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Therapeutic Massage and Healing Touch Improve Symptoms in Cancer

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Complementary therapies are increasingly used to reduce side effects of cancer treatment, without evidence for their effectiveness. In a randomized, prospective, 2-period, crossover intervention study, the authors tested the effects of therapeutic massage (MT) and healing touch (HT), in comparison to presence alone or standard care, in inducing relaxation and reducing symptoms in 230 subjects. MT and HT lowered blood pressure, respiratory rate (RR), and heart rate (HR). MT lowered anxiety and HT lowered fatigue, and both lowered total mood disturbance. Pain ratings were lower after MT and HT, with 4-week nonsteroidal anti-inflammatory drug use less during MT. There were no effects on nausea. Presence reduced RR and HR but did not differ from standard care on any measure of pain, nausea, mood states, anxiety, or fatigue. MT and HT are more effective than presence alone or standard care in reducing pain, mood disturbance, and fatigue in patients receiving cancer chemotherapy.

Keywords: *massage; healing touch; presence; complementary therapies; neoplasms; chemotherapy; symptom management; randomized controlled trials*

Despite improved pharmacological management, patients receiving cancer chemotherapy continue to experience a variety of treatment-related side effects, including nausea, fatigue, anxiety, and pain. Although there are few randomized controlled trials, preliminary evidence suggests that complementary therapies may reduce adverse symptoms and improve well-being in patients receiving cancer chemotherapy.

Massage is one of the most commonly used complementary therapies in adults with cancer.[1-4] Therapeutic massage (MT) involves rhythmic and methodical stretching and compressing of the muscles and connective tissue through touch of the therapist's hands, with the benefit of increasing circulation, stimulating venous and lymphatic drainage, improving muscle tissue metabolism and elasticity, and promoting relaxation through enhanced parasympathetic and reduced sympathetic nervous system activity.[5,6] Massage has been shown to reduce stress-related physiological responses such as blood pressure, heart rate, epinephrine, and cortisol in rats[7] and humans[6,8-9] and has been used for effective symptom management in acute and chronic medical and surgical conditions in adults and children.[5-6,10]

In cancer, massage has reduced symptoms of anxiety,[11-15] pain,[11,12,16-18] fatigue,[11] and nausea[11,19]; reduced muscle tension[20]; and improved quality of life.[17] However, some studies found no effect on analgesic use[17] or pain.[11] Only one study used a crossover design in which 6 female breast cancer patients undergoing radiotherapy received a 10-minute massage on 3 consecutive days followed by (or preceded by) 3 days of rest.[21] Subjects who received the massage first reported a 15.4% improvement in total symptom distress ($P = .05$).

Healing touch (HT) is an energy therapy that involves the use of the practitioner's hands above and on the patient's body, but without the deep-muscle stimulation offered through massage. Instead of the mechanical stimulation of massage, HT uses light touch to assess and determine areas of energy imbalance, felt as a change in temperature, texture, or vibration.[22] The practitioner unblocks energy through the body, promoting physical healing and emotional, mental, and spiritual balance. While the mechanism of action is not known, the goal of HT is to restore harmony and balance in the energy system to help the person self-heal.[23] Clinical benefits of HT include relaxation, reduced anxiety and pain, and a sense of general well-being.[24]

Most research on energy therapies has tested the effectiveness of therapeutic touch (TT), an energy therapy that is more focused on one technique, does not

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involve touch, and is usually shorter in length. One meta-analysis of 38 studies investigating TT found benefits of reduced anxiety, stress, tension headaches, pain, nausea, and vomiting and improved wound-healing rate.[25]

Of the 3 studies published on HT, only 1 used randomization[26]; sample sizes range from 22 to 60, with 10 to 22 per treatment group, and intervention lengths range from a single 30-minute HT treatment[24,26] to twice-weekly 30-minute treatments for 3 weeks.[27] Two of the 3 studies included a presence component to the control condition. Populations studied included healthy adults,[24] family caregivers of patients receiving inpatient stem cell transplant,[27] and patients in postoperative recovery for surgical hysterectomies.[26] No HT studies were found with persons with cancer as the subjects. Outcomes focused on physical postoperative symptoms[26]; anxiety, depression, fatigue, and caregiver burden[27]; and stress, perceived health, and salivary secretory immunoglobulin A (sIgA).[24]

Similar to the current study, Rexilius and colleagues[27] compared the effects of HT, MT, and control/presence over 3 weeks of intervention. They found that 13 adult caregivers receiving massage had lower anxiety, depression, and general, motivational, and emotional fatigue (but not physical fatigue). HT had similar effects but with only 10 subjects did not reach significance. Wilkinson and colleagues found increased sIgA and lower perceived stress and pain after a single 30-minute HT session.[24] Of interest is their finding that subjects of the more experienced HT practitioners had higher sIgA levels than those of the less experienced practitioners. However, the level of experience was not defined in terms of years of practice or level of training achieved. Silva provided daily 20-minute sessions of HT, MT, or standard care for 3 days after surgery and found that HT reduced blood pressure, heart rate, and narcotic use and increased measures of lung and gastrointestinal function postoperatively.[26]

Controversy exists over whether the MT and HT intervention itself produces the desired response or if the patient responds to the presence of a caring professional. Presence is an important nursing intervention helpful in reducing anxiety,[28] and several HT and MT studies use presence to control for the intent of the practitioner as a placebo effect.[16,24,27,29] In this study, we tested for the specific effects of presence of a caring professional. Presence consisted of the same interaction, environment, and provider as the interventions but without the touch therapies.

Despite preliminary evidence for effectiveness of complementary and alternative medicine (CAM) interventions in cancer, sample sizes have been small and interventions inconsistent in dose and administration (length of treatment and frequency). The purpose of this study was to determine in a powered randomized control trial if MT and HT were more effective than standard care or presence alone at reducing symptoms of anxiety, mood disturbance, pain, nausea, and fatigue and increasing relaxation and satisfaction with care.

Methods

Eligibility and Recruitment

Eligibility criteria included adult patients from 2 outpatient Midwestern chemotherapy clinics who had a histologically documented cancer diagnosis and were receiving chemotherapy with an identical repeating cycle for 2 or more remaining cycles. They also had pain, nausea, or fatigue rated 3 or more on a scale of 0 to 10 (where 10 is the worst imaginable) and were able to read and write English and give informed consent. Following approval by the hospital and university institutional review boards, eligible patients were identified and asked to participate after receiving approval from their oncologist.

Between September 1998 and April 2001, 549 patients who met the eligibility criteria were asked to participate in the study. A total of 319 patients declined, citing transportation or travel issues (26%), feelings of being too ill (18%) or too overwhelmed to consider participating (14%), inability to accommodate the schedule (11%), or lack of interest in one of the study arms (3%). No rationale was given by 89 patients (28%). Two hundred thirty patients (42%) signed written consents and were randomized to 1 of 3 groups: therapeutic massage (MT), healing touch (HT), or caring presence (P).

Procedures

All subjects received 4 weekly 45-minute sessions of their assigned intervention (MT, HT, or P) and 4 weekly sessions of a standard care/control. The order of conditions (intervention or control) was randomized. Session 1 of the intervention or control started prior to chemotherapy on the first day of their next scheduled chemotherapy treatment cycle. After the 4 weekly sessions, subjects "crossed over" to the alternate assigned condition for 4 weekly sessions. One subject started on day 15 of treatment and crossed over on day 15 of an identical cycle. The time between weekly visits was a mean of 6.9 to 7.2 days, and the time between crossover periods was a mean of 16.7 days (range, 3-56). All but 3 subjects crossed over on the same day of an identical chemotherapy cycle.

Pre- and postsession assessments of vital signs (heart rate, respiratory rate, blood pressure) and self-

report of current pain and nausea ratings on a scale of 0 to 10 were measured just prior to and just after each intervention session. Because of the time commitment for subjects, the length of each control session consisted only of completing a baseline assessment and did not require a 45-minute stay with post-assessment.

Assessments of intervention effects over 4 weeks included anxiety, mood states, and fatigue, measured at the beginning of the first and last session of each 4-week crossover period (sessions 1, 4, 5, and 8). Diaries recording use of analgesics and antiemetics were collected at each weekly session. Overall satisfaction with care was assessed at baseline (session 1) and at the end of each 4-week period (sessions 4 and 8). To obtain subjective responses, an open-ended questionnaire evaluating each intervention was administered at the last session of the intervention period (session 4 or 8).

Interventions

All intervention sessions (MT, HT, P) were 45 minutes in length. MT and HT therapies were provided by certified and credentialed MT and HT practitioners who also were registered nurses. Except for an occasional substitution, the same practitioner provided all 4 sessions. Intervention technique was documented through written notes of the practitioners. A customized CD of soft piano and nature music was played in the background, and a sign was posted outside the closed door to prevent interruptions. Sessions started with a 3-minute scripted centering message, with messages to focus on breathing and letting go of extraneous thoughts.

Therapeutic massage. A written Swedish massage protocol with defined strokes was followed, using Biotone® massage gel, consisting of apricot, grapeseed, and sesame oils. The participants began the massage lying prone, with effleurage strokes (gentle rhythmic gliding strokes) applied to the upper back, then petrissage, (gentle kneading) and friction/rubbing of the lower back, hips, buttocks, and extremities. In the supine position, the therapist used effleurage and gentle petrissage to the upper chest, neck, face, scalp, and the anterior torso, abdomen, legs, and feet. The massage was sometimes modified to avoid tumor or surgical sites and to adapt the depth of touch according to individual tolerance.

Healing touch. HT followed the protocol developed by Healing Touch International Levels 1-3, using both touch and nontouch techniques. Energy techniques included centering, unruffling, magnetic unruffling, full-body connection, mind clearing, chelation, and lymphatic drain to modulate the energy field. The session began with the therapist setting the intent for the greatest good of the subject and performing an energy field assessment to determine areas of increased or decreased energy flow. Unruffling was done over the body to release areas of blocked energy and was followed by one or more of the other techniques, depending on the individual assessment. The session ended with a grounding technique for the subject. Subjects remained clothed, except for the removal of shoes.

Presence. The environment was replicated for the caring presence group. At the beginning of each session, the presence provider asked the participants how they were feeling and if they had any questions. Participants were instructed to remain clothed and to lie for 45 minutes on the same table used for the MT and HT sessions. The same relaxing music was played softly during the session. One of the 8 MT or HT therapists sat with the participant during the presence session. The purpose was to be attentive and caring but to avoid therapy or physical intervention. The subject rested, and conversation sometimes occurred, similar to MT and HT.

Control. All subjects received the control condition, which consisted of 4 weekly sessions of standard cancer treatment alone. Subjects came to the same location as the intervention sessions, completed the same preintervention symptom assessments, and had vital signs assessed. Subjects left after the assessments were done.

Instruments

Outcome measures assessed before and after each intervention and once at each control session included heart rate, respiratory rate, blood pressure, and a 1-item score of current pain and current nausea, rated on a scale of 0 to 10. Outcomes assessed over the 4-week period prior to the first and fourth intervention or control session for each period included the Brief Pain Index (BPI), Brief Nausea Index (BNI), and fatigue, anxiety, and mood disturbance, as measured by the Profile of Mood States (POMS). Analgesic and antiemetic use was recorded daily and calculated as a total weekly dose. Satisfaction with care and evaluation of HT and MT were assessed with investigator-developed questionnaires after the fourth session of the each period. Ongoing CAM use outside of the study was assessed prior to and at the end of each period.

Vital signs. Blood pressure was taken manually with a portable sphygmomanometer (Tycos #129292868). Heart rate and respiratory rate were counted for 1

minute each to determine beats/respirations per minute.

Pain. Level of pain and pain interference with activity was measured using the BPI.[30] Pain was rated on a 0 to 10 linear analog scale, with 0 indicating *no pain* and 10 indicating *worst possible pain*. Current pain was used as a 1-item assessment before and after each intervention/control session. A pain index score was calculated as the average of scores for worst, least, current, and average pain over the past week. Pain interference/function was the average of 7 items assessing how much pain interfered with activities of daily living, including sleep, work, walking, and mobility. The BPI has been used extensively in pain research and has been found to reliably assess levels of pain and pain relief from various interventions and has established face and content validity.[30,31]

Nausea. Self-reports of nausea were measured by adapting the BPI with permission. The word *nausea* was substituted for *pain* for each item, and nausea index and nausea interference scores were calculated identical to pain index and pain interference scores. Poststudy reliability (Cronbach α) at preintervention baseline indicated strong and similar reliability for pain index (α = .88, n = 196), pain interference (α = .92, n = 196), nausea index (α = .82, n = 200), and nausea interference (α = .94, n = 192).

Medication use. Use of analgesics and antiemetics was recorded by subjects in a daily log that was turned in at each weekly session. Data included medication name, dose, route, frequency of use, and total amounts used of each analgesic and antiemetic. Nonopioids included nonsteroidal anti-inflammatory drugs (NSAIDs) and acetaminophen. Opioids were converted into morphine equivalents and calculated as a total weekly dose. Combination drugs that contained both opioid and nonopioid components were also calculated as morphine equivalents according to guidelines from the American Pain Society.[32] Propoxyphene hydrochloride was the only combination medication that was counted as an NSAID only, despite containing small amounts of the opioid propoxyphene napsylate. There is no appropriate conversion of this medication to opioid equivalents.

Anxiety, fatigue, and mood disturbance (POMS). The POMS is a checklist of 65 adjectives with 6 subscales of anger, anxiety, depression, confusion, fatigue, and vigor and a total mood disturbance score.[33] Although all subscales were recorded, measures of fatigue (15 items), tension/anxiety (9 items), and total mood disturbance (65 items) were the primary variables for this study. High scores indicated greater mood disturbance. Reliability of 0.90 and test-retest of 0.65 to 0.74 have been established in persons with cancer.[34,35]

Satisfaction. An overall satisfaction survey measured satisfaction with the time spent, information received, listening, management of pain, and symptom assessment provided by the practitioner. Total satisfaction scores were obtained by the use of 6 items ranked as *very satisfied*, *somewhat satisfied*, *dissatisfied*, or *very dissatisfied*. Scores ranged from 1 to 4, and an average score was computed for each item as well as a total score.

The evaluation survey ranked satisfaction with the specific intervention received on a 4-point scale rated as *very helpful/satisfied*, *helpful/satisfied*, *somewhat helpful/satisfied*, and *not helpful/not satisfied*. One item asked subjects if they would recommend the intervention to others. A final open-ended question asked subjects to describe their specific experience with MT or HT. The evaluation assessment had good reliability (α = .85, n = 173), but the satisfaction survey had relatively weak reliability, (α = .64, n = 198), with the weakest items being satisfaction with pain and symptom management. These are quite variable conditions and may not be expected to be consistent with other satisfaction items.

Analysis

The sample size for this study was determined by power analysis of the POMS total mood disturbance and subscale scores with similar samples of adults receiving chemotherapy. Sample size calculations of 32 per group (total = 96) were sufficient to detect between a medium to large effect size of 0.32 in a crossover design, with a power of 80% and α of .05. The goal for this study was to retain 64 subjects per group (n = 192) to allow for potential carryover effects. We recruited 230 subjects to allow for 20% attrition. The resulting sample size of 164 allowed us to detect a small to medium effect size of 0.18 for all variables except pain interference and ondansetron use, which had carryover effects.

Comparisons between groups on basic demographics were assessed using analysis of variance (ANOVA) for interval data and a χ^2 test of association for categorical data. The first step in using data generated from a crossover design requires assessment of period and sequence effects.[36,37] Testing for period effects determines whether the intervention in the first period (sessions 1-4) influences the response in the second period (sessions 5-8). Assessment of sequence effects determines if the order of the condition (sequence of intervention or control) influenced the response to each condition. The analysis proposed by Grizzle was used to assess period (carryover) effects by determin-

ing if the average effect for period 1 was the same as the average effect for period 2.[38] These effects were assessed by computing the sum of results of each period and assessing if there were differences between the groups for these sums. Sequence effects were assessed by summing the results of those treatments that were given first and comparing that to the sum of those treatments given second. For normally distributed data, *t* tests were used; nonparametric analyses (Mann-Whitney *U*) were used for variables not normally distributed (pain, nausea, medication use, satisfaction, evaluation). If there were no period or sequence effects, periods 1 and 2 were combined and the complete data set used for analysis.

Both immediate effects (before and after each 45-minute intervention) and condition effects (session 1 premeasure through session 4) were evaluated. Immediate effects were tested by computing area under the curve (AUC) for the pretreatment measures and the posttreatment measures over the 4 treatment sessions. To compare the intervention to the control group (which had only 1 measure), it was assumed that the postmeasure in the control would have been the same as the premeasure (an assumption of no change). The AUCs for the control period were first compared between groups. If they were not significantly different, the posttreatment AUC was assessed between groups using the pretreatment AUC as a covariate. If the overall analysis of covariance (ANCOVA) was significant, Tukey's HSD was used as a post hoc pairwise comparison. Nonnormally distributed measures were compared using Kruskal-Wallis ANOVA; post hoc comparisons were done for significant overall results using pairwise Mann-Whitney *U* with the alpha adjusted to account for multiple comparisons ($P < .016$ is required for significance between 3 groups).

Effects of the interventions over the 4-week period in comparison to the control conditions were assessed in 2 ways. Differences between groups were assessed with ANCOVA to determine differences in the session 4 measures of the treatment period, using the first baseline value as the covariate for the normally distributed data. For nonnormal data, the difference between the session 1 measure and session 4 measure was compared between groups using a Kruskal-Wallis ANOVA. Intervention conditions were then analyzed separately, with session 1 measures compared to session 4 for both the control condition and intervention condition to determine differences within condition using paired *t* tests (parametric) or Wilcoxon matched-pairs signed-rank test (nonparametric). Repeated-measures analysis (GLM, SPSS 10.0) was used to determine group by time interaction effects for parametric variables (comparisons among intervention groups with control condition over time).

Results

Sample Description

Of the 230 patients who signed consents to participate in the study (42% consent rate), 164 completed all 8 sessions (29% attrition). Of the 164, 63 received massage, 56 had HT, and 45 were in the presence group. A greater number of subjects assigned to presence dropped prior to the first session because they did not want to be assigned to the presence group. Of the 66 who dropped, 15 were assigned to MT, 21 to HT, and 30 to presence. Half of the subjects dropped because they wanted a different treatment or their schedules changed (n = 33), and half were discontinued by the study team because their treatment protocols changed (n = 30) and they no longer met the crossover criteria or they died prior to any treatment (n = 3).

Comparing the 66 who dropped with the remaining 164 in the study, there were no differences in diagnosis ($\chi^2 = 9.5$, $P = .15$), time from diagnosis ($z = -0.10$, $P = .92$), or time from first chemotherapy ($z = -0.57$, $P = .57$). There was a trend, however, for the 66 who dropped to have higher stage disease ($\chi^2 = 9.3$, $P = .054$). Of the 66 who dropped, 57.6% had stage IV disease, in comparison to 38.4% of the 164 who remained in the study. The 66 who dropped also had significantly higher pain (index score, $z = -2.02$, $P = .044$), nausea (index score, $z = -2.04$, $P = .041$), total mood disturbance (POMS, $z = -2.10$, $P = .036$), and fatigue scores (POMS, $z = -2.98$, $P = .003$) at baseline than the 164 who remained in the study.

Demographic characteristics of the 164 who remained in the study were similar to those who dropped. Mean age was 54.7 years for both samples (range, 27-83 years). Most of the 164 participants who completed the entire study were female (n = 142, 87%), Caucasian (n = 161, 98%), married (n = 111, 68%), and had some college education (n = 52, 32%) or were college graduates (n = 67, 41%). Approximately half were employed (n = 97, 59%) with incomes greater than $35,000 per year (n = 89, 54%).

Participants (n = 164) had breast cancer (52%), gynecological or genitourinary cancer (19%), gastrointestinal cancer (11%), hematological malignancies (9%), lung cancer (5%), or other cancer (4%). The majority of participants (56%) had stage III or IV disease. The mean time since original diagnosis was 17.4 months (SD of 28.8 months and range of 15 days to 14.1 years). Eleven subjects were in their first month of treatment (7%), 85 were 2 to 5 months from diagnosis (52%), and 67 (41%) had been diagnosed 6 months or longer. The mean time from the first chemotherapy treatment to session 1 was 8.4 months, with half (50%) in the first month of treatment. Subjects were

Table 1. Sample Characteristics of Subjects by Intervention Condition

	Total (N = 230)		*Therapeutic Massage (n = 78)*		*Healing Touch (n = 77)*		*Presence (n = 75)*			
Characteristic	*n*	*%*	*n*	*%*	*n*	*%*	*n*	*%*	χ^2	P *Value*
Gender									2.21	.33
Female	198	86.1	64	82.0	66	85.7	68	90.7		
Male	32	13.9	11	14.1	14	18.2	7	9.3		
Cancer diagnosis									16.0	.59
Breast	114	49.6	35	44.9	35	45.5	44	58.7		
Gynecological	25	15.2	13	16.7	11	14.3	7	9.3		
Gastrointestinal	29	11.0	9	11.5	10	13.0	10	13.3		
Hematological	15	9.1	11	14.1	7	9.1	7	9.3		
Lung	8	4.9	2	2.6	10	13.0	3	4.0		
Genitourinary	6	3.7	3	3.9	1	1.0	2	2.7		
Other	7	4.3	2	2.6	6	7.8	2	2.7		
Stage									9.18	.16
I	25	10.9	8	10.3	7	9.1	10	13.3		
II	55	23.9	21	26.9	13	16.9	21	28.0		
III	34	14.8	13	16.7	9	11.7	12	16.0		
IV	101	43.9	29	37.2	45	58.4	27	35.1		
Unstaged	15	6.5	7	9.0	3	3.9	5	6.7		
			M	*SD*	*M*	*SD*	*M*	*SD*		
Symptom rating (0-10)										
Pain (71% ≥ 3)			3.9	2.3	3.3	2.9	3.3	2.5	2.82	.42
Fatigue (90% ≥ 3)			4.6	2.6	5.2	2.4	4.6	2.2	1.93	.59
Anxiety (60% ≥ 3)			4.0	3.1	3.1	2.9	3.0	2.6	1.76	.62
Nausea (47% ≥ 3)			3.6	3.2	2.6	2.9	1.6	2.2	5.07	.17
Age	54.7	11.2	54.9	9.8	53.9	11.7	55.5	11.9	$F_{2,227} = 0.37$	.69

receiving various chemotherapy treatments; 8 were receiving Aredia® only.

Eligibility criteria required having at least one symptom rated as 3 or greater on a scale of 0 to 10, with 10 being the *worst imaginable*. At entry into the study, symptoms rated 3 were fatigue (90%), pain (71%), anxiety (50%), and nausea (47%). There were no significant differences among the MT, HT, or presence groups on symptoms at baseline, demographic characteristics, diagnosis, stage of disease, mean time from diagnosis, or mean time from first chemotherapy (see Table 1).

Use of CAM during the study was assessed before and after each period. Subjects were asked not to seek massage or HT outside of the study. Past CAM use included none (n = 50, 22%), therapies other than massage or HT (n = 43, 19%), and massage or HT (n = 6, 4%). Almost half (n = 71) left this question blank.

Crossover and Sequence Effects

There were no sequence effects, indicating that the order of the condition received did not affect outcomes. Despite a wash-out mean time of 16.7 days (range, 3-56 days) between conditions, there were 2 outcomes with carryover effects, indicating that response to the variable in the first period influenced response in the second period: ondansetron use ($z = -2.15$, $P = .031$) and pain interference ($z = -3.76$, $P < .0001$). As a result, only the first period data (sessions 1-4 and not sessions 5-8) were used for testing these 2 variables, resulting in less power to detect a difference for pain interference and ondansetron use.

Presence Versus Control

The presence condition was compared to the control condition to determine if presence of a caring professional had an intervention effect on outcome measures. Using AUC analysis, subjects in the presence condition had lower respiratory rate and heart rate ($P < .001$) before and after each session, indicating that resting on a table for 45 minutes in the presence of a caring professional with calming music induced a relaxed state. The presence condition was not different from the control condition, however, on blood pressure or any outcome measure of pain function, pain index, nausea function, nausea index, anxiety, fatigue, analgesic or antiemetic use. Mood disturbance was close to significance, with subjects in the presence condition having less mood disturbance than during the control period ($t_{44} = 1.95$, $P = .058$).

Pre-Post (Immediate) Intervention Effects

Immediate pre- and postsession outcomes included pain and nausea ratings and vital sign measures of relaxation (heart rate, respiratory rate, blood pressure). Using AUC analysis over all 4 sessions for each

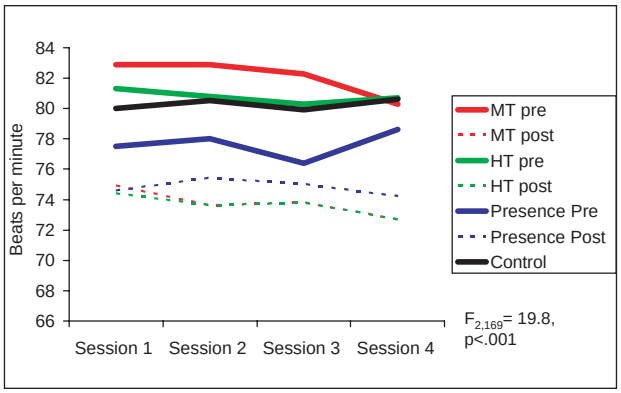

Figure 1 *Heart rate pre- and postintervention. MT = therapeutic massage; HT = healing touch.*

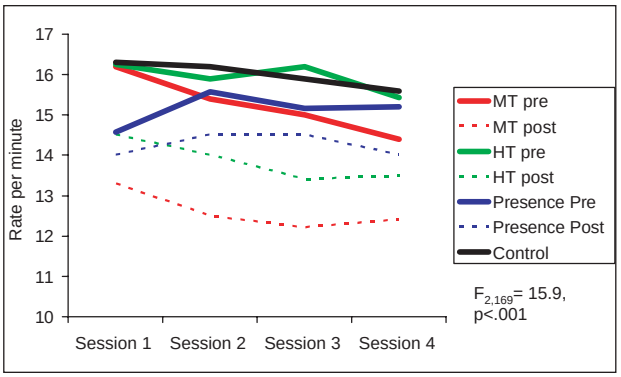

Figure 2 *Respiratory rate pre- and postintervention. MT = therapeutic massage; HT = healing touch.*

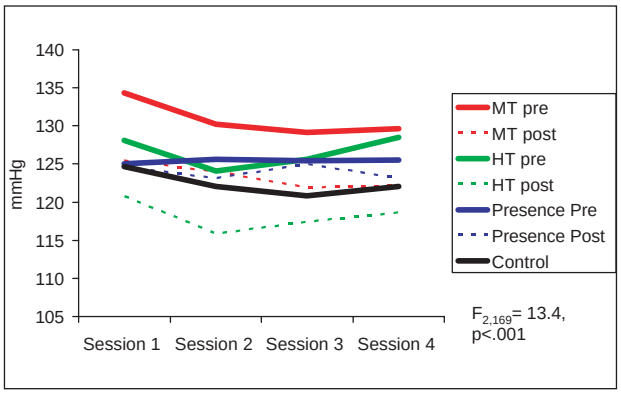

Figure 3 *Systolic blood pressure pre- and postintervention. MT = therapeutic massage; HT = healing touch.*

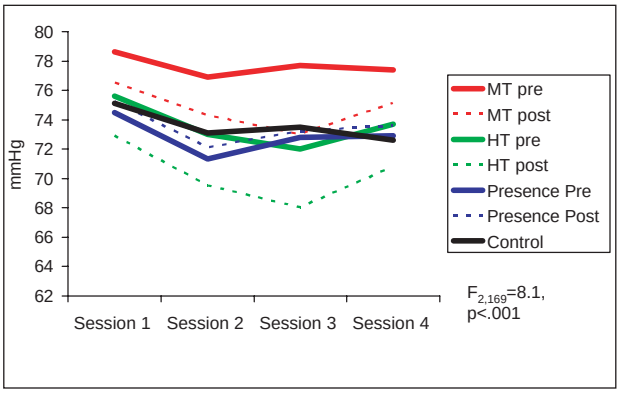

Figure 4 *Diastolic blood pressure pre- and postintervention. MT = therapeutic massage; HT = healing touch.*

condition, MT and HT reduced respiratory rate ($P <$ .001), heart rate ($P <$ .001), and systolic ($P <$ .001) and diastolic blood pressure ($P <$ .001) in comparison to control (Figures 1-4). Current levels of pain also were lower in the MT ($P <$ .001) and HT ($P <$ .011) conditions in comparison to the control condition (Figure 5). Compared to presence, MT and HT were more effective in reducing heart rate (P = .011), systolic blood pressure ($P <$ .01), and pre-post current pain ($P <$ .001). There were no differences between MT and HT in comparison to presence on pre-post nausea at time 1 or time 4. AUC analyses were not done for nausea, as ANOVA effects were not significant.

Intervention Effects Over 4 Weeks: Condition Effects

Intervention (MT, HT, presence) effects over 4 weeks were compared to control effects on outcomes of pain index, nausea index, pain interference (function), nausea interference, analgesic use, antiemetic use, anxiety, total mood disturbance, fatigue, and satisfaction with care. Overall treatment versus control effects were compared using ANCOVA and GLM analyses, with the very first measure used as a covariate. There were no significant interactions or between-treatment effects on any POMS measure. There was a significant decrease in total mood disturbance (F = 6.06, P = .015) for all the treatment groups (MT, HT, presence) over time in comparison to the control condition.

Comparing individual interventions with their matched control periods in paired t tests, MT reduced total mood disturbance (t_{61} = 3.0, P = .004) and anxiety (t_{61} = 2.3, P = .023), while MT effect on fatigue was close to significance (t_{61} = 1.9, P = .057) (Table 2). HT reduced total mood disturbance (t_{55} = 3.2, P = .003) and fatigue (t_{55} = 2.3, P = .028). Presence was no different than control on POMS measures, although mood disturbance came close to significance (t_{44} = 2.0, P = .058).

There were no significant changes over time within any of the intervention groups or differences in the intervention effect between groups on pain index or interference in living due to pain (Table 3). Despite

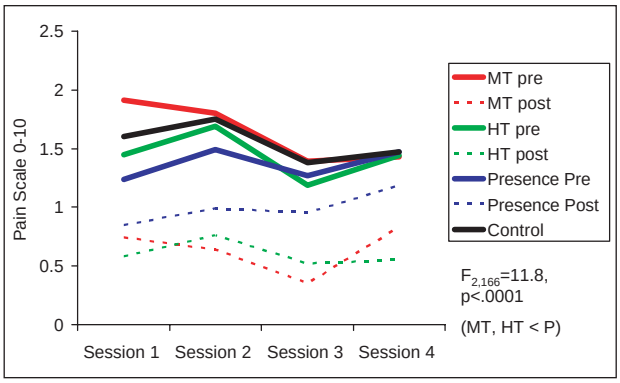

Figure 5 Pain pre- and postintervention. MT = therapeutic massage; HT = healing touch.

71% reporting a pain score of 3 or greater at study entry, mean pain scores for each intervention and control sessions were all less than 3.0 (scale of 0-10). Subjects receiving massage, however, used less NSAID medications during the massage than during the control period ($z = -2.4$, $P = .018$) (Table 4). Although not significant, there was a wide variance in morphine sulfate (or equivalent narcotic) use, which averaged 15.4 mg (51.2 mg SD) during MT versus 36.4 mg (122.2 mg SD) during control.

There were no differences between any intervention and control conditions on nausea index, nausea interference, or use of antiemetics. There was a significant difference in use, however, between treatment groups during the intervention period ($\chi^2 = 9.0$, $P = .011$), with the presence group using less (mean of 5.1 mg; range, 0-80 mg) than the massage group (mean of 9.1 mg; range, 0-58 mg,) ($z = -2.69$, $P = .007$). This use was not different from the control condition.

Overall satisfaction with care was similar between intervention and control conditions ($\chi^2 = 2.75$, $P = .43$). Mean satisfaction scores ranged from 3.6 to 3.9, with a maximum score of 4.0 (most satisfied). Subjects receiving MT and HT, however, evaluated the overall helpfulness and satisfaction with these treatments much higher than those who received presence ($\chi^2 = 28.66$, $P < .0001$, adjusted α of .016).

Subjective responses provided on the evaluation survey supported the study findings. Of importance is that no adverse events in response to the interventions were reported during or at the end of the study. Comments regarding MT alluded to less fatigue and anxiety: "I felt totally relaxed with the fatigue gone. The anxious feeling eliminated. . . . This is my first experience with massage. I've missed a lot in 60 years. I plan to continue." Other comments suggested that MT helped reduce nausea, despite nonsignificant group effects. "It was a relief to have such a noticeable improvement in nausea. Food smells don't bother me now." "It helped me relax. After chemotherapy I had less nausea and felt better in a shorter time."

Participants found HT gave them more energy and a peaceful feeling, and they were better able to sleep with fewer symptoms. Comments included, "I believe it helped greatly with my symptoms for 2 or 3 days out." "I felt calmer after the first 3 treatments, more energy after the last one. I also did not get meds for the first time and slept well." "My shoulder pain is totally gone now." "How do you describe something so wonderful . . . peaceful, energizing, healing . . . a total freedom from tension and unpleasant anxieties." "I expected little or nothing from this treatment but after each treatment felt better both physically and mentally. . . . I will be scheduling treatment on my own."

Discussion

MT and HT were more effective than presence alone or standard care in inducing physical relaxation, reducing pain, and improving mood states and fatigue. Presence lowered heart and respiratory rates but was no different than the control condition on any symptom measure. The decrease in total mood disturbance over time in all 3 intervention groups together, but not the control group, suggests that the presence of a caring practitioner has some influence in improving mood. The specific intervention effects of MT and HT on blood pressure, current pain and NSAID use (MT only), fatigue (HT only), and mood disturbance, however, suggest that the touch and energy therapies have an additive beneficial effect in improving mood and reducing pain and fatigue. Although resting in the presence of a caring practitioner helped relax subjects, it was not the presence of the therapist alone that influenced physical and emotional outcomes but the actual touch and healing interventions. While other studies have included presence within the control group, this is the first study to differentiate the specific and individual effect of presence of a caring professional. These results clearly suggest a benefit to both massage and HT that goes beyond the mere presence of a caring practitioner.

Both MT and HT induced a relaxed state, with lower respiratory and heart rates and lower systolic and diastolic blood pressure over all 4 sessions. Heart rates decreased 7.6 to 9.3 beats per minute in massage and 6.0 to 7.1 beats in HT. Changes in heart rate were greater than the average decreases of 4 to 6 beats per minute reported in hospice care,[13,17] men with cancer,[12] and nursing home residents.[39] Relaxation is assumed to be an effect in adults receiving massage and HT, but no studies have measured physiological responses to

Table 2. Intervention Effects on Anxiety, Mood Disturbance, and Fatigue (Profile of Mood States)

		Control Condition				*Intervention*				*Intervention Effects*					
		Session 1		*Session 4*		*Session 1*		*Session 4*		*Sessions 1-4*			*Intervention Between Groups*		
	n	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*	t[a]	df	P *Value*	f[b]	df	P *Value*
Mood disturbance													0.93	2, 160	.40
MT	62	31.0	28.0	29.6	28.3	32.9	28.1	17.8	27.9	3.0	61	.004			
HT	56	29.9	28.5	31.8	32.2	32.7	31.9	20.3	34.1	3.2	55	.003			
Presence	45	25.2	26.5	28.4	32.0	30.7	29.3	23.0	27.1	2.0	44	.06			
Anxiety													0.99	2, 160	.37
MT	62	10.8	6.5	9.6	5.0	11.1	6.5	7.6	5.6	2.3	61	.02			
HT	56	10.0	5.6	10.5	6.3	10.8	6.5	7.7	5.9	0.92	55	.36			
Presence	45	8.8	4.6	8.5	5.9	10.1	5.9	8.2	5.7	1.0	44	.34			
Fatigue													0.54	2, 160	.58
MT	62	11.9	6.7	12.5	7.0	12.1	7.1	9.8	6.7	1.9	61	.06			
HT	56	11.5	6.1	12.0	6.6	12.3	6.9	10.1	6.5	2.3	55	.03			
Presence	45	11.1	6.9	11.5	7.1	11.2	6.1	10.4	6.5	0.38	44	.70			

MT = therapeutic massage; HT = healing touch.
a. *t* test based on change from session 1 to 4 for control period compared to change in session 1 to 4 in treatment period.
b. ANCOVA using treatment session 4 values with first baseline as covariate.

Table 3. Intervention Effects on Pain

		Control Condition				*Intervention*				*Intervention Effects*		*Intervention Between Groups*	
		Session 1		*Session 4*		*Session 1*		*Session 4*		*Sessions 1-4*			
	n	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*	*z-score*[a]	P *Value*	χ^2	P *Value*
Pain index (scale 0-10)												5.1	.08
MT	61	2.1	2.0	1.7	1.7	2.3	2.0	1.7	1.6	–1.3	.20		
HT	56	2.2	2.0	1.7	2.0	1.8	1.5	1.7	1.8	–0.08	.94		
Presence	45	1.7	1.9	1.9	2.2	1.6	1.6	1.7	2.0	–0.50	.62		
Pain interference												0.001	.99
MT	61	2.0	2.1	1.7	2.2	2.1	2.3	1.2	1.6	–1.4	.17		
HT	56	2.3	2.6	1.7	2.1	1.9	2.2	1.6	1.9	–2.5	.80		
Presence	45	1.3	1.7	1.9	2.1	1.5	1.7	1.5	1.9	–1.3	.19		

MT = therapeutic massage; HT = healing touch.
a. Wilcoxon matched-pairs signed-rank test.
b. Kruskal-Wallis ANOVA based on comparing the difference in session 1 to session 4 for the intervention period.

Table 4. Analgesic Use by Intervention

		Control Condition		Intervention			
	n	*Total Milligrams*	*SD*	*Total Milligrams*	*SD*	*z score*[a]	P *Value*
NSAID use							
MT	61	3710.7	5303.4	2193.4	2728.3	–2.4	.02
HT	55	4564.0	6058.6	4116.2	5586.0	–0.66	.51
Presence	45	4544.3	2725.0	2888.6	4116.9	–1.6	.11
Morphine equivalency							
MT	61	36.4	122.2	15.4	51.2	–4.7	.64
HT	55	58.4	164.4	64.8	222.9	–0.81	.42
Presence	45	56.5	174.0	56.0	178.9	–0.71	.48

a. Mann-Whitney *U* test.

HT, and responses to massage are often measured only one time. The consistency of the decrease over all 4 sessions for all vital signs attests to the relaxation effect of both massage and HT.

MT and HT were effective at reducing pain in one 45-minute intervention. This short-term relief was consistent across all sessions. Only the massage group was able to reduce their use of medications (NSAIDs) over the 4-week period, however, and no other long-term effects on pain were measured in response to the interventions. Although morphine (and equivalent narcotic) use was not significantly different from the control condition, the total dose was lower in the MT group. Overall pain levels and narcotic use were low and extremely variable in this sample. A larger sample size or study of subjects with consistent reports of pain may more accurately detect a difference in response to MT or HT.

In other studies, massage has been effective at reducing both acute[8,40,41] and chronic pain in nonmalignant disease[42-44] and acute pain in cancer.[11,12,16-18,45] Wilkie and colleagues reported a greater decrease in pain intensity in response to 4 massage sessions over 2 weeks than in the control group.[17] In the only HT study to measure pain, postoperative pain and narcotic analgesic use was lower in the 20 women who received HT versus than in those who received back massage or no treatment.[26] While acute pain responds to massage and HT, further study is needed to determine effects of massage and HT on chronic pain.

All intervention groups had some effect in reducing overall mood disturbance over time. Other massage studies found similar improvements in mood states in persons with cancer.[11,20,45] Although no standardized instruments were used, Wilkinson and colleagues reported less perceived stress and enhancement of health in healthy subjects receiving HT.[24]

Massage was the only intervention to lower anxiety, although anxiety decreased in the expected direction in HT. Other studies also found less anxiety in response to massage, measured by the State Trait Anxiety Inventory,[12,45-47] Hospital Anxiety and Depression Scale,[48] and Beck Anxiety Inventory.[27] Dunn et al found no effect of massage on anxiety, measured on a 4-point scale, in 122 intensive care patients.[49] Only one other HT study measured anxiety and found a similar nonsignificant decrease in 36 caregivers of transplant patients.[27]

HT was more effective at reducing fatigue, although massage effect was close to significance. Other studies in cancer showed reduced fatigue in response to massage[11,27] but no effect in response to HT.[27] This is the first study to demonstrate reduced fatigue in response to HT. Less fatigue might be expected, given that HT is an energy therapy. However, fatigue is a complex symptom, with physical, emotional, and motivational components. Fatigue measured by the POMS reflects primarily musculoskeletal tension and anxiety reflected in vague, diffuse states (anxious, uneasy).

Despite 47% of subjects reporting nausea scores of 3 or more at study entry, mean presession and postsession nausea scores for each session were consistently less than 1.0 on a scale of 0 to 10. This discrepancy can be explained by the timing of the intervention sessions prior to chemotherapy on the day of treatment. Nausea typically resolves within a few days of chemotherapy, which would be several days before the next intervention or control session. The lack of significance most likely reflects a floor effect, in which there is no room for improvement in response to an intervention. Qualitative analysis revealed that at least some subjects found HT and MT helpful in reducing their nausea or use of antiemetics.

Despite nonsignificant differences on the overall satisfaction survey, subjects evaluated the specific benefits of HT and MT much higher than the control and presence conditions. The limitation of satisfaction surveys is that they are often too general to be sensitive to individual differences. Many patients also tend to mark extremes on satisfaction surveys; they are either highly satisfied or highly critical. The evaluation

assessment of the specific interventions provided positive feedback to the practitioners and a qualitative assessment of their benefit. In any research on complementary or alternative therapies, a randomized controlled trial that controls subject burden risks missing important responses not captured or measurable with selected standardized instruments. Subjective and qualitative data can yield important insights for further research. However, a more rigorous measure of subjective benefit should be developed for future study.

Crossover designs provide greater power with a smaller sample size (if no carryover effects exist) and eliminate heterogeneity between intervention and control groups. They also offer an incentive to potential subjects, who may not want to risk being randomized to the control-only group. The disadvantage, however, is the lengthy commitment to completing the entire study and the risk of losing subjects in the second crossover period. The 29% drop out in this study was somewhat higher than that typically expected with longitudinal intervention studies.[50] With 44% of the subjects having stage IV disease, it is not surprising that half were dropped because of advancing disease and a subsequent change in treatment protocol making them ineligible for the crossover period. Crossover designs may be more appropriate for healthy subjects or those with earlier stage disease.

Other limitations of the study include the potential bias of the 42% who consented versus the 58% who declined to participate and the difference in outcomes of pain, nausea, fatigue, and mood disturbance of the 66 who dropped versus the 164 retained in the study. Other limitations potentially influencing accuracy of measures are the lack of blinding and variability of the research assistant and practitioners collecting instrument and vital sign assessments, as well as the variation in intervention technique. Despite the limitations, 164 subjects completed all data for all 8 sessions, reflecting the largest database for an outcome study of massage and HT.

Conclusion

This randomized clinical trial design conclusively supported the hypothesis that therapeutic massage and HT were more effective than presence of a caring professional alone or standard care in inducing a relaxed state and reducing short-term pain, mood disturbance, and fatigue in adult patients with cancer undergoing chemotherapy. Participants rated both interventions highly regarding overall helpfulness and satisfaction. There was no clear benefit of one intervention over the other. This is the first published randomized study reporting positive effects of HT in cancer. Although this study provides support for the short-term effects of MT and HT, further study is needed to test the long-term effects and the longevity of specific effects on symptoms.

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