The Effects of Therapeutic Touch on Patients with Osteoarthritis of the Knee

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BACKGROUND. The purpose of this study was to determine if therapeutic touch, an alternative medicine modality, is effective in the treatment of osteoarthritis of the knee.

METHODS. A single-blinded randomized control trial was conducted in a family practice center of a community hospital family practice residency program in Pennsylvania. The patients were between the ages of 40 and 80, had been given a diagnosis of osteoarthritis of at least one knee, had not had knee replacement, and had no other connective tissue disease. The patients were randomized to therapeutic touch, mock therapeutic touch, or standard care. The main outcome measures were pain and its impact, general well-being, and health status measured by standardized, validated instruments, as well as the qualitative measurement of a Depth interview.

RESULTS. Twenty-five patients completed the study. The treatment group had significantly decreased pain and improved function as compared with the placebo and control groups. The qualitative Depth interview confirmed this result.

CONCLUSION. Despite the small numbers, significant differences were found in improvement in function and pain for patients receiving therapeutic touch. A larger study is needed to confirm these results. Alternative therapies can neither be accepted nor rejected without being subjected to the scientific method.

KEY WORDS. Touch; therapeutic touch [non-MeSH]; alternative medicine; osteoarthritis; knee. *(J Fam Pract 1998; 47:271-277)*

Osteoarthritis is the most common joint disease and the leading cause of chronic disability in developed countries,[1] yet our treatment options for this disorder are limited. Osteoarthritis patients may be among those who are looking to alternative medicine for additional possibilities for relief from their symptoms. In 1991, the National Institutes of Health (NIH) acknowledged the range of alternative options now available and created the Office of Alternative Medicine to begin evaluating these therapies.

Therapeutic touch (TT), a form of complementary medicine that the NIH categorizes as a "manual healing method," is an intervention that could benefit patients with osteoarthritis. Developed by Krieger and Kunz in the 1970s,[2] TT has since been taught in more than 80 universities and is a part of the nursing protocol in an increasing number of hospitals.[3] The theory states that everyone has an energy system that may become imbalanced with illness. Like acupuncture or other schools of healing that postulate such a theory, TT attempts to bring the body system back into balance.

TT has been the subject of several studies that support its effects on anxiety[4] and pain,[5] and it is being used in diverse medical settings. Because there is some doubt, however, about its biologic plausibility,[6] the most rigorous methods are necessary to test its value.

The purpose of this study was to investigate the effects of TT on pain, level of functioning, and general well-being in patients with osteoarthritis of the knee. Qualitative measures were used in addition to quantitative measures to assess clinical significance and patient experience.

METHODS

Data Collection

Our study was a randomized controlled trial comparing TT, sham treatment (mock TT), and no treatment. Data collection ran from August 1995 to November 1995 at the Lawrenceville Family Health Center, one of two residency offices affiliated with the University of Pittsburgh Medical Center, St. Margaret Memorial Hospital, Family Practice Residency Program. Approximately 14,000 low- to middle-income patients are seen there each year.

Patients recruited for this study were between the ages of 40 and 80, had been given a diagnosis of osteoarthritis of at least one knee, and were able to read and speak English. Those patients with a diagnosis of connective tissue disorder, bilateral total knee replacement, or total knee replacement of their only affected knee were excluded from the study. Patients were iden-

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tified by a chart review of those with relevant diagnoses over the past year, and were then recruited by telephone. Thirty-one patients met the inclusion criteria and agreed to participate. Informed consent was obtained. These patients were assigned a rating of mild, moderate, or severe osteoarthritis, according to their responses on the Osteoarthritis of the Knee form[7] and a rheumatologist's reading of their bilateral knee radiograph. The questionnaire and radiograph readings were equally weighted in describing the severity of the arthritis. Subsequently, the patients within each rating were assigned to one of the three study groups, using a proportionate randomization. This insured that there were equal numbers of patients with each severity rating in each group.

Baseline data were gathered on all patients, using the Stanford Health Assessment Questionnaire (HAQ),[8] the West Haven-Yale Multidimensional Pain Inventory, version 2.1 (MPI),[9] and two visual analog scales to measure pain and general well-being. The HAQ is a general questionnaire regarding the patients' health status, functional status, medications, and use of medical services. The MPI addresses the patient's pain and the perception of its impact, and his or her functioning and social interactions. The visual analog scales are horizontal lines with the extreme responses printed at either end that allow patients to identify their level of pain or well-being on a scale from one to ten. These scales were completed before and after each treatment or placebo treatment as interim measures in both groups. The visual analog scales were not administered to the control group because we wanted to minimize any inadvertent placebo effect resulting from this contact.

All groups continued to receive their usual care throughout the study period. In addition, the treatment group received a TT treatment once a week for 6 weeks, and the placebo group received a mock treatment at the same rate, for identical amounts of time.

Since much of TT deals with the practitioner's perceptions, it appears as though he or she is simply moving her hands a few inches away from the patient's body. Previous studies have taken advantage of this fact by designing a series of movements to be done as a mock treatment, while the performer focuses on a cognitive task rather than on the patient.[5,10] We used this method with the placebo group. The actual TT practitioner did not give the mock treatments because it is theorized that some of the therapeutic process becomes automatic, and it is difficult for trained practitioners to go through the motions and not do TT.[11,12] The mock therapeutic touch (MTT) practitioner was chosen to resemble the TT practitioner in several ways; both were women of approximately the same age with experience in health care.

Before the study, both actual and mock TT treatments were videotaped and reviewed to insure that objective observers could not tell the difference.

Outcome measures were pain and its impact, general well-being, and health status. These measures were obtained using visual analog scales before and after each treatment, the HAQ, the MPI, and the qualitative technique of the Depth interview.[13] The Depth interviews were designed to further investigate the patients' experiences and ascertain whether they noted any changes that were not adequately addressed by our instruments. These interviews were piloted prior to the study. They were administered by an anthropology doctorate student who was previously unacquainted with the patients. In addition, an auditor was used to review the interviews once the analysis had been completed. This was done to insure that there was no evidence in the transcribed interviews that contradicted our conclusions.

All groups completed the HAQ, MPI, and the two visual analog scales in the first week. In addition, the treatment and placebo groups had a TT or MTT treatment and then completed both visual analog scales again afterward. During weeks 2 through 5, only the treatment and placebo groups were seen. The subjects completed the two visual analog scales before and after each weekly treatment. At the sixth week, they also participated in a Depth interview. At week 7, all subjects (treatment, placebo, and control groups) again completed the HAQ, MPI, and the two visual analog scales. There was then no contact by the investigators with any of the groups until week 13, when all subjects completed the HAQ, MPI, and both visual analog scales for the final time. The treatment and placebo groups also had their second Depth interviews at this time.

Statistical Analysis

Initially, one-way analysis of variance was used to compare treatment, placebo, and control groups at baseline for continuous-level measured variables obtained from the HAQ, MPI, and visual analog scales. Chi-square tests of homogeneity of proportions were used to compare categorical variables. Assumptions of these procedures were examined using residual diagnostics.

The HAQ and the MPI were examined between groups over time by using a 2-factor repeated-measures analysis of variance. Post hoc individual tests (such as comparing the treatment group at week 1 with itself at week 13) were performed using Fisher's least significant difference method.

The visual analog scales, given before and after each treatment session, were studied within groups using the paired t test. The differences between the before and after scores were tested between groups over time using analysis of variance.

All statistical tests used SAS software.[14] Levels of significance were considered at $P<.05$. The Depth interviews were analyzed by the method described by Crabtree and Miller.[13]

TABLE 1

Subject Characteristics (N=27), by Randomized Group

Characteristic	Treatment Group (n=8)	Placebo Group (n=11)	Control Group (n=8)
Age			
Average, in years	64.38	64.45	68.75
Sex			
Female, no. (%)	5 (62.5)	8 (72.7)	5 (62.5)
Severity score*			
Average (SD)	2.7 (.6542)	2.84 (.8774)	2.82 (.8534)

SD denotes standard deviation.
*Average severity scores were assigned on a scale of 1 to 5, where 5 is the most severe.

RESULTS

Thirty-one patients were enrolled and randomized. All were white and English-speaking. No significant differences were found in the ages or the severity scores of the groups (Table 1). Of these 31, two were unable to participate because of schedule conflicts. One patient was found to be unqualified for this study, and one left without explanation after looking at the questionnaire. Of the remaining 27 patients, 25 completed the entire study. The other 2 patients, 1 from the treatment and 1 from the placebo group, completed treatments and the first two sets of data collection only. They were unable to be reached to schedule the final interview and set of questionnaires.

Pain and function were evaluated by analysis of the MPI, HAQ Functional Disability Index, and Depth interviews. The MPI consists of 13 scales that evaluate different aspects of pain, coping with pain, and function.[9] The sections of the HAQ that deal with pain, function, and general health status make up the HAQ Functional Disability Index, which has been previously used in studies to report on arthritis patients.[15-17]

The treatment group had significantly decreased pain and improved function as compared with both the placebo and control groups. This was demonstrated by repeated-measures analysis on 10 of 13 scales on the MPI (Table 2). Several of the scales showed some improvement in the placebo group and additional improvement in the group that received the actual treat-

TABLE 2

MPI Repeated Measures Results

Scales in which increasing score indicates clinical improvement:

Scale	Groups: Treatment Average (SD)	Groups: Placebo Average (SD)	Groups: Control Average (SD)	*P* values: T vs P	*P* values: T vs C
Life control	4.95 (.191)	4.35 (.168)	4.08 (.178)	.0259	.0085
Support	3.65 (.304)	3.15 (.268)	2.98 (.284)	.2255	.2656
Solicitous responses	2.94 (.245)	2.65 (.183)	3.04 (.224)	.3497	.7727
Distracting responses	2.42 (.230)	1.92 (.171)	2.75 (.209)	.0975	.3036
Household chores	4.77 (.244)	4.65 (.182)	3.67 (.223)	.6988	.0043
Outdoor work	2.57 (.225)	1.39 (.167)	1.78 (.205)	.0005	.0178
Activities away from home	3.72 (.237)	2.41 (.177)	2.18 (.217)	.0003	.0003
Social activities	3.05 (.202)	2.51 (.150)	2.36 (.184)	.0443	.0510
General activity level	3.53 (.161)	2.74 (.120)	2.50 (.147)	.001	.0005

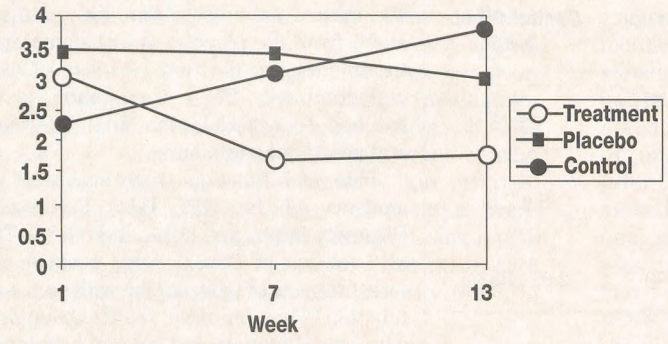
Scales in which decreasing score indicates clinical improvement:

Scale	Groups: Treatment Average (SD)	Groups: Placebo Average (SD)	Groups: Control Average (SD)	*P* values: T vs P	*P* values: T vs C
Pain severity	2.14 (.196)	3.27 (.173)	3.06 (.183)	.0002	.002
Interference	1.50 (.214)	2.36 (.189)	2.65 (.201)	.0056	.0016
Affective distress	1.32 (.255)	2.67 (.225)	2.32 (.239)	.0005	.0081
Punishing response	0.67 (.345)	1.84 (257)	1.72 (315)	.0137	.0365

Note: Averages represent the average score across all three time points.

FIGURE 1

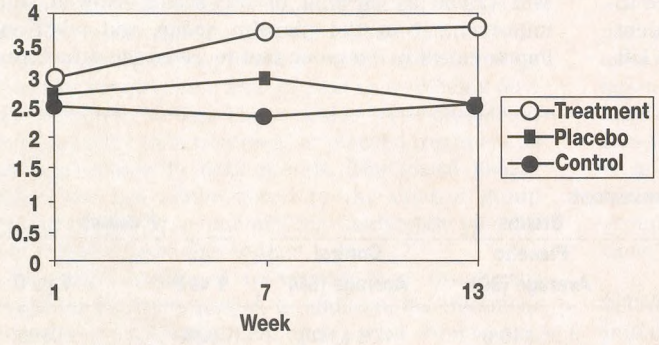
Pain Severity Scores on MPI



MPI denotes West Haven-Yale Multidimensional Pain Inventory.
P= .0006

FIGURE 2

General Activity Level Scores on MPI



MPI denotes West Haven-Yale Multidimensional Pain Inventory.
P= .0005

ment (Figures 1 and 2). The treatment groups began to relapse after the treatment had stopped, but remained generally improved above baseline. An analysis of these results that included the two patients who did not complete the study did not change the results.

There were no significant differences noted on the HAQ Functional Disability Index (Table 3). There were, however, significant improvements seen on the HAQ general health status questions. The treatment group did statistically better than the placebo group on two measures of current health status (continuous and ordinal, P =.05 and P =.001, respectively), dealing with the frustrations of arthritis at week 7 (P =.05), and number of tender joints (P =.02). They improved significantly more than the control group on measures of energy level (P =.02), coping with the frustrations of arthritis at week 13 (P =.02), mood (P =.04), and general health status. The placebo group did not improve significantly more than the control group on any of these measures. There was no difference between the groups in the change in pain scores on visual analog scores before and after TT or MTT, except once when the placebo group improved more than the treatment group. The average scores on each visual analog scales question did demonstrate greater improvement over time in the TT treatment group than in either the placebo or the control groups (Figures 3 and 4).

The qualitative data supported the improvement in the treatment group that was noted on the MPI. One patient in the treatment group who had only rare pain at baseline noted little change. All the other patients in the treatment group reported decreased pain and arthritis symptoms with a concomitant increase in activity. Patients' comments included: "But for all the time I was coming here the pain was very small," and "Everything [has changed]. I can walk. I have no pain. I have no swelling." Many described an increased activity level or increased ease of participation in their activities. When one subject was asked if she was able to be more or less active since the treatment, she replied, "Oh, more, definitely. . . . I don't mind my job so much."

Several patients in the treatment group also noted that they were able to delay or decrease other measures that were usually needed to control their symptoms. One patient said during her first interview, "I was at one point taking four doses a day of Extra Strength Tylenol. Each time since having the therapy I only take two tablets in the morning and don't have to take any the rest of the day." Weeks later this patient felt that having had TT may have "changed the fact that I might have to get a knee replacement as quickly." Other patients in the treatment group also noted that TT had allowed them to delay steroid injections or medications or walk farther without subsequent pain and swelling. During their second interview (7 weeks after the treatments had stopped), most patients in the treatment group felt that their symptoms had begun to worsen but that they were still improved compared with their pretreatment status. All the patients in the treatment group found TT a pleasant experience, and many commented that they wished it would continue.

The placebo group described a more heterogeneous response. Five of 11 patients had some decreased pain, but three of these were guarded in their descriptions: "It has let up a little bit, but not that much," and "I think I feel better." Four other patients noted that they felt better, but described the effect as one of "relaxation," "at peace" or "it is like something has been lifted." The remaining patient in the placebo group did not note any changes. Two patients did note a decreased "tightness in

TABLE 3

Results of the Stanford Health Assessment Questionnaire Functional Disability Index

	Week 1	Week 7	Week 13
Dressing and grooming			
Treatment group	0.25	0	0.07
Placebo group	0.35	0.18	0.3
Control group	0.13	0.07	0.56
Arising			
Treatment group	0.75	0.38	0.29
Placebo group	0.9	0.65	0.65
Control group	0.69	0.07	0.94
Eating			
Treatment group	0	0	0
Placebo group	0.23	0.18	0.18
Control group	0.04	0	0.21
Walking			
Treatment group	0.88	0.44	0.21*
Placebo group	0.95	0.8	0.5
Control group	0.71	0.86	1.21*
Hygiene			
Treatment group	0.33	0.04	0.09
Placebo group	0.53	0.36	0.46
Control group	0.37	0.52	0.46
Reach			
Treatment group	0.25	0.13*	0.14
Placebo group	0.65	0.73*	0.65
Control group	0.44	0.36	0.56
Grip			
Treatment group	0	0*	0
Placebo group	0.27	0.45*	0.23
Control group	0	0.09	0.17
Activities			
Treatment group	0.33	0.08	0.05
Placebo group	0.89	0.63	0.75
Control group	0.75	0.48	0.71

* Significant difference between groups; $P < .05$.

the joints." One patient stated that she felt it helped her and that she "would pay to do this." Most of these patients enjoyed the treatments and wished they could continue, but described a variety of reasons for this, such as "I miss coming out [to the office]," and "They were calming . . . even if they didn't take the pain away, something about them felt good."

During their second interviews, patients in the placebo group who had previously improved were more likely to describe symptoms as long-standing than were those in the treatment group, who described their experience in terms of what had happened during the treatments and since the treatments ended, commenting on the differences between these periods. Patients in both groups who spontaneously commented on their practitioner expressed positive feelings about her.

DISCUSSION

This study was designed as a randomized controlled trial in an attempt to clarify the effects of TT, with the knowledge that the placebo effect may account for the improvements seen with many pain treatments.[18] The mock treatment was designed to be as similar to TT as possible from the patients' perspective, to elicit the same placebo effect. Patients' expectations of the treatment may also have contributed to their response. By the random assignment of patients to one of the three groups, the bias due to self-selection was eliminated. It was possible to make this only a single-blinded study, since the TT practitioner cannot be blinded to the treatment she is giving. The study duration was chosen because 6 weeks was felt by practitioners to be a sufficient period to show any short-term change due to TT.

Our results showed that TT decreased arthritis pain, and improved function and general health status in these patients. This improvement was significantly greater than that seen in the placebo group. The treatment group also demonstrated a slower return to baseline than did patients who improved with the MTT. These results were demonstrated with both quantitative and qualitative measures. The qualitative findings reinforced the quantitative findings and assured the clinical impact of this magnitude of improvement.

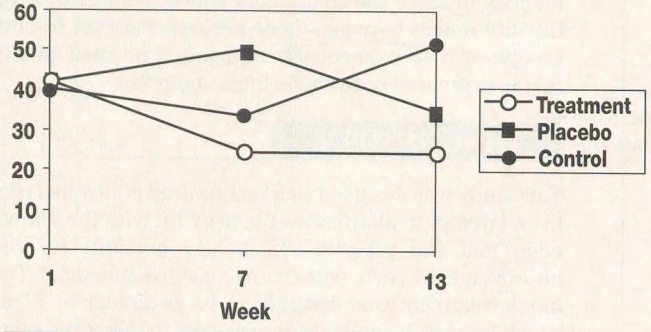
The fact that there was no difference in the amount of change between groups on the interim visual analog scales implies that there was no greater effect with either MTT or TT immediately following a treatment. If any of the effects were due to a greater placebo effect or rapport with the practitioner, one would expect to see greater improvement in that group immediately after treatment.

The HAQ Functional Disability Index, however, did not demonstrate improvement in any of the groups, which was not consistent with the rest of our findings. This may be because each scale consists of only two or three questions, most of which are extremely task-specific (eg, "Are you able to bend down to pick up clothing from the floor?") Each MPI scale contains between 3 and 11 questions, making this a more powerful instrument. Measures of general health status on the HAQ did show significant changes that were all consistent with the findings of the MPI and interviews in the direction of improvement of the treatment group.

The difference in outcomes between treatment and placebo groups allows us to distinguish the effect of TT

FIGURE 3

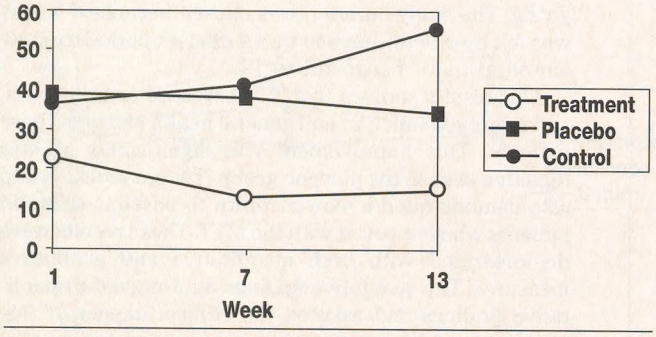
Average Visual Analog Scores Before Treatment on Question 1: Pain Level



On a scale of 0-100, where lower scores indicate less pain.

FIGURE 4

Average Visual Analog Scores Before Treatment on Question 2: General Well-being



On a scale of 0-100, where lower scores indicate better well-being.

from that of the relationship with the practitioner. The treatment group clearly improved, and more so than the placebo or control group. If additional improvement was not due to TT, then some other factor would have had to affect the treatment group differently. The practitioner was a variable that was different between groups, but this was controlled for in several ways that have been described previously. Two visual analog scales measuring the patients' perception of their practitioner as either warm or concerned showed no difference between groups. The interviews supported this, as patients in both groups spontaneously expressed positive feelings about their practitioner.

Changes in use of medications over time were analyzed to insure that this had not influenced one group more than another. There was no significant difference between groups in the change of number of medications.

Other studies have investigated the effects of TT on pain,[5,10] stress or anxiety,[19-22] and wound healing.[11,25-27] Criticisms of these studies have included the lack of control for placebo effect, time limitations on practitioners, inappropriate measurement tools, and the lack of both subjective and objective data.[17-19] This study was designed so that there would be both a baseline control and a placebo group. The time limitations on the TT were removed, but the placebo treatments matched. Previously validated instruments were used, and a qualitative component was employed to confirm the clinical impact of quantitative findings.

Our study did have the limitation of a small sample size. Despite this, many of our measures achieved statistical significance. Some of the absolute changes on the ordinal scales are only 1 to 2 points (on 6- or 10-point scales), but the interviews have assured us that changes of this magnitude are clinically significant and, indeed, often seemed dramatic to the patients.

Our positive findings have several implications. Although large studies are needed to confirm the effect, TT may offer a means of symptom control for osteoarthritis patients without the side effects caused by current modalities such as NSAIDs and corticosteroid injections.[27] Complementary therapies are often rejected because of a lack of belief in their theory, even when well-designed randomized controlled trials show evidence of their efficacy. The authors of a 1991 meta-analysis of controlled trials of homeopathy stated, "Based on this evidence, we would be ready to accept that homeopathy can be efficacious, if only the mechanism of action were more plausible."[28] If we are confident that the methodology of a randomized controlled trial is our best tool for discerning objective evidence, then we must be prepared to reconsider our theoretical framework if we find that it conflicts with the evidence.

Future research could study larger groups and answer subsequent questions on the efficacy of TT in several ways. TT is thought to help with healing, but osteoarthritis is a condition in which there are chronic structural changes, so the gradual return of symptoms after the cessation of treatment is not surprising. Future studies could use other conditions with more defined end points, such as following the healing rate of similar operative incisions. Other issues that will need to be addressed include the amount of training required to perform TT effectively and its effects on other commonly seen patient complaints.

It may well be that TT works in a different way than by manipulating energy fields. If other, larger studies confirm our findings of the effectiveness of this treatment, it will be important to design studies into the mechanism of action. In the meantime, it would be imprudent to reject a safe and effective therapy because we do not understand or do not accept its mode of action.

REFERENCES

1. Wilson JD, Braunwald E, Isselbacher KJ, et al. Harrison's principles of internal medicine, 13th ed. New York, NY: McGraw-Hill, Inc, 1991;1692.
2. Krieger D. Therapeutic touch: two decades of research, teaching and clinical practice. NSNA/Imprint 1990; Sept/Oct:83-88.
3. Williams G. The lowest-tech medicine ever. Longevity 1992; Jan:61.
4. Heidt PR. The effect of therapeutic touch on the anxiety level of hospitalized patients. Nurs Res 1981; 30:32-7.
5. Keller E, Bzdek VM. Effects of therapeutic touch on tension headache pain. Nurs Res 1986; 35:101-6.
6. Rosa L, Rosa E, Sarner L. A close look at therapeutic touch. JAMA 1998; 279:1005-10.
7. Health Outcomes Institute. Osteoarthritis of the Knee Form. 1991.
8. Ramey D, Raynauld JP, Fries J. The health assessment questionaire 1992, status and review. Arthritis Care Res 1992; 5:119-29.
9. Kearns RD, Turk DC, Rudy TE. The West Haven-Yale multidimensional pain inventory. Pain 1985; 23:345-56.
10. Meehan TC. Therapeutic touch and postoperative pain: a Rogerian research study. Nurs Sci Q 1991; 6:69-78.
11. Quinn JF. Future directions for therapeutic touch research. J Holistic Nurs 1989; 7:19-25.
12. Horrigon B, Quinn JF. Therapeutic touch and a healing way. Alt Therapies 1996; 2:70.
13. Crabtree B, Miller W. A qualitative approach to primary care research: the long interview. Fam Med 1991; 23:145-51.
14. SAS Institute, Inc. SAS/STAT User's Guide, version 6, 4th ed, vol 1. Cary, NC: SAS Institute, Inc, 1989.
15. Pincus T, Summer JA, Sorac SH Jr, Wallston KA, Hummon, NP. Assessment of patient satisfaction in activities of daily living using a modified Stanford health assessment questionnaire. Arthritis Rheum 1983; 26:1346-53.
16. Thompson PW, Pegley FS. A comparison of disability measured by the Stanford health assessment questionnaire disability scales in male and female rheumatoid outpatients. Br J Rheumatol 1991; 30:398-400.
17. Fries JF, Spitz PW, Young DY. The dimension of health outcomes: the health assessment questionnaire, disability and pain scales. J Rheumatol 1982; 9:789-93.
18. Turner JA, Demayo RA, Loeser JD, et al. The importance of placebo effects in pain treatment and research. JAMA 1994; 271:1609-14.
19. Vaughan S. The gentle touch. J Clin Nurs 1995; 4:359-68.
20. Quinn J. Therapeutic touch as energy exchange: testing the theory. Adv Nurs Sci 1984; Jan:42-9.
21. Kramer NA. Comparison of therapeutic touch and casual touch in stress reduction of hospitalized children. Ped Nurs 1990; 16:483-5.
22. Heidt PR. The effect of therapeutic touch on the anxiety level of hospitalized patients. Nurs Sci 1981; 30:32-7.
23. Wirth DP. The effect of non-contact therapeutic touch on the healing rate of full thickness dermal wounds. Subtle Energies 1990; 1:1-20.
24. Wirth DP. Complementary healing interventions and dermal wound reepithelialization: an overview. Int J Psychosom 1995; 42:1-4.
25. Clark PE, Clark MJ. Therapeutic touch: is there a scientific basis for the practice? Nurs Res 1984; 33:37-41.
26. Quinn JF. Building a body of knowledge: research on therapeutic touch. J Holistic Nurs 1988; 6:37-45.
27. Brandt KD. NSAIDS in the treatment of osteoarthritis, friends or foes? Bull Rheum Dis 1993; 42:1-4.
28. Kleijnen J, Knipschild P, Riet G. Clinical trials of homoeopathy. Br Med J 1991; 302:321.