered to dyads together by masters-prepared nurses. Target areas: - involvement - attitude - coping - uncertainty - symptom management Brief FOCUS intervention: 3 sessions over 10 weeks. Extended FOCUS intervention: 6 sessions over 10 weeks. Control: Usual care.	Appraisal Caregiving appraisal: (Appraisal of Caregiving Scale) Uncertainty: (Mishel Uncertainty in Illness Scale Hopelessness: (Beck Hopelessness Scale) Coping Coping: (Brief Cope) Healthy Lifestyle: (researcher developed scale) Interpersonal Relationships Dyadic Support:	-Improvements in coping style, healthy behaviors, and self-efficacy were not sustained in intervention groups through 6 month point. -Emotional quality of life improved and sustained for intervention caregivers through 6 month point.

Table 1. (cont'd)

Study	Caregiver & Patient Characteristics (NG – not given)	Care Activities Performed on Behalf of Cancer Patients		Supportive Intervention for Caregivers	Caregiver Outcomes	
		Category	Measures (instrument)		Measures (instrument)	Results
					(Social Support Questionnaire subscale modified)	
					Efficacy Self efficacy: (Lewis Cancer Self-efficacy Scale)	
					Quality of Life: (Functional Assessment of Cancer Therapy modified)	
Sherwood et al., (2012). 2-group RCT Repeated measures over 16 weeks	169 caregiver-patient dyads (solid tumor cancer) Mean age: Group 1: 54 years Group 2: 56 years Sex: Group 1: 58% female Group2: 42% female Race: NG Relation to pt.: Group 1: 75% spouse Group 2: 67% spouse Distance to pt. home: NG Experience caregiving: NG Education: NG Minority: NG Patient Dx.: Solid tumor cancer Patient mean age: NG Patient sex: NG Patient race: NG	a,d,e* Assistance with patient symptoms (a) Communication with patient (d) Decision-making (e)	Caregiver Symptom Involvement: (questionnaire designed for study)– caregiver response of "yes/no" for 15 symptoms followed by "yes/no" for whether they provided assistance. Scored as total number of symptoms caregiver assisted with during past 7 days. (a)	1,2** 3 sessions over 16 weeks of problem-solving intervention delivered by master's prepared nurse. Topics: -Role in symptom assistance & care activities to promote patient self-care strategies -Provision of emotional support for patient -Communication with patient about symptoms techniques Symptom-management toolkit Control: 3 sessions over 16 weeks of caregiver coaching to use	Depressive symptoms: (CES-D) Caregiver Burden: (Caregiver Reaction Scale) Mastery: (Mastery Scale)	- No significant main effect of caregivers providing more patient assistance associated with intervention. - Depression values lower in intervention group over time, but not at significant level. - Caregivers with lower levels of depression more likely to provide assistance to patient. - Caregivers less

Table 1. (cont'd)

Study	Caregiver & Patient Characteristics (NG – not given)	Care Activities Performed on Behalf of Cancer Patients		Supportive Intervention for Caregivers	Caregiver Outcomes	
		Category	Measures (instrument)		Measures (instrument)	Results
	Patient dx. stage: Group 1: 88% late stage Group 2: 84% late stage Note: All participants stage III or IV		Results: Caregivers more likely to assist with moderate and severe symptoms than mild. Communication with patient: (ENRICH Marital Inventory) (d) Results: No significant change.	toolkit delivered by staff with no formal oncology or symptom management training. Symptom-management toolkit		likely to provide assistance when depressed, schedule burdened, and patient with more symptoms. -Spouses already providing patient assistance initially less likely to provide assistance than non-spouse caregivers over time. -Improved self-esteem among intervention caregivers (could be at least partially social desirability bias). -Caregivers reported more depressive symptoms when patient experienced more symptoms. -Caregivers more confident in abilities when patient symptoms fewer, spouse of patient, and earlier in trajectory of

Table 1. (cont'd)

Study	Caregiver & Patient Characteristics (NG – not given)	Care Activities Performed on Behalf of Cancer Patients		Supportive Intervention for Caregivers	Caregiver Outcomes	
		Category	Measures (instrument)		Measures (instrument)	Results
						disease. - Mastery higher earlier in cancer care, among spouses, and when fewer patient symptoms present.

Ward et al., (2009).
 	
3-group RCT
 	
Repeated measures over 9 weeks
	161 caregiver-patient dyads (cancer with moderate to severe pain in 3 weeks prior to study enrollment)
	Mean age: Group 1: 54 years
	        Group 2: 54 years
	Sex: Group 1: 61% female
	        Group 2: 58% female
	Race: Group 1: 92% White
	        Group 2: 91% White
	Relation to pt.: Group 1: 79% spouse
	        Group 2: 60% spouse
	Distance to pt. home: NG
	Experience caregiving: NG
	Education: mean 14 years
	Minority: 8% both groups
	Patient Dx.: cancer (no further descriptor)
	Patient mean age: Both groups: 58 years
	Patient sex: Group 1: 53% female
	        Group 2: 58% female
	Patient race: Group 1: 90% White
		a,d*
		
		Pain management (a)
		
		Communication with patient about pain management (d)
			No measures identified.
			
			Note: The measure of talking to patient about cancer pain could potentially have been used as a measure of communication with the patient, but was identified as an intervention outcome measure.
				1,2**
				
				1 20-80 minute face to face session followed by 2 5-10 minute telephone sessions delivered by master's prepared nurses and psychologists.
				
				Topics:
				-Beliefs about cancer pain cause, consequences, timing, and control.
				- Identification of misconceptions about pain and analgesia.
				- Education about pain management.
				-Coping strategies for pain management.
				
				Group 1: caregiver and patient received intervention together.
				
				Group 2: patient only received intervention.
				
				Control:
				Usual care.
					Change in thinking about cancer pain and pain medication: (Study Participation Evaluation Form)
					
					Increase in talking to patient about pain management: (Study Participation Evaluation Form)
						-No intervention effects for caregivers attitudinal barriers.
						
						-Dyad trained caregivers with higher pain management scores than patient intervention only and control groups.

Table 1. (cont'd)

Study	Caregiver & Patient Characteristics (NG – not given)	Care Activities Performed on Behalf of Cancer Patients		Supportive Intervention for Caregivers	Caregiver Outcomes	
		Category	Measures (instrument)		Measures (instrument)	Results
	Group 2: 89% White Patient dx. stage: NG					

*Categories of Care Activities:
a. Managing cancer and comorbidities
b. Accessing community resources
c. Navigating the health system
d. Communication
e. Decision-making/problem solving

**Categories of Caregiver Interventions:
1. Psychoeducation to develop knowledge/skills related to patient's disease.
2. Coping, communication, problem solving skill development.
3. Counseling for reactions to caring for cancer patient.

Instrument Key:
BPI – SF – Brief Pain Inventory – Short Form
CES-D – Center for Epidemiological Studies – Depression Scale
CQOLC – Caregiver Quality of Life – Cancer Scale
CRA – Caregiver Reaction Assessment
ESAS – Edmonton Symptom Assessment System
FACT-G – Functional Assessment of Cancer Therapy – General Scale
HADS – Hospital Anxiety and Depression Scale
MFI - Multidimensional Fatigue Inventory
MSAS – Memorial Symptom Assessment Scale
OARS – Older Americans Resources and Services
PANAS – Positive and Negative Affect Schedule
POMS – Profile of Mood States
PSS – Perceived Stress Scale
PSS-FA – Perceived Social Support – Family Scale
QLQ-C30 - Quality of Life Questionnaire-Core
REALM-R – Rapid Estimate of Adult Literacy in Medicine
SF–36 – MOS 36-item short-form health survey.
SV-POMS – Shortened Version Profile of Mood States

Table 2. Care Activities Performed by Caregivers

Authors	Managing Cancer Symptoms and Comorbidities	Communication	Decision-making/ Problem Solving	Accessing Community Resources	Navigating the Health System
Badger, et al. (2010).		X		X	
Boele, et al., (2013).	X	X	X		
Chih, et al., (2013).	X	X			
Couper, et al., (2015)	X	X			
DuBenske, et al., (2014).	X	X		X	
Heinrichs et al., (2012).	X	X	X		
Hendrix et al., (2013).	X				
Hendrix et al., (2016)	X				
Hultgren et al., (2016)	X	X			
McLean et al., (2013).	X	X	X		
Meyers et al., (2011).			X		
Northouse et al., (2013).	X	X			
Sherwood et al., (2012).	X	X	X		
Ward et al., (2009).	X	X			

Table 3. Care Activities Instruments

Instrument	Study First Author	Care Activity	Instrument Description	Study-specific Performance
Caregiver Symptom Involvement (researcher developed)	Sherwood	Managing Cancer and Comorbidities	15 items; - yes/no scale; did caregiver observe symptom in patient - yes/no scale; did caregiver provide assistance for symptom Scored as total number of symptoms caregiver assisted patient with during previous 7-day period.	Not available
ENRICH Marital Inventory	Sherwood	Communication	10 items; 5 point Likert-type scale Scored by summing points; higher scores indicative of better communication. Family communication subscale used. Internal consistency established at 0.90 in a sample of 40,133 couples.	Not available
Lewis Mutuality and Sensitivity Scale	Northouse	Communication	5 point Likert-type scale Higher scores indicative of higher levels of illness-related communication between patient and caregiver.	α 0.93
Partnership Questionnaire Communication subscale	Heinrichs	Communication	10 items; scale; score range 0-30 Low-quality mean score = 13 High-quality mean score = 20	α 0.86 (women) α 0.82 (men)
Social Problem-Solving Inventory -Revised	Meyers	Problem-Solving	52 items; 5 scales measuring 2 dimensions - Positive problem orientation - Rational problem solving - Negative problem orientation - Impulsivity/Carelessness style - Avoidance style	Not available
Spouse Treatment Mediation Inventory (adapted)	Hultgren	Managing Cancer and Comorbidities	2 items; 5 point Likert-type scale Scored by summing score of items for single index of motivation.	Pearson r = 0.86

Table 4. Caregiver Outcomes Instruments

Instrument	Study(s) First Author	Caregiver Outcome Measure	Instrument Description	Study-specific Performance
Appraisal of Caregiving Scale	Northouse	Caregiving appraisal	Higher scores indicative of more negative appraisal	α 0.89
Beck Depression Inventory II	McLean	Psychological symptoms	21 items; score range 0-63 Higher scores indicative of higher levels of depression Use in cancer populations established	α 0.92
Beck Hopelessness Scale	McLean Northouse	McLean: Psychological symptoms Northouse: Hopelessness	20 items; true/false scale; total score range 0-20 Higher scores reflective of increased hopelessness	McLean: α 0.88 Northouse: α 0.84
Brief COPE	Couper Northouse	Coping	Couper: Derived from longer Coping Orientation of Problems instrument. - Global adaptive scale: 16 items; 0-48 score range - Problem-focused coping - Emotion-focused coping Northouse: factored into active coping and avoidant coping Higher scores indicative of higher levels of coping.	Couper: α 0.85-0.87 Northouse: Active coping: α 0.88 Avoidant coping: α 0.78
Caregiver Burden Inventory (Physical Burden Scale)	Chih	Caregiver physical burden	4 items; 5 point scale; scores calculated as means across items.	α 0.78 – 0.85
Caregiver Burden Scale	McLean	Caregiver burden	2 subscales used: - demand; 14 tasks; 1-5 scale; - difficulty; 14 tasks; 1-5 scale; Score range for each subscale: 0 – 70 Higher scores reflective of higher burdern	α 0.93
Caregiver Mastery Scale	Boele	Caregiver mastery	7 items; higher score indicated less mastery.	Not available
Caregiver Quality of Life – Cancer Scale	Hendrix (2011)	Caregiver well-being	35 items; 5 point LIkert-type scale 4 subscales: - burden - disruptiveness - positive adaptation - financial concerns Total possible score 140; higher scores indicative of better quality of life Instrument test-retest reliability reported as α 0.95 and internal consistency of 0.91 in population of 263 caregivers of cancer patients.	Not available
Caregiver Quality of Life – Cancer Scale –	DuBenske	Burden	10 items; Likert-type scale Scored as means across items multiplied by number of	α $\geq$ 0.89

Table 4. (cont'd)

			items. Higher scores indicate greater burden.	
Burden Subscale				
Caregiver Quality of Life – Cancer Scale Disruptiveness Subscale	DuBenske	Disruptiveness	7 items; Likert-type scale 0-4 Scored as means across items multiplied by number of items. Higher scores indicate greater disruptiveness.	α 0.83
Caregiver Reaction Scale	Hendrix (2016) Sherwood	Caregiver burden	Likert-type scale; summation of individual scores to calculate 3 subscale scores; Higher scores indicative of higher levels of burden for schedule and abandonment subscales and lower levels of burden for self-esteem subscale. 3 subscales utilized: - Impact of providing care on caregivers' schedule - Impact of providing care on caregivers' feeling abandoned - Impact of providing care on caregivers' self-esteem -	Not available for either study sample; reported α > 0.79 for all subscales among varying caregiver populations.
Center for Epidemiological Studies – Depression Scale	Badger Hendrix (2016) Sherwood	Depression	20 items; score range 0-60;	Badger: α ≥ 0.88 Hendrix: not available Sherwood: α 0.90
CHESS System use (researcher developed)	DuBenske	Electronic system usage	Count of passworded logins	Not applicable
City of Hope Quality of Life Instrument – Family Version	Meyers	Quality of life	37 items; adapted from patient version; tested with 219 family caregivers of patients with cancer. Rescaled from 0-100 to allow for comparison of patients and caregivers	Not available
Comfort with use of Internet (researcher developed)	Chih	Comfort in use of Internet	1 item; Likert-type scale range 0-4; higher score indicated more comfort	Not available
Dyadic Adjustment Scale (adapted)	Hultgren	Relationship quality	3 aspects; agreeability, activities, happiness Aspects assessed - agreeability between patient and caregiver: 14 items, 5 point Likert-type scale (-2 to 2), single score - activities performed together: 4 items, 5 point Likert-type scale (-2to 2), single score - happiness in relationship: 1 item, 5 point Likert-type scale (-2 to 2), single score	Agreeability: α= 0.91 Activities: α= 0.78 Happiness: not applicable
Dyadic Coping	Heinrichs	Coping with stress in relationship	37 items; 1-5 scale; total sum score range 35-175	Not available
Edmonton Symptom Assessment	Chih	Patient symptom distress as	9 items; 0-10 scale; score range 1-90	Chih: Not available

Table 4. (cont'd)

System	DuBenske	perceived by caregiver.	Decision to replace original instrument items made based on oncologists' feedback. Modified by replacement of 3 items: Not used: - activity - drowsy - wellbeing Replaced with: - fatigue - constipation - diarrhea	DuBenske: α 0.79
Family Relationship Index	Couper	Relationship function	3 subscales; 0-4 scale - cohesion - expressiveness - conflict resolution Global score of relationship function score range 0-12. Established, sensitive measure of relationship functioning in context of cancer.	α 0.57 - 0.65
Fear of Progression Questionnaire	Heinrichs	Psychosocial distress	12 items; Likert-type scale "never" to "very often"	α 0.87
Functional Assessment of Cancer Therapy – General Scale Version IV	Northouse	Quality of life	Instrument slightly modified for caregivers to report their own quality of life. 4 domains: - social - emotional - functional - physical well-being Higher scores indicative of better quality of life.	Social domain: α 0.83 Emotional domain: α 0.81 Functional domain: α 0.84 Physical domain: α 0.81
Healthy Lifestyle (researcher developed)	Northouse	Healthy behaviors encouraged in intervention	Exercise, nutrition, adequate sleep Higher scores indicative of higher levels of healthy behaviors.	α 0.67
Hospital Anxiety and Depression Scale	Hendrix (2011)	Caregiver well-being	14 items (7 for depression, 7 for anxiety) 4 point Likert-type scale; score range 0-21	Not available
Impact of Events Scale (revised)	Couper	Cancer-specific distress	22 items; 0-4 scale 3 subscales Global score range 0-12; higher scores indicate greater distress.	α 0.84 – 0.92

Table 4. (cont'd)

Lewis Cancer Self-Efficacy Scale	Northouse	Self-efficacy	Higher scores indicative of higher levels of self-efficacy	α 0.98
Mastery Scale	Sherwood	Caregiver mastery of the tasks of care	7 items; Likert-type scale; higher scores indicative of higher levels of mastery.	α > 0.76
Mental Health Inventory	Couper	Mental health	10 item psychological well-being and psychological distress subscales used; score range 1-6; higher scores indicate better mental health.	α 0.80 – 0.97
Mishel Uncertainty in Illness Scale	Northouse	Uncertainty	Higher scores indicative of higher uncertainty	α 0.75
MOS 36-item short-form health survey	Boele	Health Related Quality of Life Higher order summary scores created for: - Physical component - Mental component	36 items 8 scales: - physical functioning - role function limitation: physical - role function limitation: emotional - pain - vitality - social functioning - mental health - general health perception	Not available
Multidimensional Fatigue Inventory	Badger	Fatigue	20 items;	α > 0.89
Participant Evaluation Form (researcher developed)	Ward	Change in thinking about cancer pain and pain medication. Increase in talking to patient about pain management (? Care activity)	3 items; response options 0-4.	Not available
Perceived Social Support – Family Scale	Badger	Family support	20 items;	α > 0.79
Perceived Stress Scale	Badger	Stress	10 items; score range 0-40	α > 0.88
Positive and Negative Affect Schedule	Badger	Affect	20 items; score range 10-50	α > 0.86
Posttraumatic Growth Inventory	Heinrichs	Benefit Finding	21 item; 3 point Likert-type; score range 0-42	α 0.91 - 0.92
Preparedness Scale of Family Care Inventory	Chih	Caregiver preparedness	4 items; subscale of Family Care Inventory 0-4 scale rating confidence in: - ability to care for pt. physical needs - ability to care for pt. emotional needs - identify and obtain services for pt. - cope with stress of caregiving	α 0.79 – 0.85
Quality of Marriage Index	Heinrichs	Relationship (marital)	6 items; 0-10 scale; score range 6–45	α 0.95

Table 4. (cont'd)

			satisfaction	Higher score indicative of higher relationship satisfaction. Wording modified to account for not all couples married.	
Rapid Estimate of Adult Literacy in Medicine	Hendrix (2016)	Caregiver health literacy	8 items (8 health related words); tests recognition and pronunciation. Score of ≤ 6 indicates poor health literacy	Not available
Revised Dyadic Adjustment Scale	McLean	Marital Functioning	14 items; score range 0-69 Lower scores indicative of higher marital distress Validity in cancer populations established	α 0.90
Profile of Mood States	Chih DuBenske Hendrix (2016)	Caregiver negative mood	Chih: Number of items used not clear DuBenske: 16 items Chih & DuBenske: (modified from original version); 0-4 scale: - tension/anxiety - anger/hostility - depression/dejection Chih: Scores calculated as means across items. DuBenske: Single scale created from 3 subscales as higher scores indicate higher negative mood. Hendrix: Anxiety subscale; 5 items; 0-4 scale	Selected items compared with original instrument. Original version: α 0.94 Version used: α 0.92 Chih: α 0.95-0.96 DuBenske: α 0.95 for combined single scale Hendrix: not available
Social Support Questionnaire (subscale modified)	Northouse	Dyadic support	Higher scores indicative of higher levels of dyadic support	α 0.87
Social Well-Being Scale (modified)	Badger	Social well-being	8 items	α ≥ 0.78

Table 5. 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)
Aunt/Uncle	2 (3)
Daughter/Step Daughter Son/Step Son	15 (19)
Friend	5 (5)
Other	3 (4)

Table 6. Fidelity Summary Measures

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

Table 7. Caregiver Demographic Characteristics at Baseline

Caregiver characteristic	Reflexology N=94	Control N=86	*p*-value
Characteristic	Mean (SD)	Mean (SD)	
Age: years	55.5 (15.34)	53.0 (15.25)	.29
	N (%)	N (%)	
Sex: Male Female	53 (56) 41 (44)	49 (57) 37 (43)	.94
Relationship to patient: Spouse or partner Parent or step parent Friend Other	50 (54) 19 (20) 8 (9) 16 (17)	49 (57) 11 (13) 14 (16) 12 (14)	.25
Employment: Full time Part time Other	35 (38) 13 (14) 45 (48)	44 (51) 8 (9) 34 (40)	.17
Education: Completed high school Some college/technical training Completed college Completed graduate/professional degree	18 (19) 30 (32) 29 (31) 17 (18)	14 (16) 23 (27) 25 (29) 23 (27)	.54
Marital status: Married or living with partner Other	69 (73) 25 (27)	67 (78) 19 (22)	.48
Ethnicity: Hispanic or Latino Not Hispanic or Latino Refused	3 (3) 90 (96) 1 (1)	3 (3) 82 (95) 1 (1)	.99
Race: American Indian or Alaska Native Asian Black or African American White Refused/NA	0 (0) 4 (4) 9 (10) 76 (81) 5 (5)	1 (1) 1 (1) 8 (9) 73 (85) 3 (3)	.55
Comorbidity: Number of conditions reported	2.3 (2.8)	2.1 (2.5)	.55

Table 8. Descriptive Statistics for Caregiver Variables at Baseline

Outcome	Reflexology Mean (SD)	Control Mean (SD)	p-value
Caregiver Psychological Health:			
Anxiety [mean (SD)]	48.0 (9.1)	48.2 (7.8)	.83
Caregiver Depression [mean (SD)]	45.3 (7.8)	44.9 (6.0)	.68
Caregiver Physical Health:			
Physical functioning [mean (SD)]	53.4 (7.0)	52.9 (6.9)	.63
Fatigue [mean (SD)]	46.6 (8.5)	48.0 (7.6)	.24
Sleep Disturbance [mean (SD)]	45.6 (8.5)	45.6 (7.6)	.99
Pain Severity (0-10) [mean (SD)]	1.54 (2.0)	1.73 (2.0)	.52
Comorbidities	2.48 (2.9)	2.23 (2.6)	.24
Caregiver Social Health:			
Satisfaction with participation in social roles [mean (SD)]	55.3 (7.8)	55.5 (7.8)	.86
Pain Interference [mean (SD)]	46.9 (7.9)	47.2 (7.1)	.78

Table 9. Caregiver Outcomes at Weeks 5 and 11, between Study Groups

Outcome	Reflexology LS Mean (SE)	Control LS Mean (SE)	p value
Caregiver Psychological Health			
Anxiety 5 weeks 11 weeks	46.6 (.74) 46.2 (.76)	48.0 (.77) 47.4 (.83)	.17 .30
Depression 5 weeks 11 weeks	44.5 (.63) 44.8 (.65)	45.0 (.65) 44.2 (.69)	.58 .53
Caregiver Physical Health			
Fatigue 5 weeks 11 weeks	45.7 (.79) 44.9 (.80)	48.4 (.82) 47.2 (.87)	**.02*** **.05***
Pain Severity (0-10) 5 weeks 11 weeks	1.57 (.20) 1.59 (.20)	1.66 (.20) 1.77 (.20)	.74 .54
Physical Function 5 weeks 11 weeks	52.9 (.57) 53.2 (.58)	52.7 (.59) 52.0 (.63)	.80 .19
Sleep Disturbance 5 weeks 11 weeks	45.0 (.85) 44.4 (.87)	45.7 (.88) 45.0 (.93)	.56 .69
Caregiver Social Health			
Satisfaction with Social Roles 5 weeks 11 weeks	56.7 (.89) 56.2 (.91)	55.4 (.92) 54.7 (.98)	.30 .26
Pain Interference 5 weeks 11 weeks	47.3 (.76) 47.3 (.77)	47.0 (.78) 48.0 (.82)	.78 .55

Significance level $\leq$ .05

Table 10. Association of increasing number of sessions delivered on caregiver outcomes

Variable	Model coefficient (SE)	p-Value
Caregiver Psychological Health: Anxiety Caregiver Depression	- .07 (.12) - .12 (.10)	.59 .27
Caregiver Physical Health: Physical functioning Fatigue Sleep Disturbance Pain Severity (0-10)	- .06 (.10) - .23 (.14) - .04 (.15) .07 (.15)	.59 **.09** .80 .65
Caregiver Social Health: Satisfaction with participation in social roles Pain Interference	- .15 (.18) - .03 (.04)	.39 .46

Bold = Trend toward significance.

APPENDIX B

Figures

Figure 1. "Organizing Framework for Caregiver Interventions" VanHoutven et al., 2011.

Figure 2. Caregiver Outcomes Model adapted from Van Houtven et al., 2011

1. Supportive Interventions for Caregivers
a) Psychoeducation:
b) Skill Development:
- coping
- communication
- problem-solving
- psychomotor
c) Counseling

2. Care Activities Performed on Behalf of Cancer Patients
a) Managing cancer symptoms and comorbidities
b) Communication with the patient, family and providers
c) Decision making/problem solving
d) Accessing community resources
e) Navigating the health system

3. Caregiver Outcomes
a) Psychological Health
b) Physical Health
c) Social Health
d) Other outcomes

Patient Outcomes
a) Psychological Health
b) Physical Health
c) Social Health
d) Other outcomes

4. Caregiver Charateristics
a) Age/Sex/Race/Ethnicity
b) Relationship to patient
c) Employment
d) Education
e) Health Status (comorbid conditions)
f) Distance between caregiver and patient residence
g) Caregiving experience

5. Patient Characteristics
a) Age/Sex/Race/Ethnicity
b) Cancer diagnosis

-------- Denotes potential moderation
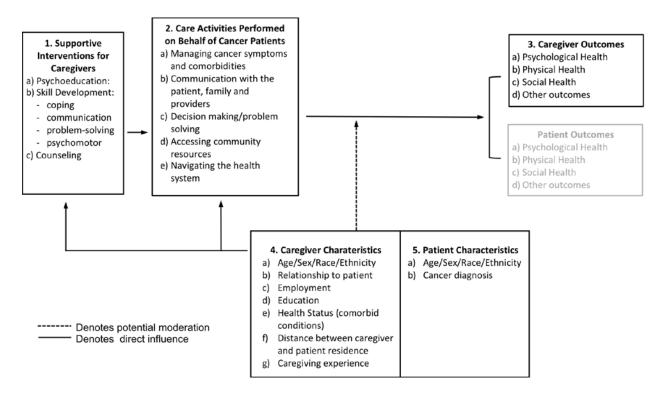——— Denotes direct influence

Figure 3. PRISMA Diagram of article selection

Figure 4. Intervention Fidelity Scorecard

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	$\geq$ 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 $\geq$ 90% = 1; < 90% =0	(range 0 – 1)
2. Provider Training: Caregiver achievement of intervention accuracy during training session with reflexologist: $\geq$ 90%	Reflexologist "Encounter Form" visit #1	Training	$\geq$ 90% = 1; < 90% =0	(range 0 – 1)
3. Intervention Delivery Caregiver demonstration of accuracy in delivery of reflexology protocol to patient: $\geq$ 90%	Reflexologist "Encounter Form" visit #2	Demonstration of delivery of reflexology	$\geq$ 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	$\geq$ 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 5. Encounter Form

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 6. Caregiver Outcomes Model adapted from: The Organizing Framework fro Caregiver Interventions (Van Houtven, et al., 2011)

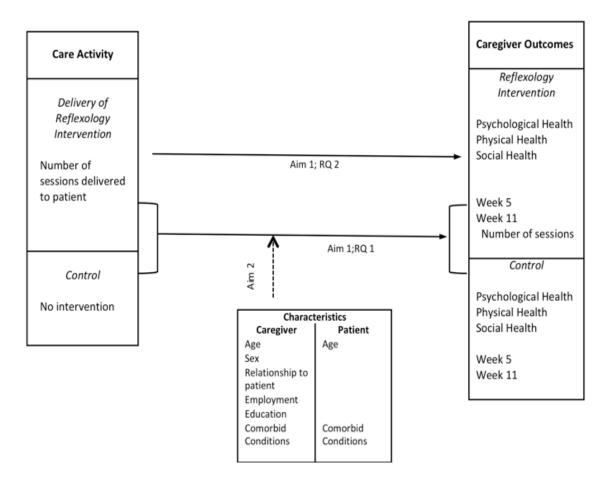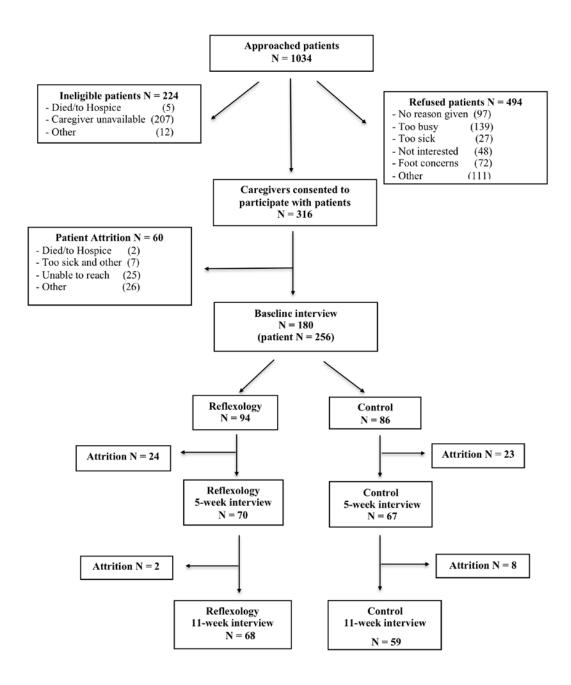Figure 7. Data Collection Schedule and Instruments for Caregivers

Data Collection	Instrument(s)	Aim/Research Question (RQ)	Time Point			
			Baseline (Week 0)	Weeks1-4	Week 5	Week 11
Variable						
Psychological Health	• PROMIS Anxiety[1] • PROMIS Depression[1]	Aim1, RQ 1	X		X	X
Physical Health	• PROMIS Fatigue[1] • PROMIS Pain Severity[1] • PROMIS Physical Function[1] • PROMIS Sleep Disturbance[1]	Aim 1, RQ 1	X		X	X
Social Health	• PROMIS Pain Interference[1] • PROMIS Satisfaction with Participation in Social Roles[1]	Aim 1, RQ 1	X		X	X
Intervention – Session Completion Information (Intervention Group Only)						
Intervention dose	Care Activity; Week 11 Interview question on the number of sessions	Aim 1, RQ 2	X	X	X	X
Age	Demographics	Aim 2	X			
Sex	Demographics	Aim 2	X			
Race/ethnicity	Demographics	Aim 2	X			
Marital Status	Demographics	Aim 2	X			
Relationship to patient	Demographics	Aim 2	X			
Employment	Demographics	Aim 2	X			
Health Status	Bayliss Comorbidities	Aim 2	X			
Key: [1] PROMIS-29 Profile v 1.0						

Figure 8. CONSORT Chart for Caregiver Participation in Home-Based Symptom Management via Reflexology for Breast Cancer Patients

APPENDIX C

Data Collection Instruments

DEMOGRAPHICS

1. What is your birth date?
                                                ____ / ____ / ____
                                                Month / Day/ Year
                                                ____Refused/NA

2. You are
    ____ Male
    ____ Female

3. What is your highest level of education completed?
    ____ No formal education
    ____ Completed grade school
    ____ Completed some high school
    ____ Completed high school
    ____ Completed some college/technical training
    ____ Completed college
    ____ Completed graduate/professional degree (post baccalaureate degree)
    ____ Refused/NA

4. What is your ethnic background?
    ____ Hispanic or Latino
    ____ Not Hispanic or Latino
    ____ Refused/NA

5. What is your racial background?
    ____ American Indian or Alaska Native
    ____ Asian
    ____ Black or African American
    ____ Native Hawaiian or Other Pacific Islander
    ____ White
    ____ Refused/NA

6. What is your spiritual preference?
    ____ Christian
    ____ Jewish
    ____ Buddhist
    ____ Hindu
    ____ Muslim
    ____ Other (specify: [Text box])
    ____ None
    ____ Refused/NA

7. What is your marital status?
    ____ Married or living with a partner
    ____ Single

PROMIS–29 Profile v1.0

Please respond to each question or statement by marking one box per row.

		Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do
1	Are you able to do chores such as vacuuming or yard work?..........................	☐	☐	☐	☐	☐
2	Are you able to go up and down stairs at a normal pace?	☐	☐	☐	☐	☐
3	Are you able to go for a walk of at least 15 minutes?	☐	☐	☐	☐	☐
4	Are you able to run errands and shop?.......	☐	☐	☐	☐	☐

In the past 7 days...		Never	Rarely	Sometimes	Often	Always
5	I felt fearful...	☐	☐	☐	☐	☐
6	I found it hard to focus on anything other than my anxiety	☐	☐	☐	☐	☐
7	My worries overwhelmed me.....................	☐	☐	☐	☐	☐
8	I felt uneasy	☐	☐	☐	☐	☐

In the past 7 days...		Never	Rarely	Sometimes	Often	Always
9	I felt worthless	☐	☐	☐	☐	☐
10	I felt helpless	☐	☐	☐	☐	☐
11	I felt depressed	☐	☐	☐	☐	☐
12	I felt hopeless	☐	☐	☐	☐	☐

In the past 7 days...		Not at all	A little bit	Somewhat	Quite a bit	Very much
13	I feel fatigued	☐	☐	☐	☐	☐
14	I have trouble <u>starting</u> things because I am tired..	☐	☐	☐	☐	☐
15	How run-down did you feel on average? ...	☐	☐	☐	☐	☐
16	How fatigued were you on average?.........	☐	☐	☐	☐	☐

PROMIS–29 Profile v1.0

In the past 7 days...	Very poor	Poor	Fair	Good	Very good
17 My sleep quality was................................	☐	☐	☐	☐	☐

In the past 7 days...	Not at all	A little bit	Somewhat	Quite a bit	Very much
18 My sleep was refreshing............................	☐	☐	☐	☐	☐
19 I had a problem with my sleep	☐	☐	☐	☐	☐
20 I had difficulty falling asleep	☐	☐	☐	☐	☐

In the past 7 days...	Not at all	A little bit	Somewhat	Quite a bit	Very much
21 I am satisfied with how much work I can do (include work at home)	☐	☐	☐	☐	☐
22 I am satisfied with my ability to work (include work at home)............	☐	☐	☐	☐	☐
23 I am satisfied with my ability to do regular personal and household responsibilities..............................	☐	☐	☐	☐	☐
24 I am satisfied with my ability to perform my daily routine	☐	☐	☐	☐	☐
25 How much did pain interfere with your day to day activities?	☐	☐	☐	☐	☐
26 How much did pain interfere with work around the home?	☐	☐	☐	☐	☐
27 How much did pain interfere with your ability to participate in social activities?	☐	☐	☐	☐	☐
28 How much did pain interfere with your enjoyment of life?...................................	☐	☐	☐	☐	☐

In the past 7 days...

29 How would you rate your pain on average?

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0 No pain	1	2	3	4	5	6	7	8	9	10 Worst imaginable pain

Bayliss Instrument
Disease Burden: Morbidity Assessment by Self-Report*

This is a list of common chronic medical conditions.

For each condition please tell me whether you have this condition. If you do have it, please tell me how much it limits your daily activities from 1 (NOT AT ALL) to 5 (A LOT).

	I DON'T HAVE THIS CONDITION	I DO have this condition and it limits my daily activities…				
		NOT AT ALL				A LOT
High blood pressure	0	1	2	3	4	5
High cholesterol	0	1	2	3	4	5
Asthma	0	1	2	3	4	5
Diabetes	0	1	2	3	4	5
Thyroid disorder	0	1	2	3	4	5
Chronic back pain or sciatica	0	1	2	3	4	5
Rheumatoid arthritis	0	1	2	3	4	5
Rheumatic disease such as fibromyalgia or lupus	0	1	2	3	4	5
Stomach problem such as an ulcer or gastritis or reflux	0	1	2	3	4	5
Colon problem such as irritable bowel or colitis	0	1	2	3	4	5
Poor blood circulation in your legs	0	1	2	3	4	5
Overweight	0	1	2	3	4	5
Hard of hearing	0	1	2	3	4	5
Vision problem	0	1	2	3	4	5
Chronic bronchitis or emphysema	0	1	2	3	4	5
Osteoarthritis ("regular" arthritis, not rheumatoid arthritis)	0	1	2	3	4	5
Osteoporosis (thinning of the bones)	0	1	2	3	4	5
Congestive heart failure	0	1	2	3	4	5
Heart disease such as angina (chest pain from heart problem), heart attack, bypass surgery or angioplasty	0	1	2	3	4	5
Stroke	0	1	2	3	4	5
Do you have any other chronic medical conditions that were not mentioned above? If so, please list them here:						
	0	1	2	3	4	5
	0	1	2	3	4	5

*Sensitivity relative to chart review for all conditions:
Mean: 79.4
Median: 78.0
Range: 41.0 (one condition) – 100.0 (two conditions)

It is possible to add other conditions to the list as there is no 'ceiling' score.

Total score is the sum of all responses.

Modified from: Bayliss EA, Ellis JL, Steiner JF. (2009). Seniors' self-reported multimorbidity captured biopsychosocial factors not incorporated into two other data-based morbidity measures. *Journal of Clinical Epidemiology, 62,* 550-557.

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