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Feasibility of a Reflexology and Guided Imagery Intervention During Chemotherapy: Results of a Quasi-Experimental Study

Gwen Wyatt, PhD, RN, Alla Sikorskii, PhD, Azfar Siddiqi, PhD, and Charles W. Given, PhD

Purpose/Objectives: To evaluate patient characteristics to predict selection and maintenance of a complementary therapy and the feasibility of a randomized clinical trial (RCT) of complementary therapies.

Design: Quasi-experimental, exploratory study, unblinded and nonrandomized.

Setting: A comprehensive cancer center in Michigan.

Sample: 96 patients undergoing chemotherapy, predominantly Caucasian women.

Methods: Consenting patients with caregivers could choose a reflexology, guided imagery, guided imagery plus reflexology, or interview-only group. Patients without caregivers were restricted to guided imagery or interview-only groups. Data on demographics, depression, anxiety, and functional status were collected using established instruments.

Main Research Variables: Quality of life (QOL) and patient characteristics in relation to complementary therapy choice.

Findings: Patients who chose a complementary therapy rather than an interview only tended to be older and in worse health and had higher percentages of lung cancer, late-stage cancers, higher anxiety, depressive symptoms, and physical limitations at baseline. Patients lost from the guided imagery and guided imagery plus reflexology groups had greater symptom severity, depressive symptoms and anxiety, and worse physical and emotional well-being than those lost from the reflexology group.

Conclusions: Patient characteristics influence choice of complementary therapies, highlighting the need for RCTs to evaluate the true effect of complementary therapies on the QOL of patients with cancer. Further research on complementary therapies can help healthcare providers identify patients who are likely to benefit most by addressing nursingsensitive outcomes.

Implications for Nursing: An RCT of reflexology as a single therapy for females with breast cancer is most feasible compared to other complementary therapies.

otivated by the desire to become active participants in their treatment, patients with cancer are increasingly turning to complementary therapies (Wyatt, Friedman, Given, Given, & Beckrow, 1999). Studies show that complementary therapies are used by 60%–80% of patients with cancer (Boon et al., 2000; Richardson, Sanders, Palmer, Greisinger, & Singletary, 2000). Individuals interested in complementary therapies often use them in hopes of augmenting the efficacy of the treatment they receive from their conventional healthcare providers (Eisenberg et al., 1998; Guzzetta, 1996; Jonas, 1998). Complementary therapies are defined as treatments used in addition to conventional care as a complement or supplement (Cassileth, 2000). Alternative therapies are used in the place of conventional health care (Harpham, 2001). The

Key Points . . .

- Selection of the appropriate complementary therapy for patients is critical.
- Feasibility work should be done before investing in a fullscale randomized clinical trial of any complementary therapy.
- Complementary therapy research can meet the same "gold standard" as other clinical trials with a carefully thought-out design.

phrase "complementary and alternative medicine" also is used commonly, as is "integrative therapies," but because the present study focuses only on supplemental therapies, the appropriate phrase is complementary therapies.

To contribute to the body of knowledge on complementary therapies, this quasi-experimental exploratory study evaluated the types of patients with cancer most inclined to participate in complementary therapies, the strength of self-selected therapies to maintain patient involvement over time, and the feasibility for use in a randomized clinical trial (RCT). The goal of this article is to demonstrate the need for RCTs through a descriptive study and current literature. Quasi-experimental research lays the necessary groundwork for the next RCT. Participant characteristics that were outcome variables of interest included quality-of-life (QOL) domains and related variables that may affect QOL for patients with cancer as they move through the course of treatment. Participants could select to be in one of four groups: a guided imagery group (with or without a family caregiver), a reflexology group (with a family caregiver), a guided imagery plus reflexology group (with a family caregiver), or participation only in interviews without taking part in a complementary therapy. Patients' demographic characteristics, QOL, and illness-related variables were evaluated in relation to

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patient choices, whether patients completed the study to evaluate characteristics that predict selection and maintenance of specific complementary therapies, and feasibility considerations when planning an RCT from pilot work.

This article extends the findings discussed in a previous publication of the data (Kozachik, Wyatt, Given, & Given, 2006). Specifically, the study attempted to determine what characteristics were associated with group selection and continued involvement in the study and the feasibility of an RCT involving complementary therapies.

Literature Review

Much of the current literature focuses on the efficacy of complementary therapies among patients with cancer but has not addressed specific characteristics of patients who choose and maintain a therapy or which therapies are most appealing. Characteristics of interest (i.e., QOL domains, anxiety, depression, and demographics), which move beyond descriptive reports, first must be considered through quasi-experimental work before embarking on a full-scale RCT.

Current literature addresses demographic characteristics of patients with cancer who use complementary therapies without an emphasis on which therapies were used for which population of patients. Diefenbach et al. (2003) conducted a survey of 417 men with prostate cancer and found that the initiation of complementary therapies was associated with being a member of an ethnic minority group and having a higher level of education. Kumar et al. (2002) reported on a retrospective, secondary review of data and found that of patients in treatment, Caucasians aged 60 years and older were the principal users of what they referred to as complementary and integrative nutritional therapies. Cassileth and Vickers (2005) summarized existing surveys and reported that the best predictors of complementary therapies among patients with cancer were being female, better educated, of higher socioeconomic status, and younger.

A few authors described some of the psychosocial needs that may be associated with complementary therapy use. Davidson, Geoghegan, McLaughlin, and Woodward (2005) found that patients' use of complementary therapies fulfills an important psychological need. Further evidence of the connection between complementary therapy use and relief of psychological distress and physical symptoms was found by Lengacher et al. (2006).

Factors associated with patients' continued participation in complementary therapies are not well addressed in the literature. Evaluating the willingness of patients to maintain an eight-week program of complementary therapies is critical in beginning to address which complementary therapy to select for patients. Determining sufficient dosage for a desired effect also is necessary. The only report identified that provided information on continued participation factors indicated that participation in a complementary therapy did not decrease adherence to conventional medical treatment (Feldman et al., 2004). The finding is a key point because complementary therapies are intended to serve as an enhancement to conventional care and not a replacement; however, the literature did not address the maintenance of a recommended complementary therapy protocol.

Fonteyn and Bauer-Wu (2005) discussed the high cost of implementing complementary therapy studies and the need for rigorous testing. They suggested that preliminary work can provide rich and detailed information that will save time and cost in a larger-scale study. Rodeheaver, Taylor, and Lyon (2003) further supported the need for an RCT aimed at testing the efficacy of complementary therapies.

Overall, the descriptive literature has documented a high rate of complementary therapy use by patients with cancer, the demographic characteristics of the patients, and the most commonly used therapies. However, the literature has not yet incorporated a quasi-experimental design to link a more comprehensive set of patient characteristics (e.g., QOL, anxiety levels, depressive symptoms, demographic characteristics) with specific therapy selection, maintenance, and feasibility issues associated with an RCT. The analyses used the next design step in the evidence hierarchy (Management of Cancer Pain Guideline Panel, 1994) as well as demographic, psychosocial, and physical characteristics of patients with cancer who do and do not maintain a self-selected complementary therapy protocol.

Conceptual Framework

The Wyatt QOL Model (Wyatt & Friedman, 1996) (see Figure 1) was used in the current study. The model is holistic in that it acknowledges the interaction of physical, psychological, social, and spiritual QOL domains. The study included all domains of the model through the outcome variables, such as physical well-

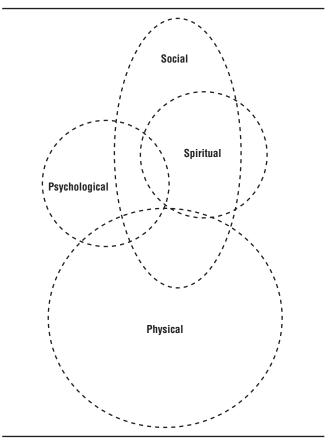


Figure 1. Wyatt Quality-of-Life Model Interaction and Proportion of Quality-of-Life Domains

Note. From "Development and Testing of a Quality-of-Life Model for Long-Term Female Cancer Survivors," by G.K. Wyatt and L.L. Friedman, 1996, *Quality of Life Research, 5,* p. 391. Copyright 1996 by Springer Science and Business Media. Reprinted with permission.

being (physical), anxiety (psychological), family relationships (social), and existential beliefs (spiritual). However, in this report of the study, only the physical, social, and psychological domains are incorporated in addition to demographic variables.

Methods

Eligibility

To participate in the study, patients had to be aged 21 years or older, be able to perform activities of daily living, have no documented history of mental illness, be able to speak English and communicate on the telephone, and currently be receiving chemotherapy. Patients in hospice or institutionalized, bedridden, or undergoing bone marrow transplantation were excluded. Patients with cancer using complementary therapy modalities similar to the ones prescribed in the study's protocol were ineligible to participate. Patients who were using complementary therapies different from the ones prescribed in the study's protocol were eligible, and data on their complementary therapy use at baseline were collected.

Recruitment

Participants were recruited for the study through convenience sampling at a comprehensive cancer center in Michigan. A nurse recruiter approached eligible participants (based on chart review) and informed them of the study. Interested patients were asked about the availability of family caregivers who could participate in the study with them and be trained to implement the reflexology therapy at home. Patients without caregivers were not excluded but were limited to guided imagery that could be done independently. Participants also could elect to take part only in interviews. The study was approved by the institutional review boards of Michigan State University and the participating site.

Intervention

To target complementary therapies selected for the project, an informal patient survey was distributed to 34 patients at the study site. The survey asked patients to rank 17 complementary therapies that they would like to have offered at their cancer clinics. Guided imagery and reflexology were selected based on the informal survey and because beginning evidence is available of the efficacy of guided imagery and reflexology related to several variables of interest that affect QOL (Burish, Carey, Krozely, & Greco, 1987; Burish & Jenkins, 1992; Burish, Snyder, & Jenkins, 1991; Hodgson, 2000; Kolcaba & Fox, 1999; Richardson et al., 2000; Stephenson, Weinrich, & Tavakoli, 2000). A unique aspect of the study was that patients were allowed to self-select the therapy in which they would participate. The intent was to glean as much information about preference as possible from the pilot work to learn which patients would agree to participate and maintain enrollment in an RCT.

A generic definition of guided imagery is that it uses soothing mental images (Moore & Spiegel, 2000). The complementary therapy modality is used to facilitate relaxation and to address pain and anxiety associated with cancer (Lang & Pratt, 1994; Spiegel, 1993). Reflexology is a deep massage targeted at reflex points on the palms of the hands and soles of the feet; the reflex points are theorized to correspond with major organs in the body (Kastner & Burroughs, 1996).

Participation in the complementary therapy protocol included completion of one or both of the aforementioned

therapies and taking part in five scheduled encounters with an intervention nurse at two-week intervals. The details of the protocol are presented in Tables 1 and 2. The interview-only patients participated in two interviews.

Data Collection

Data were collected by telephone interviews at the beginning of the study before the complementary therapy intervention was initiated as well as 10 weeks after baseline when all intervention encounters were complete. Interviews were approximately 35 minutes long and scheduled for a time convenient for patients and interviewers. Interviews were conducted over the phone by trained interviewers. Participants were called at home and interviewers were located at the research office. All instruments were used for each telephone interview. Demographic data were

Table 1. Protocol for Reflexology

Session	Form of Contact	Length (Minutes)	Protocol
1	In person at the clinic	45–60	Patients and family caregivers were informed about reflexology. Family caregivers were taught to perform a foot massage technique, lasting for 20 minutes, by nurses trained by the reflexologist. ^a Family caregivers were given a demonstration by nurses, including how to find a comfortable position to elevate the foot. Family caregivers watched a video of steps. The steps were developed
			so that family caregivers could learn them easily and carry them out at home. Family caregivers gave nurses a return demonstration.
			Patients and family caregivers were instructed to take 20 minutes per week to conduct a session at home.
			Patients and family caregivers were provided with an instruction sheet of the steps of the sessions.
2 and 4	Telephone	10–15	Nurses called patients and family caregivers to provide encour- agement for maintaining foot sessions.
0	In naroon	15 00	Nurses assessed self-reported ad- herence and technique questions.
3	In person at the clinic	15–20	Family caregivers demonstrated a foot session to nurses. Patients and family caregivers were encouraged to ask questions about foot sessions.
5	In person	10–15	Nurses assessed self-reported adherence. Nurses assessed self-reported ad- herence and answered questions about reflexology and the project.

^a The caregiver is not expected to perform reflexology as well as certified reflexologists. The technique was developed by Barbara Brower (2000), CPR, based on the Ingham Method of Reflexology. Brower has been a practitioner and educator of reflexology for 25 years.

Table 2. Protocol for Guided Imagery

Session	Form of Contact	Protocol	
1	In person at the clinic	45–60	Patients and family caregivers were given a cassette tape. Patients listened to the tape designed for chemotherapy recipients. Family caregivers listened to the tape designed as a general wellness tape. Both cassette tapes are 20 min- utes long and have a calm musical background. ^a Nurses demonstrated how to use the tape in the recorder and had the patients and fam- ily caregivers return the dem- onstration. Patients and family caregivers were instructed to take the tape home, listen to it daily,
2 and 4	Telephone	10–15	and record frequency of use. Nurses called patients and fam- ily caregivers to encourage the use of the tape. Nurses recorded the self-report of adherence. Nurses assessed technique ques- tions (e.g., hearing problems resulting from a noisy room). Nurses assessed self-reported
3	In person at the clinic	15–20	adherence. Patients and family caregivers demonstrated their use of the tapes. Patients and family caregivers were encouraged to ask ques- tions about the use of tapes or problems encountered (e.g., trouble finding time or quiet place to listen). Nurses assessed self-reported adherence.
5	In person at the clinic	10–15	Nurses assessed self-report adherence and answered any questions about the tapes or project.

^a The tapes were produced by Health Journeys and incorporate the voice of Belleruth Naparstek (1998), MA, LISW. Naparstek has practiced psychotherapy for more than 25 years, teaches at Case Western Reserve University in Hudson, OH, and is the author of the book, *Staying Well With Guided Imagery* (1995).

collected at baseline. Every tenth interview was tape-recorded and checked for quality assurance. Although the rate of adherence can be evaluated objectively with interviews, the actual home use of the therapies was self-reported. The researchers assumed that if participants were continuing with the interview process, they had adhered to therapy protocol.

Measures

Demographics included age, gender, race, level of education, marital status, site and stage of cancer, and presence of a family caregiver. Depressive symptomatology was measured using the **Centers for Epidemiological Studies–Depression 20 Scale (CES-D)** (Radloff, 1977). The scale is scored from a range of 0–60. The Cronbach's alpha coefficient for the scale was 0.90. The instrument tapped the psychological domain of the conceptual model.

The **State-Trait Anxiety Inventory** is a self-report scale for measuring state and trait anxiety (Spielberger, Gorsuch, Lushene, Vagg, & Jacobs, 1983). The scale is scored on a 20–80 range, with higher scores indicating higher levels of anxiety. The Cronbach's alpha coefficient was 0.95. The scale addressed the psychological domain of the conceptual model.

The Functional Assessment of Cancer Therapy–General (FACT-G) is a commonly used 29-item instrument made up of five subscales that measure QOL in patients with cancer (Cella & Bonomi, 1994). The FACT-G has a range of 0–116, with higher scores indicating higher levels of well-being on each subscale as well as for the total score. The Cronbach's alpha coefficients for physical, emotional, and functional well-being subscales exceeded 0.80. The instrument provided information on physical, social, and psychological participant characteristics.

Analytical Approaches

Chi-square tests were used to compare the participants in the four groups with respect to categorical variables. One-way analysis of variance (ANOVA) was used to compare the means of the variables in the four groups. When ANOVA resulted in significant differences among four groups, pairwise comparisons of each group were performed using Duncan's multiple range tests (Montgomery, 1997) to clarify which group(s) differed from others. Statistical tests were two-sided. Analysis was performed using SAS software.

Results

Of patients screened, 376 were eligible for the study, but only 100 patients chose to participate. Eighty participants had signed consent forms from family caregivers. Reasons cited by patients for not participating included being too ill (n = 19, 7%), feeling overwhelmed by research (n = 10, 4%), not wanting to be interviewed (n = 14, 5%), being too busy (n = 38, 13%), having no interest in complementary therapy (n = 126, 46%), having their families refuse participation (n = 5, 2%), or other unspecified reasons (n = 64, 23%). Ninety-six patients (96%) completed the baseline interview, of which 22 (23%) elected to use guided imagery, 40 (41%) guided imagery plus reflexology, 21 (22%) reflexology, and 13 (14%) to participate in interviews only. All patients in the reflexology and guided imagery plus reflexology groups had family caregivers, 12 patients (55%) in the guided imagery group had caregivers, and 4 patients (31%) in the interview-only group had caregivers. Figure 2 summarizes the number of patients enrolled and lost at each step.

Characteristics Associated With Group Selection

Table 3 provides a summary of participants' demographics. Of the 96 patients who completed the baseline interview, 69% were women, and the distribution of gender did not differ in the four groups. Distributions of race and marital status also were the same in the four groups. The guided imagery plus reflexology and reflexology groups had similar site of cancer distribution with 8% and 10%, respectively, of patients in the groups having lung cancer. No patients in the interview-only

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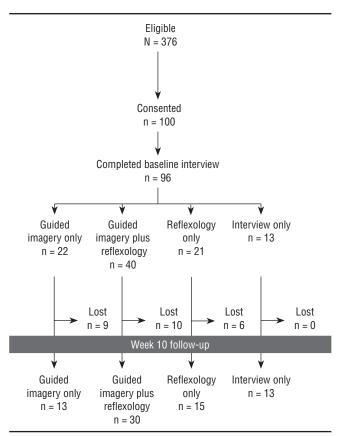


Figure 2. Flowchart of the Study

group and 27% of patients in the guided imagery group had lung cancer diagnoses. The percentages of patients with latestage cancers were 73% in guided imagery, 75% in guided imagery plus reflexology, 62% in reflexology, and 38% in the interview-only group. The interview-only group had a significantly lower mean age compared to the complementary therapy groups. The four groups had different level of education distributions. Most patients in the interview-only group (92%) had more than a high school education; the corresponding percentage in the guided imagery group was 36%.

Patients who chose to participate in guided imagery or guided imagery plus reflexology had significantly worse anxiety, CES-D, and FACT-G emotional well-being and total scores at baseline compared to patients who chose to participate in reflexology or interview only (see Table 4).

Characteristics Associated With Continued Involvement

The overall attrition rate was 26%, with 25 of 96 patients dropping out of the study from baseline to week 10. The 13 patients who chose not to participate in a complementary therapy completed a week 10 interview. The attrition rates in reflexology and guided imagery plus reflexology group were similar, 29% and 25% respectively. The highest attrition rate was in the guided imagery group, which lost 41% of patients from baseline to week 10. Patients who did not complete the week 10 interview did not differ in gender, level of education, marital status, and site and stage of cancer (see Table 5).

Patients who dropped out from reflexology, guided imagery plus reflexology, and guided imagery groups had some differences of statistical significance. Patients who dropped out from guided imagery and guided imagery plus reflexology groups had significantly higher anxiety and depressive symptoms, lower physical and emotional well-being, and total FACT-G scores at baseline than patients who dropped out from the reflexology group (see Table 6).

Feasibility of a Randomized Clinical Trial Including Complementary Therapy

With the small size of the interview-only group, multiple baseline differences to adjust for, and discrepancies in attrition, the analysis of differences in QOL outcomes in groups at week 10 would not produce reliable results and was not pursued. To be able to compare the effects of the complementary therapy on QOL outcomes, an RCT is needed. Of the complementary therapies considered in the study, guided imagery has the lowest potential of being tested successfully in an RCT. Guided imagery attracted patients with high levels of anxiety and low emotional well-being, yet it failed to retain patients. Participants who dropped out from the guided imagery group had mean FACT-G physical well-being scores of 16.22 versus 19.61 for participants retained (p = 0.03), emotional well-being scores of 12.44 versus 17.1 for participants retained (p = 0.07), and total FACT-G scores of 74.00 versus 85.85 for participants retained (p = 0.03). The results are summarized in Table 7.

In addition, high attrition among patients who chose guided imagery would make evaluation of the intervention effect

Table 3. Demographic and Disease Characteristics of the Participants in Four Groups

	Guided Imagery (N = 22)		lma Pi Refle	ded gery us xology : 40)		xology = 21)	Interview Only (N = 13)		
Characteristic	n	%	n	%	n	%	n	%	
Gender									
Male	7	32	15	38	5	24	3	23	
Female	15	68	25	63	16	76	10	77	
Race									
Caucasian	22	100	39	98	19	90	13	100	
Minorities	-	-	1	3	2	10	-	-	
Education									
Less than high school	4	18	1	3	1	5	-	-	
High school	10	45	9	23	10	48	1	8	
More than high school	8	36	30	75	10	48	12	92	
Marital status									
Unmarried	5	23	5	13	4	19	2	15	
Married	17	77	35	88	17	81	11	85	
Cancer site									
Gastrointestinal	4	18	10	25	3	14	2	15	
Breast	5	23	12	30	8	38	6	46	
Lung	6	27	3	8	2	10	-	-	
Blood and lymph	2	9	6	15	3	14	3	23	
Genitourinary	3	14	6	15	3	14	1	8	
Other sites	2	9	3	8	2	10	1	8	
Cancer stage									
Early	6	27	10	25	8	38	8	62	
Late	16	73	30	75	13	62	5	38	

Note. Because of rounding, not all percentages total 100.

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		ided gery	Image	ded ry Plus kology	Reflex	cology	Intervie		
Variable	X	SD	X	SD	X	SD	X	SD	р
Age	53.37	11.90	52.78	9.98	53.34	9.93	44.15	12.45	0.06
Anxiety score ^a	41.09	12.04	38.93	14.09	28.33	8.45	28.00	6.87	< 0.01
Depressive symptoms (CES-D score) ^a	18.27	10.72	17.88	11.33	10.33	7.70	10.15	7.32	< 0.01
FACT-G physical well-being score	18.23	3.85	16.90	6.30	21.81	4.64	18.85	6.12	0.01
FACT-G emotional well-being score ^a	15.18	5.93	16.50	4.88	21.10	3.27	19.69	2.63	< 0.01
FACT-G functional well-being score	18.86	3.82	19.60	4.55	21.33	4.25	22.31	4.23	0.06
FACT-G total score ^a	81.00	13.46	82.50	15.93	95.10	12.79	93.31	12.00	< 0.01

^aGuided imagery and guided imagery plus reflexology groups significantly differed from reflexology and interview-only groups. Guided imagery and guided imagery plus reflexology did not differ from each other. Reflexology and interview-only groups did not differ from each other, except in age.

CES-D—Centers for Epidemiological Studies–Depression; FACT-G—Functional Assessment of Cancer Therapy–General

problematic. In the study, reflexology seemed most promising for the possibility of being tested in an RCT. Patients who chose reflexology were comparable to those who chose interview only and had a moderate drop-out rate. Patients who dropped out from the reflexology group had mean baseline CES-D scores of 4.83 compared to 12.53 of patients who were retained (p < 0.01). Similarly, retained patients had worse emotional well-being than those who dropped out from the reflexology group. The results suggest that the reflexology group retained patients with worse outcomes who potentially needed an intervention and lost patients who had better outcomes at baseline.

Discussion

A higher percentage of women than men agreed to participate in the study. The finding confirms results from Richardson et al. (2000) and Cassileth (1999). The guided imagery group had a preponderance of patients with lung cancer potentially leading to more seriously ill patients in the group. The large number of patients with lung cancer in the guided imagery group may have contributed to the higher attrition. Of patients in complementary therapy groups, 62%-75% had late-stage cancer, whereas the interview-only group had 38% late-stage diagnoses. Astin (1998) found that patients with specific health problems were more likely to use complementary therapies; however, the health concerns mentioned in the report were back and urinary tract problems and chronic pain. Although some of the patients in the pilot with late-stage cancer may have had the symptoms reported by Astin, no clear parallel existed. The interview-only group was younger and had higher levels of education than complementary therapy groups, which differs from Cassileth (1999), who predicted that patients with those characteristics would be in one of the complementary therapy protocols. On the other hand, Richardson et al. found that indigent people were more likely to participate. The findings are linked loosely in that patients with less education were more likely to be in a complementary therapy group than in the interview-only group.

The interview-only group was healthier, younger, and more educated than patients who selected complementary therapies, which may imply that they had greater resources to draw from. Therefore, patients in the interview-only group may not have felt a need for the added support of complementary therapies. Patients who chose guided imagery alone or in combination had more symptoms and lower QOL at baseline than the other groups. Guided imagery may not be the best complementary therapy to recommend for patients with greater illness who may benefit more and maintain the protocol better with a touch therapy, such as reflexology.

Guided imagery may have attracted more very ill patients because the general public is aware that it does not require personal interaction and can be done anywhere. Patients who chose guided imagery may have found that they were too ill to

Table 5. Characteristics of Patients Lost to Follow-Up From Baseline to Week 10

	Im	iided agery = 9)	lmage Refle	ided ery Plus exology = 10)	Reflexology (N = 6)		
Characteristic	n	%	n	%	n	%	
Gender							
Male	3	33	6	60	3	50	
Female	6	67	4	40	3	50	
Race							
Caucasian	9	100	10	100	6	100	
Minorities	-	-	-	-	-	_	
Education							
Less than high school	2	22	-	_	_	_	
High school	4	44	5	50	2	33	
More than high school	3	33	5	50	4	67	
Marital status							
Unmarried	1	11	1	10	1	17	
Married	8	89	9	90	5	83	
Cancer site							
Gastrointestinal	2	22	3	30	2	33	
Breast	1	11	2	20	2	33	
Lung	4	44	-	_	1	17	
Blood and lymph	1	11	3	30	-	-	
Genitourinary	-	_	1	10	_	_	
Other sites	1	11	1	10	1	17	
Cancer stage							
Early	3	33	1	10	3	50	
Late	6	67	9	90	3	50	

Note. The interview-only group had no attrition.

Note. Because of rounding, not all percentages total 100.

Table 6. Mean Age, Symptoms, and Quality of Life of Patients Who Were Lost to Follow-Up

	Guided	Imagery		lmagery flexology	Reflex		
Variable	x	SD	X	SD	x	SD	р
Age (years)	51.53	11.90	54.02	10.19	51.05	8.39	0.82
Anxiety score ^a	43.78	7.31	37.90	13.17	24.33	5.39	< 0.01
Depressive symptoms (CES-D score) ^a	20.67	10.10	19.10	12.84	4.83	2.93	0.02
FACT-G physical well-being score ^a	16.22	3.96	15.00	6.11	23.83	2.48	< 0.01
FACT-G emotional well-being score ^a	12.44	6.29	17.10	4.07	23.33	0.82	< 0.01
FACT-G functional well-being score	18.11	2.67	19.00	3.92	23.00	4.82	0.06
FACT-G total score ^a	74.00	11.18	82.00	11.12	102.17	10.03	< 0.01

^a The reflexology group differed significantly from both guided imagery and guided imagery plus reflexology groups. Guided imagery and guided imagery plus reflexology groups did not differ from each other.

CES-D—Centers for Epidemiological Studies–Depression; FACT-G—Functional Assessment of Cancer Therapy–General

Note. The interview-only group had no attrition.

maintain it, the daily protocol was too intense, or, if they were in the combination group of guided imagery and reflexology, that undertaking two complementary therapies was too demanding. Also, the home environment may not have been conducive to quiet listening of the tapes. Large variation exists in what patients and family caregivers find soothing in a taped message or background music.

The pilot work helps determine which cancer diagnoses to target and what factors to use as eligibility criteria in a larger study, which is a useful way to ensure adequate enrollment and avoid noncompliance and wasted research resources. As investigators continue to work on the evidence base for various complementary therapies, many therapies may provide comfort to patients in the clinical setting. The pilot results obtained from the sample show that, of the therapies tested, the strongest complementary therapy for an RCT is reflexology. The target population would be late-stage women with breast cancer.

Limitations

The use of a convenience sample limits the conclusions from the analyses. Further research should include a larger sample of patients with similar cancer diagnoses. The strategies for analyzing outcomes were limited by differences in the groups at baseline and in attrition. Small sample size, especially in the interview-only group, further limited the generalizability of the data. Research also is needed on the long-term efficacy of complementary therapies.

Implications

A knowledgeable healthcare workforce is necessary to educate patients on evidence-based treatment modalities that might enhance their conventional care. Research is making progress with the many survey and small-scale studies that now are available. The level of research is analogous to the assessment phase of the nursing process. The next research step in the evidence hierarchy is the quasi-experimental design. Investigators can greatly benefit from pilot testing their ideas before engaging in the cost and time of an RCT. The study represents one of the key middle stages in preparing research data that eventually can be translated to clinical practice. The next stage is the RCT and, finally, the meta-analysis of several RCTs to determine how a therapy can be translated to clinical practice best with a solid evidence base.

This article sheds light on the state of the science related to two complementary therapies. Many patients currently are providing practitioners with self-reports about the benefits of complementary therapies. Patient feedback is, to a great extent, what has driven the interest and funding for complementary therapy research.

		Guid	led Imag	jery		Guided Imagery Plus Reflexology					Reflexology				
	Lost		Retained			Lost		Retained			Lost		Retained		
Variable	X	SD	X	SD	р	X	SD	x	SD	р	X	SD	X	SD	р
Age (years)	51.53	11.90	54.64	12.22	0.56	54.02	10.19	52.36	10.05	0.65	51.05	8.39	54.26	10.61	0.51
Anxiety score	43.78	7.31	39.23	14.52	0.39	37.90	13.17	39.27	14.59	0.79	24.33	5.39	29.93	9.05	0.17
CES-D score	20.67	10.10	16.61	11.22	0.39	19.10	12.84	17.47	10.99	0.67	4.83	2.93	12.53	7.97	< 0.01
FACT-G physical well-being score	16.22	3.96	19.61	3.23	0.03	15.00	6.11	17.53	6.33	0.28	23.83	2.48	21.00	5.11	0.21
FACT-G emotional well-being score	12.44	6.29	17.10	5.07	0.07	17.10	4.07	16.30	5.18	0.66	23.33	0.82	20.20	3.47	< 0.01
FACT-G functional well-being score	18.11	2.67	19.38	4.48	0.45	19.00	3.91	19.80	4.79	0.63	23.00	4.82	20.67	3.98	0.26
FACT-G total score	74.00	11.18	85.85	13.10	0.03	82.00	11.12	82.67	17.40	0.91	102.17	10.03	92.27	12.95	0.11

CES-D—Centers for Epidemiological Studies–Depression; FACT-G—Functional Assessment of Cancer Therapy–General

Note. Unequal variance assumed

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limiting the random search for an appropriate complementary therapy. The study addressed patient characteristics that are associated with sustained use of two different individual complementary therapies and one bundled complementary therapy intervention.

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