



Published in final edited form as:

Appl Nurs Res. 2016 February ; 29: 136–139. doi:10.1016/j.apnr.2015.05.019.

Dyadic Recruitment in Complementary Therapy Studies: Experience from a Clinical Trial of Caregiver-Delivered Reflexology

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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.

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Keywords

breast cancer; caregivers; nursing role in home care; reflexology; dyadic enrollment

Dyadic Recruitment in Complementary Therapy Studies: Experience from a Clinical Trial of Caregiver-Delivered Reflexology

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 is little data on their response to taking on specific symptom management interventions for the patient.

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).

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.

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 percent, 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?

Methods

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.

Sample

The study has currently enrolled 120 women with advanced breast cancer receiving chemotherapy and/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 > 90% accuracy according to training procedures (Wyatt et al., 2011–2016).

Sampling Method and Data Collection

Nurse recruiters for the study are employed at one of the seven Midwestern oncology clinics involved in the study, though 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 two 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).

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).

Of the eligible participants approached ($N = 435$), 153 consented, resulting in a 35.17% consent rate (RQ2). The most common reason for refusal was that the patient was too busy (33.33%). Less common reasons for refusal included being too sick (4.61%) or overwhelmed by the prospect of research (3.83%) (see Table 2 for all refusal reasons) (RQ3).

Discussion

The difficulties in identifying and recruiting eligible late-stage breast cancer patients and their lay caregivers into an RCT of caregiver-delivered foot reflexology pose potentially negative implications for patients, caregivers, clinicians and researchers. Strategies to enhance enrollment are needed to recruit these important dyads that represent the future of home-based health care.

Effects of Dyadic Recruitment on Eligibility

For patients to be eligible to participate in the current study, they must have a caregiver who is willing to participate. A third of otherwise eligible patients indicated they had no caregiver available, which is problematic. Lay caregivers are highly important to female cancer patients undergoing treatment (Ockerby, Livingston, O'Connell, & Gaskin, 2013). In addition, socially isolated women have a higher risk of mortality following a breast cancer diagnosis (Kroenke, Kubansky, Schernhammer, Holmes, & Kawachi, 2006).

For caregivers who refused, emphasizing the value of the intervention and the potential for both members of the dyad to benefit from the provision of this form of social support may be a useful strategy (see Quinn, Dunbar, Clark, & Strickland, 2010). Reminding the patient that caregivers may be interested in productive ways to help with symptom management may be effective for patients who do not want to burden their caregivers by asking them to deliver reflexology (Keefe et al., 2003; Stephenson et al., 2003).

One option to overcoming the barrier to an available friend or family caregiver would be a study design that allows for volunteer lay caregivers to deliver the intervention. Many organizations draw upon volunteerism as a resource to enhance their mission; perhaps researchers can consider this option in the future.

Consent Rates and Refusal Reasons

The current rate of consent of eligible patients in this study subsample is considerably lower than the rates of consent for studies employing a practicing reflexologist (Stephenson et al., 2003; Wyatt et al., 2012). The most common refusal reason once eligibility was determined was being "too busy," a reason found to be common in a trial with practicing reflexologists (Wyatt et al., 2012). Surprisingly, since this subsample is composed of advanced breast

cancer patients where the majority have metastasis, few cited being too sick as a reason for refusal, which is consistent with the findings of an RCT of foot reflexology provided by a practicing reflexologist (Sikorskii et al., 2011). Finally, it is worth noting that less than 20% of patients refused due to not being interested in complementary therapies, a finding consistent with the increasing popularity of these therapies (Boon et al., 2007). Better informing both patients and lay caregivers of the benefits, including patient symptom management and social support for the dyad, may further increase consent rates.

Limitations and Future Directions

One limitation of the current research is a lack of demographic and clinical information on most patients who were ineligible or refused to participate. For example, patients who cited that their caregiver refused participation may have been particularly sick, and their caregivers were too overwhelmed by other tasks (e.g., bathing) to participate. In addition, approximately one-third of the caregiver-related refusal reasons are unknown, and no data from caregivers themselves was collected. In future research, further probing by recruiters may help clarify these reasons and assist the patient in identifying caregivers.

While the present study has experienced many of the barriers mentioned, consideration of the recommendations is also underway. Lay caregivers are a largely untapped resource in the advancement of symptom management in the home, and research indicates that foot reflexology provided by a layperson reduces symptoms in cancer patients (Kohara et al., 2004; Quattrin et al., 2006; Stephenson et al., 2007; Wyatt et al., 2012). This report on strategies for overcoming barriers and challenges to dyad enrollment in an RCT has implications that inform both researchers and clinicians, including the need to further address social support, as therapies like reflexology become more widely used for symptom management.

Acknowledgments

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.

References

- Boon HS, Olatunde F, Zick SM. Trends in complementary/alternative medicine use by breast cancer survivors: Comparing survey data from 1998 and 2005. *BMC Women's Health*. 2007; 7:4. [PubMed: 17397542]
- Cohen CA, Colantonio A, Vernich L. Positive aspects of caregiving: Rounding out the caregiver experience. *International Journal of Geriatric Psychiatry*. 2002; 17:184–188. [PubMed: 11813283]
- Family Caregiver Alliance. Caregiver Assessment: Voices and views from the Field. Report from a National Consensus Development Conference (Vol. II); San Francisco. 2006.
- Fredman SJ, Baucom DH, Gremore TM, Castellani AM, Kallman TA, Porter LS, Carey LA. Quantifying the recruitment challenges with couple-based interventions for cancer: Applications to early-stage breast cancer. *Psycho-Oncology*. 2009; 18:667–673. [PubMed: 19061201]
- Friedman LC, Kalidas M, Elledge R, Chang J, Romero C, Husain I, Liscum KR. Optimism, social support and psychosocial functioning among women with breast cancer. *Psycho-Oncology*. 2006; 15:595–603. [PubMed: 16287209]

- Girgis A, Lambert SD, McElduff P, Bonevski B, Lecathelinais C, Boyes A, Stacey F. Some things change, some things stay the same: A longitudinal analysis of cancer caregivers' unmet supportive care needs. *Psychooncology*. 2013; 22:1557–1564. [PubMed: 22941765]
- Keefe FJ, Ahles TA, Porter LS, Sutton LM, McBride CM, Pope MS, Baucom DH. The self-efficacy of family caregivers for helping cancer patients manage pain at end-of-life. *Pain*. 2003; 103:157–162. [PubMed: 12749970]
- Kohara H, Miyauchi T, Suehiro Y, Ueoka H, Takeyama H, Morita T. Combined modality treatment of aromatherapy, footsoak, and reflexology relieves fatigue in patients with cancer. *Journal of Palliative Medicine*. 2004; 7:791–796. [PubMed: 15684846]
- Kroenke CH, Kubansky LD, Schernhammer ES, Holmes MD, Kawachi I. Social networks, social support, and survival after breast cancer diagnosis. *Journal of Clinical Oncology*. 2006; 24:1105–1111. [PubMed: 16505430]
- McMillan S, Weitzner M. Methodologic issues in collecting data from debilitated patients with cancer near the end of life. *Oncology Nursing Forum*. 2003; 30:123–129. [PubMed: 12515990]
- Ockerby C, Livingston P, O'Connell B, Gaskin CJ. The role of informal caregivers during cancer patients' recovery from chemotherapy. *Scandinavian Journal of Caring Sciences*. 2013; 27:147–155.
- Quattrin R, Zanini A, Buchini S, Turello D, Annunziata MA, Vidotti C, Brusaferrero S. Use of reflexology foot massage to reduce anxiety in hospitalized cancer patients in chemotherapy treatment: Methodology and outcomes. *Journal of Nursing Management*. 2006; 14:96–105. [PubMed: 16487421]
- Quinn C, Dunbar SB, Clark PC, Strickland OL. Challenges and strategies of dyad research: Cardiovascular examples. *Applied Nursing Research*. 2010; 23:e15–e20. [PubMed: 20420989]
- Reinhard, SC.; Given, B.; Petlick, NH.; Bemis, A. Supporting family caregivers in providing care. In: Hughes, RG., editor. *Patient safety and quality: An evidence-based handbook for nurses*. Rockville, MD: Agency for Healthcare Research and Quality; 2008. p. 341–404.
- Sharp DM, Walker MB, Chaturvedi A, Upadhyay S, Hamid A, Walker AA, Walker LG. A randomised, controlled trial of the psychological effects of reflexology in early breast cancer. *European Journal of Cancer*. 2010; 46:312–322. [PubMed: 19906525]
- Sikorskii A, Wyatt G, Siddiqi A, Tamkus D. Recruitment and early retention of women with advanced breast cancer in a complementary and alternative medicine trial. *Evidence-Based Complementary Alternative Medicine*. 2011; 1:1–7.
- Stephenson NL, Dalton J, Carlson J. The effect of foot reflexology on pain in patients with metastatic cancer. *Applied Nursing Research*. 2003; 16:284–286. [PubMed: 14608562]
- Stephenson NL, Swanson M, Dalton J, Keefe FJ, Engelke M. Partnerdelivered reflexology: Effects on cancer pain and anxiety. *Oncology Nursing Forum*. 2007; 34:127–132. [PubMed: 17562639]
- Turner-Cobb JM, Sephton SE, Koopman C, Blake-Mortimer J, Spiegel D. Social support and salivary cortisol in women with metastatic breast cancer. *Psychosomatic Medicine*. 2000; 62:337–345. [PubMed: 10845347]
- Watson, S.; Voner, V. *Practical reflexology: Interpretation and techniques*. New York, NY: McGraw-Hill; 2008.
- Wyatt G, Sikorskii A, Rahbar MH, Victorson D, You M. Health-related quality-of-life outcomes: A reflexology trial with patients with advanced-stage breast cancer. *Oncology Nursing Forum*. 2012; 39:568–577. [PubMed: 23107851]
- Wyatt G, Sikorskii A, Siddiqi A, Given CW. Feasibility of a reflexology and guided imagery intervention during chemotherapy: Results of a quasi-experimental study. *Oncology Nursing Forum*. 2007; 34:635–642. [PubMed: 17573322]
- Wyatt G, Sikorskii A, Wills CE, Su H. Complementary and alternative medicine use, spending, and quality of life in early stage breast cancer. *Nursing Research*. 2010; 59:58–66. [PubMed: 20010046]
- Zick SM, Wyatt GK, Murphy SL, Arendt JT, Sen A, Harris RE. Acupressure for persistent cancer-related fatigue in breast cancer survivors (AcuCrft): A study protocol for a randomized controlled trial. *BMC Complementary and Alternative Medicine*. 2012; 12:132. [PubMed: 22909076]

Table 1

Demographic and Clinical Characteristics of Consented Patients and Caregivers

| Characteristic | Patients (n = 120) | Caregivers (n = 82) |
|--|---------------------------|----------------------------|
| <u>Age</u> | <u>Mean (sd)</u> | <u>Mean (sd)</u> |
| Age | 54.4 (14.2) | 52.7 (13.3) |
| <u>Race</u> | <u>Number (%)</u> | <u>Number (%)</u> |
| White | 102 (85.0) | 69 (84.2) |
| Black or African American | 16 (13.4) | 9 (11) |
| Asian | 1 (0.8) | 2 (2.4) |
| Refused | 1 (0.8) | 2 (2.4) |
| <u>Ethnicity</u> | | |
| Hispanic or Latino | 4 (3.3) | 2 (2.4) |
| Not Hispanic or Latino | 116 (96.7) | 79 (96.4) |
| Refused | 0 (0) | 1 (1.2) |
| <u>Sex</u> | | |
| Male | 0 (0) | 43 (52.4) |
| <u>Marital Status</u> | | |
| Never Married | 16 (13.3) | 9 (11) |
| Married or Living with Partner | 83 (69.2) | 66 (80.5) |
| Divorced/Separated | 14 (11.7) | 2 (2.4) |
| Widowed | 7 (5.8) | 5 (6.1) |
| <u>Employment</u> | | |
| Full Time | 21 (17.5) | 40 (48.8) |
| Part Time | 13 (10.8) | 11 (13.4) |
| Not Employed | 77 (64.2) | 20 (24.4) |
| Other | 9 (7.50) | 11 (13.4) |
| <u>Metastasis</u> | | |
| No | 48 (40) | |
| Yes | 72 (60) | |
| <u>Cancer Recurrence</u> | | |
| No | 75 (62.5) | |
| Yes | 35 (29.2) | |
| Missing | 10 (8.3) | |
| <u>Caregiver Relationship to Patient</u> | | |
| Spouse/Partner | 66 (55) | |
| Parent/Step Parent | 7 (5.8) | |
| Sister/Step Sister/Brother/Step Brother | 2 (1.7) | |
| Daughter In Law/Son In Law | 3 (2.5) | |
| Aunt/Uncle | 4 (3.3) | |
| Daughter/Step Daughter/Son/Step Son | 22 (18.4) | |
| Friend | 12 (10) | |
| Other | 4 (3.3) | |

| Characteristic | Patients (n = 120) | Caregivers (n = 82) |
|--|--------------------|---------------------|
| <u>Residential Status of Caregiver</u> | | |
| Living with patient | | 35(65) ^a |

Note.

^aPercentage based on the 54 caregivers who provided this information

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Table 2

Patient-Reported Refusal Reasons

| Refusal reason | Frequency | Percent of refusals |
|-------------------------------------|-----------|---------------------|
| Too busy | 94 | 33.33 |
| Not interested in CAM | 54 | 19.15 |
| Foot concerns | 43 | 15.25 |
| Other reasons | 43 | 15.25 |
| Not interested in research | 35 | 12.41 |
| No reason provided | 27 | 9.57 |
| Too sick | 13 | 4.61 |
| Does not want to be interviewed | 12 | 4.26 |
| Overwhelmed by prospect of research | 11 | 3.90 |
| Physician refusal | 11 | 3.90 |

Note. $N = 282$. Patients could report multiple refusal reasons.

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