

ORIGINAL ARTICLES

Complementary Therapies for Patients with Cancer: Reflexology and Relaxation in Integrative Palliative Care. A Randomized Controlled Comparative Study

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Abstract

Objectives: Comparison of the effects of reflexology and relaxation on pain, anxiety, and depression, and quality of life (QoL) of patients with cancer.

Design: A stratified random sample was selected, using an experimental design.

Location: An outpatient Palliative Care Unit in Attica, Greece.

Subjects: 88 patients suffering with cancer.

Interventions: The sample was randomly divided into two equal groups, a reflexology and a relaxation group. The number of interventions for both groups was six 30-min weekly sessions.

Outcome measures: The Greek Brief Pain Inventory (G-BPI) was used to measure pain, the Greek Hospital Anxiety and Depression Scale for screening anxiety and depression, and finally the Short Form Health Survey was used to measure QoL. Measurements of the above tools were taken three times in both groups as follows: preintervention, at fourth and at sixth week of intervention.

Results: Anxiety and depression for both groups exhibited a statistically significant decrease during the observation period ($p < 0.001$, $\eta^2 > 0.25$) but at the sixth week, there was a more significant decrease in the reflexology group compared with the relaxation group ($p = 0.062$, $\eta^2 = 0.044$ vs. $p = 0.005$, $\eta^2 = 0.096$ for anxiety), ($p = 0.006$, $\eta^2 = 0.094$ vs. $p = 0.001$, $\eta^2 = 0.138$ for depression). QoL physical and mental component measurements were significantly greater for the reflexology group ($p < 0.001$, $\eta^2 = 0.168$ and $p = 0.017$, $\eta^2 = 0.071$, respectively). The baseline-to-sixth week G-BPI measurements were markedly decreased for the reflexology group ($p = 0.207$, $\eta^2 = 0.020$).

Conclusions: Both interventions, relaxation and reflexology, seemed to be effective in decreasing anxiety and depression in patients with cancer. However, reflexology was found to be more effective in improving QoL (physical component) and to have a greater effect on pain management than relaxation.

Keywords: integrative palliative care, reflexology, relaxation, pain, anxiety and depression, quality of life

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Introduction

INTEGRATIVE PALLIATIVE CARE is the most complete treatment of patients with cancer combining palliative care and alternative/complementary therapies; it should be offered to patients at all stages of the disease and, to their loved ones, during the mourning period.^{1,2} The diagnosis of cancer is commonly accompanied by various psychological symptoms such as anxiety and depression.^{3–5} Increased levels of anxiety may adversely affect quality of life (QoL), pain, fatigue, sleep, nausea, and vomiting.^{3,5} Pain is another common symptom experienced by patients with cancer that influences QoL as it has, among others, an impact on depression, sleep quality and general wellbeing. Despite pharmacological advances in pain management and palliative care,^{6,7} pain is reported by 64% of patients with advanced or metastatic cancer and by ~30% of survivors post-treatment.^{8,9} These findings highlight the complexity of pain management and the necessity of a multidisciplinary integrative palliative care team to address QoL issues. QoL is subjective^{10,11} and cannot always be accurately assessed because of its multidimensionality; in addition, factors that may affect QoL of people with cancer may influence physical and psychosocial functioning in a number of ways.

Complementary and alternative medicine (CAM) plays an important role in palliative care.¹² Its frequency of use has increased over time with the modalities used depending on what is on offer by health services, in an *ad hoc* manner in some cases.^{13,14} Thus, there is a need to distinguish which CAM modalities are most effective in each case through clinical studies of efficacy and comparison. CAM may enhance QoL and reduce stress—however, in a palliative care setting, CAM must be practiced cautiously; some therapies may inhibit standard cancer treatments or pose health risks.¹⁵

Relaxation techniques are beneficial in palliative care for reducing anxiety, sleep disturbances, chemotherapy-induced nausea, depression, and pain.^{16–19} Relaxation therapy (RT) encompasses many different techniques such as Jacobson's Progressive Muscle Relaxation, breathing exercises, guided imagery, meditation, and Benson's Relaxation Response.^{20,21} Relaxation is one of the most frequently reported CAM (44.3%) among cancer survivors and is generally considered safe.²² Regular practice is required for full benefit, but once mastered, RT can be incorporated into the daily routine.²³ Another complementary therapy that is gentle and safe for people with severe conditions and one of the most popular CAM for people with cancer is reflexology; a preferred therapy by 35% of patients with cancer.²⁴ The main emphasis of reflexology is on restoring and maintaining homeostasis, aiding relaxation, and easing symptoms of stress. Benefits have also been reported in reducing devastating cancer symptoms such as dyspnea, fatigue, anxiety, pain, nausea, vomiting and possibly enhancing QoL.^{25,26}

Materials and Methods

Objectives

Little is known regarding the comparative merits of reflexology and relaxation in palliative care and thus the aims

of this study were as follows: comparison of the effects of reflexology and relaxation on pain, anxiety and depression and QoL of patients with cancer.

Patients and methods

Using an experimental design, a stratified random sample of 88 cancer subjects was selected in an outpatient Palliative Care Unit in Attica, Greece and was enrolled over a 3-year period.

Inclusion criteria. Adult participants with a diagnosis of cancer, written informed consent before inclusion in the study, patients' ability to communicate effectively with the researcher, and a platelet count >50,000.

Exclusion criteria. Presence of psychotic, major depressive disorder or drug addiction, pregnancy in the first trimester, and recent foot injuries.

Of the 88 participants that met the inclusion/exclusion criteria and were initially approached to participate in the study five subjects refused (three relaxation/two reflexology) to take part for various reasons (too far to travel to the unit, too ill, did not believe in such methods) and three questionnaires were excluded because of missing data points (one relaxation/two reflexology).

In consequence, both groups, reflexology and relaxation, consisted of 40 subjects each. We followed a stratified randomization block size 4 according to gender and the Eastern Cooperative Oncology Group (ECOG) criteria²⁷ (0–1 vs. 2–3 severity) to allocate patients to the two groups (reflexology and relaxation). The randomization list was concealed until the time of assignment and handled by an independent observer. Blinding was not possible, as the two groups were easily distinguishable by all.

Participation was anonymous and confidential. Permission for the study was obtained by the Research and Ethics committee of the National and Kapodistrian University of Athens, School of Medicine (No. B-81/30-10-2014).

Metrics

A demographic and clinical characteristics questionnaire and the following scales were used.

Greek Hospital Anxiety and Depression Scale

The Hospital Anxiety and Depression Scale (HADS) is a self-assessment mood scale. It is a brief screening test measuring anxiety and depression, which in turn consists of seven items each rated on a three-point (0–3) scale. HADS has been validated in a Greek sample of patients with advanced cancer.²⁸ Cronbach's α for the anxiety and depression scales were 0.887 and 0.703 respectively.

Short Form Health Survey

QoL was measured through the 12-item Health Survey. It was developed as a short form of the Medical Outcomes Study 36-item short-form (SF-36) questionnaire. It is a 12-item self-administered questionnaire that yields scores for eight areas on QoL. It consists of two summary scores: a mental component summary score (MCS) and a physical

component summary score (PCS). Short Form Health Survey (SF12v2) has been validated in a stratified representative sample of the Greek general population.²⁹

Greek Brief Pain Inventory

The Brief Pain Inventory (BPI) is a questionnaire used to measure pain, and has been validated in a Greek sample of patients with cancer. Reliability and validity of the Greek-BPI (G-BPI): Coefficient α was 0.849 for the interference items and 0.887 for the severity items.³⁰ From the questionnaire, question 5 (Q5) (How much pain are you in on average) was selected for statistical purposes.

Measurements of the above tools were taken four times in both groups as follows: preintervention, and at fourth and sixth weeks of intervention. The number of sessions for both groups was 6, one per week and the length of time per session 30 min. The same treatment room was used for both interventions. Questionnaires were completed by patients anonymously, out of sight of the investigator and placed in a box file, to reduce measurement bias. Intervention protocols were as follows: For the relaxation group the Relaxation Response method³¹ was used. For the reflexology group the Bayly method was used³² (Appendix A1).

Adverse effects

Adverse effects were systematically measured by noting their presence/absence each week during the intervention period. During the study period, none were reported.

Statistical analysis

Data were expressed as mean \pm standard deviation. The Shapiro–Wilks test was utilized for normality analysis of the parameters (Pain, Anxiety and Depression, QoL: P, A&D, and QoL).

Comparison of the parameters at each time point was performed using the one-way analysis of variance (ANOVA) model. Pairwise comparisons were performed using the Bonferroni test.

One factor repeated-measures ANOVA model was used for the comparison of different time measurements of P, A&D, and QoL parameters for each group. Pairwise multiple comparisons were performed using the Bonferroni test.

The mean percentage changes from baseline after 4 and 6 weeks, respectively, were calculated to compare the two interventions adjusted for any baseline difference. Comparison of percentage changes from baseline of Greek HADS (GHADS), SF12v2, and G-BPI parameters during the observation period between two groups was analyzed using the one-way ANOVA model; pairwise comparisons were performed using the Bonferroni test. Kruskal–Wallis and Mann–Whitney tests were used in cases of violation of normality. All tests are two-sided, statistical significance was set at $p < 0.05$. Effect size was measured using the η^2 statistic. All analyses were carried out using the Statistical Package SPSS v21.00.

Results

The groups were homogeneous at a 5% significance level with respect to the following demographic and clinical variables: gender, age, ECOG baseline (0–1/2–3), localization (breast/lung/prostate/urogenital/gastrointestinal/other); radiotherapy; metastasis; severe comorbidities; drug dosage at fourth and sixth weeks (Table 1). The Chemotherapy group is not homogeneous at a 5% significance level, however, by a very small margin; with a p -value of 0.043 the group is considered homogeneous at a 1% level.

Both groups presented a statistically significant improvement for both GHADSs during the observation period (Table 2). As given in Table 2, GHADS anxiety and depression were not significantly different between groups at baseline ($p = 0.796$, $\eta^2 = 0.001$, $p = 0.459$, $\eta^2 = 0.007$, respectively). Anxiety and depression for both groups exhibited a statistically significant decrease during the observation period ($p < 0.001$, $\eta^2 > 0.25$).

Concerning the percentage change from baseline to fourth and sixth week for GHADS anxiety, it seemed that there was a more significant decrease in the reflexology group compared with the relaxation group ($-9.50\% \pm 13.16$ vs. $-4.48\% \pm 10.46$, $p = 0.062$, $\eta^2 = 0.044$ and $-18.37\% \pm 13.01$ vs. $-10.66\% \pm 10.93$, $p = 0.005$, $\eta^2 = 0.096$), respectively.

Similarly, GHADS depression results exhibited a more significant decrease in the reflexology group (-13.61 ± 10.93 vs. -6.49 ± 11.50 , $p = 0.006$, $\eta^2 = 0.094$ and -19.58 ± 12.89 vs. -9.06 ± 13.76 , $p = 0.001$, $\eta^2 = 0.138$) than in the relaxation group respectively.

The percentage change in the baseline-to-fourth week SF12v2 PCS measurements were similar for both groups

TABLE 1. HOMOGENEITY BETWEEN GROUPS IN RELATION TO DEMOGRAPHIC AND CLINICAL VARIABLES

	Reflexology	Relaxation	p
Gender (male/female); <i>n</i> (%)	10 (25)/30 (75)	7 (17.5)/33 (82.5)	0.586
Age mean \pm SD	58.5 \pm 11.5	59.3 \pm 13.6	0.771
ECOG baseline (0–1/2–3), <i>n</i> (%)	22 (55)/18 (45)	28 (70)/12 (30)	0.248
Location (breast/lung/prostate/urogenital/gastrointestinal /other gastrointestinal/other), (%)	43/8/8/10/16/15	62/10/5/8/5/10	0.393
Radiotherapy (no/yes), <i>n</i> (%)	27 (6.5)/13 (32.5)	19 (47.5)/21 (52.5)	0.113
Chemotherapy (no/yes), <i>n</i> (%)	26 (65)/14 (35)	16 (40)/24 (60)	0.043
Metastasis (no/yes), <i>n</i> (%)	14 (35)/26 (65)	23 (57.5)/17 (42.5)	0.072
Severe comorbidities (no/yes), <i>n</i> (%)	35 (87.5)/5 (12.5)	31 (77.5)/9 (22.5)	0.378
Drug dose fourth week (stable/increase)	28 (70)/12 (30)	34 (85)/6 (15)	0.180
Drug dose sixth week (stable/increase)	29 (72.5)/11 (27.5)	35 (87.5)/5 (12.5)	0.161

ECOG, Eastern Cooperative Oncology Group; SD, standard deviation.

TABLE 2. COMPARISON OF GREEK HOSPITAL ANXIETY AND DEPRESSION SCALE ANXIETY AND DEPRESSION BETWEEN GROUPS DURING THE OBSERVATION PERIOD OF 6 WEEKS

Group	Baseline	Fourth week	Sixth week	$p_{within\ group}$	$\eta^2_{within\ group}$	% change baseline-fourth week	% change baseline-sixth week
GHADS anxiety							
Reflexology	8.45 ± 3.55	8.43 ± 3.12 ^a	7.63 ± 2.81 ^{a,b}	<0.001	0.488	-9.50 ± 13.16	-18.37 ± 13.01
Relaxation	9.25 ± 3.33	8.78 ± 3.08 ^c	8.23 ± 2.93 ^{a,b}	<0.001	0.343	-4.48 ± 10.46	-10.66 ± 10.93
$p_{between\ groups}$	0.796	0.615	0.353			0.062	0.005
$\eta^2_{between\ groups}$	0.001	0.003	0.011			0.044	0.096
GHADS depression							
Reflexology	8.55 ± 2.58	7.33 ± 2.25 ^a	6.85 ± 2.30 ^{a,d}	<0.001	0.566	-13.61 ± 10.93	-19.58 ± 12.89
Relaxation	8.98 ± 2.53	8.30 ± 2.19 ^a	8.13 ± 2.38 ^a	<0.001	0.263	-6.49 ± 11.50	-9.06 ± 13.76
$p_{Between\ groups}$	0.459	0.053	0.017			0.006	0.001
$\eta^2_{Between\ groups}$	0.007	0.047	0.071			0.094	0.138

All values are presented as mean ± SD.

^a $p < 0.005$ versus baseline.

^b $p < 0.005$ versus fourth week.

^c $p < 0.05$ versus baseline.

^d $p < 0.05$ versus fourth week.

GHADS, Greek Hospital Anxiety and Depression Scale; SD, standard deviation.

(14.17% ± 26.45 and 6.31% ± 21.48, $p = 0.149$, $\eta^2 = 0.047$, respectively). The percentage changes in the baseline-to-sixth week measurements were significantly greater for the reflexology group (20.75% ± 27.69 and 1.48% ± 13.23, $p < 0.001$, $\eta^2 = 0.168$, respectively).

SF12v2 MCS measurements were similar for both groups in the baseline-to-fourth week (6.85% ± 15.21 and 3.27% ± 11.93, $p = 0.244$, $\eta^2 = 0.017$, respectively), whereas SF12v2 MCS measurements were significantly greater for the reflexology group in the baseline-to-sixth week (13.57% ±

14.93 and 5.72% ± 13.72, $p = 0.017$, $\eta^2 = 0.071$, respectively) (Table 3).

From Table 4 one can see that the percentage change in the baseline-to-fourth week was similar for both groups concerning G-BPI—question 5 (G-BPI-Q5) measurements (-10.66% ± 21.73 and -13.75% ± 22.62, $p = 0.536$, $\eta^2 = 0.005$, respectively) whereas in the baseline-to-sixth week G-BPI-Q5 measurements were markedly greater for the reflexology group (-24.27% ± 20.85 and -18.08% ± 22.61, $p = 0.207$, $\eta^2 = 0.020$, respectively).

TABLE 3. SF12v2 COMPARISON OF PHYSICAL COMPONENT SUMMARY SCORE AND MENTAL COMPONENT SUMMARY SCORE BETWEEN GROUPS DURING THE OBSERVATION PERIOD OF 6 WEEKS

Group	Baseline	Fourth week	Sixth week	$p_{within\ group}$	$\eta^2_{within\ group}$	% change baseline-fourth week	% change baseline-sixth week
PCS							
Reflexology	34.61 ± 9.35	38.83 ± 11.10 ^b	40.67 ± 10.18 ^b	<0.001	0.279	14.17 ± 26.45	20.75 ± 27.69
Relaxation	37.84 ± 11.64	39.38 ± 11.36	37.86 ± 10.93	0.111	0.055	6.31 ± 21.48	1.48 ± 13.23
$p_{between\ groups}$	0.176	0.828	0.238			0.149	<0.001
$\eta^2_{between\ groups}$	0.023	0.001	0.018			0.047	0.168
MCS							
Reflexology	44.89 ± 10.43	47.34 ± 10.62 ^a	50.15 ± 9.94 ^{b,c}	<0.001	0.338	6.85 ± 15.21	13.57 ± 14.93
Relaxation	46.28 ± 11.64	47.02 ± 9.57	48.15 ± 10.10	0.065	0.068	3.27 ± 11.93	5.72 ± 13.72
$p_{between\ groups}$	0.567	0.885	0.376			0.244	0.017
$\eta^2_{between\ groups}$	0.004	0.0002	0.010			0.017	0.071

All values are presented as mean ± SD.

^a $p < 0.05$ versus baseline.

^b $p < 0.005$ versus baseline.

^c $p < 0.005$ versus fourth week.

MCS, mental component summary score; SD, standard deviation; SF12v2, Short Form Health Survey.

TABLE 4. COMPARISON OF G-BPI-Q5 BETWEEN GROUPS DURING THE OBSERVATION PERIOD OF 6 WEEKS

Group	Baseline	Fourth week	Sixth week	$p_{\text{within group}}$	$\eta^2_{\text{within group}}$	% change baseline-fourth week	% change baseline-sixth week
G-BPI-Q5							
Reflexology	5.78 ± 1.67	5.08 ± 1.62 ^a	4.33 ± 1.56 ^{a,b}	<0.001	0.448	-10.66 ± 21.73	-24.27 ± 20.85
Relaxation	5.38 ± 1.29	4.63 ± 1.56 ^a	4.35 ± 1.42 ^a	<0.001	0.348	-13.75 ± 22.62	-18.08 ± 22.61
p between groups	0.235	0.210	0.940			0.536	0.207
η^2 between groups	0.018	0.020	0.000			0.005	0.020

All values are presented as mean ± SD.

^a $p < 0.005$ versus baseline.

^b $p < 0.005$ versus fourth week.

G-BPI-Q5, Greek Brief Pain Inventory—question 5.

Discussion

The integration of complementary therapies in palliative care does benefit patients, increasing their wellness and QoL. Our results have shown that reflexology and relaxation can reduce both anxiety and depression symptomatology. The improvement was significant with respect to each variable's (anxiety and depression) baseline measurement and, more importantly, in comparison with the corresponding measurements of the relaxation group at the same time-points.

There is some evidence in the literature to support these findings. The 2010 breast cancer systematic review by Kim et al. found one randomized controlled trial that showed a significant difference in mood compared with self-initiated support. In addition, two trials suggested positive results for decreased anxiety and depression.^{33,34}

Moreover, the relaxation literature notes decreased anxiety and depression compared with baseline measurements or even with standard care.³⁵ However, the decrease is not always evident compared with other modalities, for example, drug therapy, music therapy, or psychological interventions.^{35–37}

Regarding QoL measurements as rated by the SF12v2 questionnaire, both the physical and mental components showed improvement after 6 weeks of treatment for the reflexology group compared with the relaxation group, but at 4 weeks of treatment the two groups exhibited similarities; this might stem from the fact that reflexology begins to take consistent effect after three to six treatment sessions, particularly when the disease has been long established³² in common with other CAM modalities such as Acupuncture.³⁸ An important finding derives from the fact that in the reflexology group the mental component of SF12v2 exhibited consistent improvement throughout the observation period. A possible explanation might be that reflexology has a stress-relieving effect that is experienced during and after treatment by the majority of people from the very first treatment sessions.^{32,39}

The positive results on QoL for reflexology recipients and a significant difference in QoL when compared with self-initiated support is supported in the literature.^{33,34,40} In contrast, the relaxation group measurements showed no significant improvement across time. In the relaxation literature, Isa et al.³⁵ reported improvements in the mental

component of health-related QoL and Koplin et al.⁴¹ showed no effect of relaxation compared with standard care on short-term QoL.

The average pain experienced was not significantly different for the two groups after 4 and 6 weeks of treatment. However, improvement in the reflexology group was consistently significant across time, whereas improvement in the relaxation group plateaued after 4 weeks. Similarly, reflexology was found to be significantly effective in reducing pain in a palliative care setting in several studies.^{42–44} In the relaxation literature also, there is some evidence that it can be effective in pain reduction.^{45,46}

The findings of this study revealed that although both groups exhibited improvement in all studied parameters compared with baseline measurements, reflexology performed consistently better in reducing anxiety and depression in patients with cancer compared with relaxation. The study compares the efficacy of two different complementary therapies in a palliative care setting something not directly attempted before in a palliative care setting and thus this strengthens our results.

Limitations

Improvement for both groups may be attributed to the “due care and attention” effects of the intervention, which gives the opportunity for discussion of concerns, hopes, and fears.

The different tumor sites included in the study may have increased the heterogeneity of the total sample.

Because of lack of funding, the interventions were conducted by the researcher.

Conclusions

The findings of this study showed that for patients with cancer receiving integrative palliative care, both relaxation and reflexology were effective in decreasing anxiety and depression. Reflexology was effective in improving QoL, in the physical component in comparison with baseline observations and with the corresponding measurements of the relaxation group. In addition, reflexology appeared to be more effective than relaxation in pain management. It appears that these safe and relatively inexpensive techniques could be applied to patients with cancer by qualified therapists, especially in palliative care settings, as part of

integrative palliative care. Further comparative studies of complementary therapies are needed to widen and strengthen our results and for a wider range of effective, evidenced-based complementary therapies to be offered to patients with cancer.

Author Disclosure Statement

No competing financial interests exist.

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APPENDIX A1

Reflexology Protocol

Initial treatment starts with a medical history. Following that shoes and socks are removed and the patient lies on a couch at an angle so that the back and legs are supported and practitioner can observe patient's face for changes in color or facial expressions.

Before treatment session begins feet are observed: color, temperature, skin elasticity, dryness, hard skin, scars, corns, edema, perspiration, odor, condition of nails and skin conditions, or infections. Adverse reactions from previous session are noted.

Feet are cleaned with antiseptic wet wipes and liquid talcum powder is massaged in. All reflex points are pressed following the Bayly method starting on the left foot three

times. During the session talking is allowed and explanations on pressure points given if required.

Length of session, 30 min.

Relaxation Protocol

At the initial session the relaxation sequence according to Benson is explained. Patient lies on a couch and is then talked through the relaxation sequence: breathing exercise, progressive muscle relaxation, visualization exercise—exploring favorite place in nature, breathing meditation. Patient is encouraged to practice at home between sessions.

Length of session, 30 min.