



Dyadic recruitment in complementary therapy studies: experience from a clinical trial of caregiver-delivered reflexology



Amanda J. Holmstrom, Ph.D.^{a,*}, Gwen K. Wyatt, Ph.D.^b, Alla Sikorskii, Ph.D.^c, Catherine Musatics, M.A.^a, Emily Stolz, M.A.^d, Neala Havener, M.A.^a

^a Department of Communication, Michigan State University, East Lansing, MI 48824, United States

^b College of Nursing, Michigan State University, East Lansing, MI 48824, United States

^c Department of Statistics and Probability, Michigan State University, East Lansing, MI 48824, United States

^d College of Communication Arts & Sciences, Michigan State University, East Lansing, MI 48824, United States

ARTICLE INFO

Article history:

Received 9 October 2014

Revised 16 April 2015

Accepted 20 May 2015

Keywords:

Breast cancer

Caregivers

Nursing role in home care

Reflexology

Dyadic enrollment

ABSTRACT

Purpose: As home-based care continues to be a growing trend in health care, involvement of friend and family caregivers in the management of illness becomes essential. However, before nurses can prepare caregivers to engage in various types of care, an evidence base needs to be established via randomized controlled trials (RCTs). Research suggests that recruiting cancer patients and their friend or family caregivers into RCTs presents challenges. The purpose of this paper is to illustrate the barriers to recruitment of patient–caregiver dyads into a RCT of caregiver-delivered reflexology and to recommend strategies to address such barriers.

Methods: This paper reports on a nurse-directed RCT that involved recruitment efforts unique to a caregiver-delivered reflexology protocol for advanced-stage breast cancer patients. Ineligibility due to caregiver-related reasons, consent among eligible patients (out of 551 approached patients), and reasons for refusal were analyzed. **Results:** Almost one-third of patients were found to be ineligible due to the lack of a caregiver to participate with them and provide this form of social support. Among eligible patients, the consent rate for this dyadic study is much lower than that of previous RCTs of reflexologist-delivered reflexology that enrolled just patients, not dyads.

Conclusion: Implications for nursing practice and research include addressing the need for greater social support for patients and strategies for problem-solving refusal reasons during study enrollment.

© 2015 Elsevier Inc. All rights reserved.

The United States health care system is increasingly expecting friend and family members (lay caregivers) to manage care at home (Feinberg, Reinhard, Houser, & Choula, 2011). Lay caregivers are people who provide unpaid assistance to a person with a chronic or disabling condition, such as cancer (Family Caregiver Alliance, 2006). Nurses are responsible for preparing caregivers for their various roles in caring for patients at home (Reinhard, Given, Petlick, & Bemis, 2008). When cancer patients go through chemotherapy for breast cancer, social support from these lay caregivers is paramount (e.g., Friedman et al., 2006). While lay caregivers may be amenable to providing social support in the form of routine tasks such as meal preparation (Feinberg et al., 2011), there are little data on their response to taking on specific symptom management interventions for the patient.

This manuscript is based on the following funded project: Wyatt, G., Sikorskii, A., Holmstrom, A., & Luo, Z. (2011–2016). Home Based Symptom Management via Reflexology for Advanced Breast Cancer Patients: National Institutes of Health, National Cancer Institute grant # R01CA157459-01.

* Corresponding author at: 404 Wilson Rd. Rm. 556, East Lansing, MI 48824. Tel.: +1 517 432 1286; fax: +1 517 432 1192.

E-mail addresses: holmstr6@msu.edu (A.J. Holmstrom), Gwen.Wyatt@hc.msu.edu (G.K. Wyatt), sikorska@stt.msu.edu (A. Sikorskii), musatics@msu.edu (C. Musatics), stolzemi@gmail.com (E. Stolz), nhavener@gmail.com (N. Havener).

To assess the efficacy of caregiver-delivered symptom management interventions, standardized protocols and randomized controlled trials (RCTs) testing these protocols are needed. Research focused on the recruitment process of cancer patient–caregiver dyads suggests that enrollment suffers when the dyad and not just the patient is required for participation (e.g., Fredman et al., 2009; McMillan & Weitzner, 2003). Ineligibility of patients due to caregiver unavailability can have negative consequences, including prolonged data collection, threats to external validity, and increased costs (e.g., McMillan & Weitzner, 2003).

0.1. Reflexology use amongst breast cancer patients

Over 80% of breast cancer patients turn to complementary therapies to alleviate symptoms (Boon, Olatunde, & Zick, 2007). One such therapy, foot reflexology, uses a firm thumb-walking motion to apply pressure to areas of the feet called reflexes. It is based on the theory that foot reflexes are related to specific organs, glands, and systems of the body, and that targeting these reflexes helps to restore balance to the body (Watson & Voner, 2008).

Breast cancer patients who receive foot reflexology report better physical functioning, reduced dyspnea (Wyatt, Sikorskii, Rahbar, Victorson, & You, 2012), and enhanced quality of life (Sharp et al.,

2010). Despite the many benefits that complementary therapies, and reflexology in particular, may offer patients, there are barriers to accessibility. One barrier is cost; complementary therapy nonusers are more likely to be unemployed than users (Wyatt, Sikorskii, Wills, & Su, 2010). Another barrier to treatment is ill health, which may keep patients homebound and unable to access these treatments.

0.2. Caregiver-delivered foot reflexology

A safe and feasible way to address these barriers and increase social support for patients is the involvement of lay caregivers as providers of reflexology (Wyatt, Sikorskii, Siddiqi, & Given, 2007). Reflexology provided to patients by lay caregivers resulted in reduced pain (Stephenson, Swanson, Dalton, Keefe, & Engelke, 2007), anxiety (Quattrin et al., 2006; Stephenson et al., 2007), and fatigue (Kohara et al., 2004). The lay caregiver can also deliver reflexology in the patient's home, making it highly accessible and reducing barriers to recruitment due to distance to care cited in other dyadic cancer research (e.g., Fredman et al., 2009). Another benefit to patients is increased social support, which is associated with better social adjustment (e.g., Friedman et al., 2006) and physical functioning (Turner-Cobb, Sephton, Koopman, Blake-Mortimer, & Spiegel, 2000) for breast cancer patients.

Caregivers may or may not benefit from delivering reflexology. The literature is mixed on the positive versus negative aspects of caregiving. Many caregivers find supporting the patient to be a personal benefit, whereas others find it an excessive burden (e.g., Cohen, Colantonio, & Vernich, 2002; Girgis et al., 2013). Research indicates that despite wanting to have an active role in the patient's care, some caregivers have a lack of confidence in their ability to help manage cancer symptoms (Keefe et al., 2003; Stephenson, Dalton, & Carlson, 2003). As suggested by Stephenson et al. (2007), training caregivers in proper reflexology techniques can provide them with the opportunity to help control the patient's symptoms, discuss symptom management, set goals, and make decisions for care.

Previous research on recruitment for reflexology studies with a practicing reflexologist resulted in high consent rates, between 76 and 80%, among eligible participants (Stephenson et al., 2003; Wyatt et al., 2012). Other complementary therapy studies using a variety of therapies have experienced similar participation rates (e.g., Sikorskii, Wyatt, Siddiqi, & Tamkus, 2011; Wyatt et al., 2007; Zick et al., 2012). However, these studies required consenting only one person, the patient, since the therapy was delivered by a practicing therapist or self-administered. When reflexology is provided by a lay caregiver, however, new challenges to recruitment and study completion may arise since both the patient and lay caregiver need to be recruited (Stephenson et al., 2007). The purpose of this work is to highlight the experience of recruiting advanced breast cancer patients and their lay caregivers into a caregiver-provided reflexology RCT. The research questions are:

- RQ1 What is the rate of patient ineligibility due to caregiver unavailability, and what specific reasons do patients provide for caregiver unavailability?
- RQ2 What is the rate of consent to the study?
- RQ3 What reasons do patients provide for refusal to participate?

1. Methods

1.1. Study overview

The ongoing two-group RCT from which the sample for this paper was derived will ultimately enroll 234 dyads where the friend/family caregiver provides foot reflexology to the patient in the home setting. The investigators' university and all study sites have granted human subjects approval for the study.

1.2. Sample

The study has currently enrolled 120 women with advanced breast cancer receiving or hormonal therapy/or hormonal therapy (Wyatt, Sikorskii, Holmstrom, & Luo, 2011–2016). Patient inclusion criteria are: (1) age 21 or older; (2) diagnosis of stage III or IV breast cancer; (3) able to perform basic activities of daily living; (4) received at least the first dose of chemotherapy or hormonal therapy; (5) able to speak and understand English; (6) have access to a telephone; (7) able to hear normal conversation; (8) cognitively oriented to time, place, and person (determined by nurse recruiter); and (9) have a lay caregiver willing to participate. Exclusion criteria are: (1) documented diagnosis of major mental illness and verified by the nurse recruiter; (2) nursing home residency; (3) bedridden; (4) currently receiving regular reflexology; or (5) diagnoses of deep vein thrombosis or painful foot neuropathy. The inclusion criteria for friend/family lay caregivers are: (1) age 18 or older; (2) able and willing to provide the 30-minute protocol for 4 consecutive weeks; (3) able to speak and understand English; (4) have access to a telephone; (5) able to hear normal conversation; and (6) cognitively oriented to time, place, and person (determined by nurse recruiter). Exclusion criterion is unwillingness or inability to perform a return demonstration of the protocol with $\geq 90\%$ accuracy according to training procedures (Wyatt et al., 2011–2016).

1.3. Sampling method and data collection

Nurse recruiters for the study are employed at one of the seven Midwestern oncology clinics involved in the study, although they do not provide direct care. Their recruiter training protocol includes a script, didactic information, role-playing, problem cases, and return-demonstration. After health-related eligibility is determined via the medical record, patients are approached by the nurse recruiter at the clinic who uses a script to introduce the study, including that patients have a 50–50 chance of being in one of two groups: one involving four weekly 30-minute reflexology sessions delivered by one of their friends or a family members in their home plus 4 weekly symptom calls, or a group that receives only the 4 weekly symptom calls. Patients are given a consent packet with a self-addressed stamped envelope for return of both consent forms to the nurse recruiter. Friend/family caregivers are not contacted by the staff until the patient consents. Patients who indicate a lack of caregiver are recorded as ineligible. Those who are ineligible, as well as eligible patients who refuse, may elect to provide reasons from a forced-choice menu or add an open-ended comment. Lay caregivers in the intervention group receive two standardized training sessions in the home by a study reflexologist that include 9 reflexes based on the Ingham Method of reflexology. Training sessions last up to 2 hours, depending on the needs of the individual caregiver. This protocol was previously established (Wyatt et al., 2012). A return demonstration checklist ensures treatment consistency. To date friend and family caregivers have been able to achieve protocol proficiency at 90% immediately after training and at the follow-up quality assurance check (Wyatt et al., 2011–2016).

2. Results

Demographic information for consented participants is summarized in Table 1. Of the 551 patients approached, 116 (29.29%) were ineligible due to caregiver-related reasons. Of the 116 patients ineligible for caregiver-related reasons, 38 (32.76%) indicated that they had no caregiver at all; 19 (16.38%) had a caregiver who refused participation; 16 (13.79%) had a caregiver who was unable to participate due to issues of time, distance, etc.; 11 (9.48%) did not want to bother her caregiver by asking him/her to participate; one (0.8%) indicated multiple caregiver-related reasons; and 31 (26.72%) did not provide a more specific response (RQ1).

Download English Version:

<https://daneshyari.com/en/article/5868199>

Download Persian Version:

<https://daneshyari.com/article/5868199>

[Daneshyari.com](https://daneshyari.com)