

Randomized Trial Comparing Traditional Chinese Medical Acupuncture, Therapeutic Massage, and Self-care Education for Chronic Low Back Pain

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Background: Because the value of popular forms of alternative care for chronic back pain remains uncertain, we compared the effectiveness of acupuncture, therapeutic massage, and self-care education for persistent back pain.

Methods: We randomized 262 patients aged 20 to 70 years who had persistent back pain to receive Traditional Chinese Medical acupuncture (n=94), therapeutic massage (n=78), or self-care educational materials (n=90). Up to 10 massage or acupuncture visits were permitted over 10 weeks. Symptoms (0-10 scale) and dysfunction (0-23 scale) were assessed by telephone interviewers masked to treatment group. Follow-up was available for 95% of patients after 4, 10, and 52 weeks, and none withdrew for adverse effects.

Results: Treatment groups were compared after adjustment for prerandomization covariates using an intent-to-treat analysis. At 10 weeks, massage was superior to

self-care on the symptom scale (3.41 vs 4.71, respectively; $P=.01$) and the disability scale (5.88 vs 8.92, respectively; $P<.001$). Massage was also superior to acupuncture on the disability scale (5.89 vs 8.25, respectively; $P=.01$). After 1 year, massage was not better than self-care but was better than acupuncture (symptom scale: 3.08 vs 4.74, respectively; $P=.002$; dysfunction scale: 6.29 vs 8.21, respectively; $P=.05$). The massage group used the least medications ($P<.05$) and had the lowest costs of subsequent care.

Conclusions: Therapeutic massage was effective for persistent low back pain, apparently providing long-lasting benefits. Traditional Chinese Medical acupuncture was relatively ineffective. Massage might be an effective alternative to conventional medical care for persistent back pain.

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BACK PROBLEMS are among the most prevalent conditions afflicting Americans and one of the most common reasons for using complementary and alternative medical (CAM) therapies. In 1997, one third of US adults with low back pain visited a CAM provider for this problem, most commonly chiropractors, massage therapists, and acupuncturists.^{1,2} Ernst³ identified only 4 randomized trials evaluating therapeutic massage, and these reached conflicting conclusions; all were judged to be of poor quality and included massage only as a "control" therapy. Studies⁴⁻⁶ of acupuncture for back pain have also been inconclusive because of poor methodological quality and treatment protocols that do not reflect common practice. Because of the lack of rigorous efficacy studies, national evidence-based guidelines for acute low back pain have not recommended the use of either acupuncture or massage.⁷ We com-

pared the effectiveness and cost of acupuncture, therapeutic massage, and educational materials emphasizing self-management techniques for chronic low back pain.

RESULTS

RECRUITMENT AND FOLLOW-UP OF PATIENTS

Between May 30, 1997, and October 21, 1997, 3996 letters were mailed to HMO enrollees 6 weeks after a primary care visit for back pain. It is not known how many of these patients were eligible (eg, still had significant low back pain). Consent forms were returned by 693 enrollees (17%) (**Figure 1**). The first 262 enrollees confirmed eligible were randomized to receive acupuncture (n=94), massage (n=78), or self-care education (n=90). Ninety-five percent of all patients were successfully interviewed at each follow-up.

PATIENTS AND METHODS

STUDY SITE

This study was conducted at Group Health Cooperative, a large staff-model health maintenance organization (HMO) in Washington State. Treatments were provided in the offices of licensed acupuncturists and massage therapists who were members of a CAM practitioner network used by the HMO. The study protocol was approved by the Group Health Cooperative institutional review board, and all participants gave written informed consent.

PATIENTS

Individuals aged 20 to 70 years who visited a primary care physician for low back pain were identified from automated visit data. Six weeks after such visits, we mailed these patients letters describing the study, specifying inclusion and exclusion criteria, and asking those interested to return a signed consent form. A research assistant telephoned respondents to answer questions, confirm eligibility, collect baseline data, and randomize those remaining eligible.

Exclusion criteria were symptoms of sciatica, acupuncture or massage for back pain within the past year, back care from a specialist or CAM provider, severe clotting disorders or anticoagulant therapy, cardiac pacemakers, underlying systemic or visceral disease, pregnancy, involvement with litigation or compensation claims for back pain, inability to speak English, severe or progressive neurologic deficits, lumbar surgery within the past 3 years, recent vertebral fracture, serious comorbid conditions, and bothersomeness of back pain rated as less than 4 on a scale from 0 to 10.

RANDOMIZATION

After baseline data were collected using computer-assisted telephone interviewing, patients were randomly allocated without stratification using a computer-generated random sequence. Immediately after randomization, initial appointments were arranged for those allocated to acupuncture or massage, and self-care materials were mailed to patients allocated to that group. Patients retained access to their usual medical care.

TREATMENTS

Acupuncturists and massage therapists were allowed to schedule up to 10 visits over 10 weeks for each patient and

were informed that treatment cost and effectiveness would be measured. Providers recorded details of treatments, including whether they felt constrained by the protocol.

Acupuncture

We studied Traditional Chinese Medical (TCM) acupuncture because it is the most common form of acupuncture used in Washington State. We invited 58 licensed acupuncturists in the CAM provider network with at least 3 years of experience to participate; 18 applied and 7 were selected, including 3 who were trained in China and 2 who received their clinical training in China. These acupuncturists and our consultants established a treatment protocol that they considered clinically reasonable. This protocol permitted basic TCM needling techniques, electrical stimulation and manual manipulation of the needles, indirect moxibustion, infrared heat, cupping, and exercise recommendations. Moxibustion is the combustion of plant material to warm specific points at or near the surface of the body, and cupping involves placing a small heated cup on the body to create a vacuum. The protocol proscribed the use of massage (including acupressure), herbs, and treatments not considered common TCM practice (eg, Japanese meridian therapy). Decisions about the number and location of needles were left to the provider.

Massage

We invited 122 licensed massage therapists in the provider network with at least 3 years of experience to participate; 20 therapists applied and 12 were selected. With the guidance of our study therapists and consultants, we developed a protocol that focused on manipulation of soft tissues (ie, muscle and fascia). Thus, we permitted commonly used therapies such as Swedish, deep-tissue, neuromuscular, and trigger and pressure point techniques but specifically prohibited so-called energy techniques (eg, Reiki and therapeutic touch) that do not involve physical contact. We also proscribed meridian therapies (eg, acupressure and shiatsu) because of the possibility that they would have effects similar to acupuncture and approaches deemed too specialized (eg, craniosacral and a system of bodywork called Roling).

Self-care Education

Patients allocated to usual care alone might believe that they had been denied useful therapies, resulting in dissatisfaction and worse outcomes. Therefore, this comparison group

BASELINE CHARACTERISTICS

The typical patient was approximately 45 years old, white, well educated, and employed (**Table 1**). Mean scores on the SF-12 Mental Health Scale were close to the national norms (49 vs 50), but mean scores on the SF-12 Physical Health Scale were substantially worse (37 vs 50).¹⁷ Most patients had first received treatment for back problems more than 1 year earlier, and most had experienced pain continuously for the past year. On average, patients reported moderately severe symptoms (bothersomeness scale score, 6.2) and dysfunction (Roland Dis-

ability Scale score, 12.2). Most were using pain medication (primarily nonsteroidal anti-inflammatory drugs). Three percent of patients had previous experience with acupuncture for back pain, and 16% had previously tried massage. Baseline characteristics were similar across the 3 treatment groups.

STUDY TREATMENTS

Ninety-four percent of patients assigned to self-care reported reading at least some of the book (55% claimed to have read more than two thirds) and 73% reported

received high-quality and relatively inexpensive educational materials designed for persons with chronic back pain: a book⁸ and 2 professionally produced videotapes⁹: a 40-minute videotape on self-management of back pain and a 25-minute videotape demonstrating exercises. These unpublished materials included information about back pain and its treatment, techniques for controlling and preventing pain and for improving quality of life, and suggestions for coping with the emotional and interpersonal problems often accompanying chronic illness. The content of the book has been published in a slightly modified form.¹⁰

OUTCOME MEASURES

Interviewers masked to treatment group used computer-assisted telephone interviews to assess outcomes 4, 10, and 52 weeks after randomization. Questions pertaining to specific interventions (eg, "Did you read the book?") were asked only after outcomes data had been collected. The outcomes of primary interest were symptoms and dysfunction. At baseline and at all follow-up interviews, patients rated how "bothersome" back pain, leg pain, and numbness or tingling had been during the preceding week, each on a scale from 0 to 10. The score for the most bothersome symptom was used. This question has demonstrated substantial construct validity.^{11,12}

A modified Roland Disability Scale^{11,13,14} was used to measure patients' dysfunction. The score is the number of positive answers to 23 questions on limitation of daily activities attributable to back pain. This instrument is reliable, valid, and sensitive.^{11,15}

Several secondary outcomes, including disability, utilization, and cost, were also examined. Disability was measured using National Health Interview Survey questions about numbers of days spent in bed, home from work or school, or with reduced activity¹⁶; the questions were modified to refer specifically to back-related restrictions.

Automated utilization data provided complete information on provider visits, radiologic procedures, operations, and hospitalizations covered by the HMO. All analgesic agents, nonsteroidal anti-inflammatory drugs, and muscle relaxant medications dispensed from HMO pharmacies were recorded, although some were undoubtedly prescribed for problems other than back pain. Visits to non-study acupuncturists, massage practitioners, and other providers not covered by the HMO were identified at the 10-week and 1-year interviews.

Other secondary outcome measures were use of medications, satisfaction with overall care for the back problem,

SF-12 Physical and Mental Health summary scales,¹⁷ and numbers of days of aerobic exercise and back exercise performed (asked only at 1 year) in the previous week.

COSTS OF CARE

The study paid \$25 for each acupuncture and massage visit (about 50% of typical insurance reimbursement in Washington). Nonstudy treatments were covered (within contract limitations) by patients' health insurance. Eighty-seven percent of HMO enrollees had coverage for acupuncture and massage for chronic low back pain on a physician's referral. The HMO's cost accounting system provided information on costs of back pain-related services. Out-of-pocket expenses were not captured. We used the fee schedule used by major insurers in Washington State who cover massage and acupuncture to estimate the costs of the intervention visits: \$48 per massage visit and \$60 per initial and \$45 per follow-up acupuncture visit.

STATISTICAL ANALYSIS

The study was designed to have 80% power to detect a 2.5-point difference on the Roland Disability Scale and a 1.5-point difference on the symptom bothersomeness scale for the comparison of acupuncture and massage. These are consistent with the smallest clinically important differences.¹¹ These measures were analyzed as continuous variables within the context of an intent-to-treat analysis using analysis of covariance (ANCOVA) with adjustment for baseline values. Overall 2-sided significance of .05 was used when comparing all 3 treatments. Pairwise comparisons were made using the Sidak adjustment for multiple comparisons.¹⁸ Simple analysis of variance and nonparametric Kruskal-Wallis analyses were performed to confirm the ANCOVA.

We did not use repeated-measures analysis because differences among treatments were not constant over time. We therefore analyzed main effects at each point adjusting for the baseline values with ANCOVA. The final models included baseline covariates predictive of the primary outcomes at 10 weeks (baseline Roland Disability Scale score, baseline symptom bothersomeness scale score, pain traveling below the knee but not meeting criteria for sciatica, more than 90 days of back pain in the past 6 months, and satisfaction with previous back care) and sex and age. We tested interactions of the covariates with treatment to assess effect modification. Logistic regression adjusted for baseline values was used for dichotomous outcomes.

watching the videotapes. Ninety-four percent of patients in the acupuncture group and 95% in the massage group visited their assigned provider and made a mean (SD) of 8.0 (2.4) and 8.3 (2.3) visits, respectively. Visits to massage therapists and acupuncturists averaged approximately 1 hour.

All patients who received acupuncture were needled and "de qi," a characteristic dull ache, numbness, or tingling sensation associated with needling, was reported for 89%. Other commonly used therapies were infrared or other lamp heat (82% of patients), cupping (66%), and electrostimulation of the needles (51%). A mean of 12

needles (range, 5-16) were inserted at each visit, with significant differences among acupuncturists ($P < .001$). Acupuncturists recommended exercise for about half of their patients, usually stretching, walking, or swimming.

At the first visit, the most commonly used massage techniques were Swedish (71%), movement reeducation (70%), deep tissue (65%), moist heat or cold (51%), trigger or pressure point (48%), and neuromuscular (45%). Treatments provided at follow-up visits were similar. Massage therapists recommended exercise, typically stretching, at the conclusion of 64% of initial visits. Most massage therapists (59%) also used "body

awareness” techniques to help clients become more aware of their physical and kinesthetic sensations, including potential early warning signals of injury.

No serious adverse effects were reported by any study patients. Eleven percent of patients in the acupuncture group and 13% in the massage group reported “signifi-

cant discomfort or pain” during or shortly after treatment.

Mean (SD) intervention costs per randomized patient were \$50 for the group receiving self-care education materials, \$352 (\$138) for acupuncture visits, and \$377 (\$139) for massage visits.

PERCEIVED LIMITATIONS OF TREATMENT PROTOCOLS

Although initially fully satisfied with the treatment protocol, acupuncturists perceived some level of constraint at 46% of initial visits and for at least 1 visit for 70% of their patients. Proscribed treatments cited most frequently were herbs (36%) and Chinese massage (20%). Three acupuncturists rarely or never felt constrained and 2 usually felt constrained. Constraints were rarely noted by massage therapists.

NONSTUDY TREATMENTS

Ten percent of patients in the massage group vs 18% and 21% in the acupuncture and self-care groups, respectively, made HMO visits for back pain during the treatment period ($P = .16$). The percentages of patients reporting visits to providers not covered by the HMO was low (0% for massage, 4% for acupuncture, and 10% for self-care; $P = .01$). One patient in the acupuncture group and 3 in the self-care group visited a massage therapist,

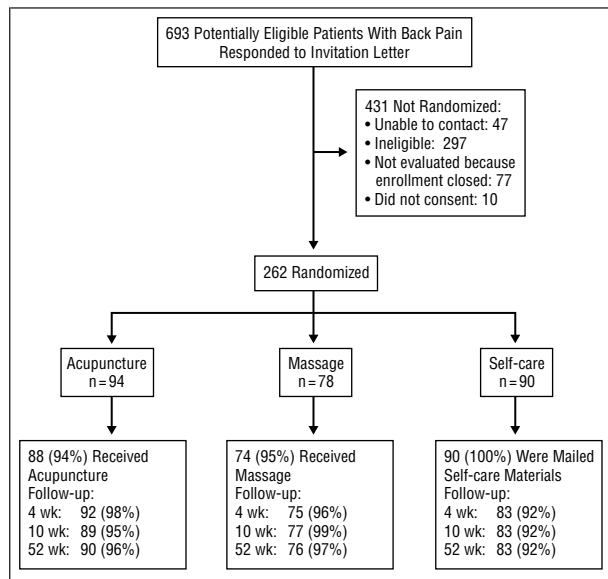


Figure 1. Trial profile. None of the 262 randomized patients withdrew because of adverse events.

Table 1. Baseline Characteristics of 262 Patients With Low Back Pain (LBP) by Treatment Group*

| Characteristic | Patients, No. | Treatment Group | | | Total |
|---|---------------|----------------------|------------------|--------------------|-------------|
| | | Acupuncture (n = 94) | Massage (n = 78) | Self-care (n = 90) | |
| Age, mean (SD), y | 262 | 45.3 (11.5) | 45.7 (11.4) | 43.8 (11.7) | 44.9 (11.5) |
| Women, % | 262 | 52 | 69 | 56 | 58 |
| Attending some college, % | 262 | 78 | 82 | 78 | 79 |
| White, % | 260 | 82 | 82 | 89 | 84 |
| Family income >\$35 000/y, % | 240 | 55 | 59 | 71 | 62 |
| Employed or self-employed, % | 262 | 82 | 90 | 82 | 84 |
| SF-12 Physical Health Scale score, mean (SD) | 257 | 37.0 (9.4) | 37.1 (8.6) | 36.5 (9.6) | 36.9 (9.2) |
| SF-12 Mental Health Scale score, mean (SD) | 257 | 48.8 (10.7) | 49.7 (10.6) | 48.8 (10.9) | 49.1 (10.8) |
| First sought LBP care > 1 y ago, % | 261 | 82 | 81 | 85 | 83 |
| Ever hospitalized for back problem, % | 262 | 11 | 10 | 7 | 9 |
| Have had a lower back operation, % | 262 | 5 | 5 | 8 | 6 |
| Previous acupuncture for LBP, % | 262 | 3 | 1 | 4 | 3 |
| Previous massage for LBP, % | 262 | 14 | 14 | 19 | 16 |
| Pain has lasted > 1 y, % | 257 | 57 | 64 | 62 | 61 |
| >90 d of LBP in the past 6 mo, % | 261 | 63 | 69 | 66 | 66 |
| Pain travels below knee, % | 260 | 24 | 31 | 30 | 28 |
| Symptoms most of past 24 h, % | 262 | 53 | 71 | 62 | 61 |
| Symptom bothersomeness during the past week (0-10 scale), mean (SD) | 262 | 6.2 (1.8) | 6.2 (1.9) | 6.1 (2.0) | 6.2 (1.9) |
| Roland Disability Scale score (0-23 scale), mean (SD) | 262 | 12.8 (5.3) | 11.8 (4.4) | 12.0 (5.3) | 12.2 (5.0) |
| ≥1 Work-loss day due to LBP in the past month, % | 233 | 26 | 14 | 26 | 22 |
| >7 d of restricted activity due to LBP in the past month, % | 259 | 48 | 36 | 41 | 42 |
| Used medication for LBP in the past week, % | 262 | 69 | 73 | 63 | 68 |
| Taking narcotic analgesics, % | 262 | 9 | 12 | 9 | 10 |
| Very satisfied with overall care for LBP, % | 252 | 8 | 3 | 6 | 6 |

* There were no significant differences among the 3 treatment groups for any of the characteristics ($P > .05$).

Table 2. Symptom Bothersomeness Scale and Roland Disability Scale Scores at Baseline, 4 Weeks, 10 Weeks, and 1 Year*

| | Treatment Group | | | P | |
|------------------------------------|-------------------------|---------------------|-----------------------|------------|-----------|
| | Acupuncture (n = 94) | Massage (n = 78) | Self-care (n = 90) | Unadjusted | Adjusted† |
| Baseline | | | | | |
| Symptom bothersomeness scale score | 6.2 (5.8-6.5) | 6.2 (5.8-6.6) | 6.1 (5.7-6.5) | .96 | ... |
| Roland Disability Scale score | 12.8 (11.7-13.8) | 11.8 (10.8-12.7) | 12.0 (10.9-13.0) | .39 | ... |
| 4 Weeks | | | | | |
| Symptom bothersomeness scale score | 4.3 (3.7-4.9) | 4.5 (4.0-5.1) | 4.9 (4.3-5.5) | .31 | .21 |
| Roland Disability Scale score | 9.1 (7.8-9.9) | 7.9 (6.9-9.0) | 9.3 (8.0-10.6) | .28 | .07 |
| 10 Weeks | | | | | |
| Symptom bothersomeness scale score | 4.0 (3.4-4.9) | 3.6 (3.0-4.2) | 4.6 (3.9-5.3) | .11 | .02 |
| Roland Disability Scale score | 7.9 (6.5-9.3) | 6.3 (5.1-7.5) | 8.8 (7.4-10.2) | .04 | <.001 |
| 1 Year | | | | | |
| Symptom bothersomeness scale score | 4.5 (3.8-5.2) | 3.2 (2.5-3.9) | 3.8 (3.1-4.5) | .04 | .003 |
| Roland Disability Scale score | 8.0 (6.6-9.3) | 6.8 (5.5-8.1) | 6.4 (5.1-7.7) | .22 | .03 |

*Data are given as means (95% confidence intervals for unadjusted means). Higher scores indicate more severe symptoms or dysfunction.
†Adjusted for baseline values and other covariates.

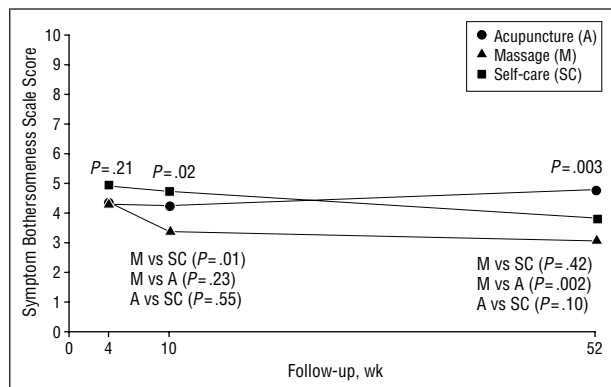


Figure 2. Mean symptom bothersomeness scale scores adjusted for baseline bothersomeness score (overall mean score, 6.2), baseline Roland Disability Scale score, pain below the knee, more than 90 days of back pain in the past 6 months, satisfaction with back care, sex, and age. Higher scores indicate more severe symptoms.

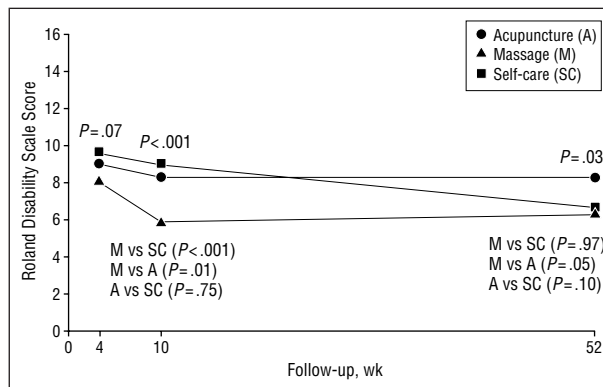


Figure 3. Mean Roland Disability Scale scores adjusted for baseline Roland Disability Scale score (overall mean score, 12.2), baseline symptom bothersomeness scale scores, pain below the knee, more than 90 days of back pain in the past 6 months, satisfaction with back care, sex, and age. Higher scores indicate greater disability.

and only one patient in the massage group and none in the self-care group visited an acupuncturist.

OUTCOMES AT THE END OF 10 WEEKS OF TREATMENT

Subjective Responses

At 10 weeks, 74% of patients rated massage as very helpful (at least 8 on a scale from 0-10) compared with 46% for acupuncture ($P<.001$). Of those using self-care materials, only 17% and 26% considered the book and the videotapes, respectively, very helpful.

Primary Outcomes: Symptoms and Dysfunction

Significant treatment effects favoring massage emerged after 10 weeks (**Table 2**, **Figure 2**, and **Figure 3**). After adjustment for baseline scores and prognostic covariates, treatments differed in their effects on symptom bothersomeness ($P=.02$) and dysfunction ($P<.001$).

The massage group had less severe symptoms than the self-care group ($P=.01$) and less dysfunction than the self-care ($P<.001$) and acupuncture ($P=.01$) groups. Analyses using square root transformations and non-parametric tests yielded similar results.

There were no significant interactions between treatment and baseline characteristics included as covariates in the final model, suggesting that there were no subgroups of patients (eg, women) especially likely to benefit from a particular treatment. There was little difference among the acupuncturists with respect to effect on patients' symptoms or function, although differences among massage therapists approached statistical significance.

At 10 weeks, only 5% of patients in the massage group compared with 19% in the acupuncture and self-care groups reported more than a week of restricted activity ($P=.02$ after controlling for baseline values). Similar results were found for the proportions of patients who spent 1 or more days in bed because of back pain (massage group, 3%; acupuncture group, 13%; and self-care

Table 3. Back Pain–Related HMO Services and Costs During the Year After Randomization*

| Type of Service | Treatment Group | | | P† |
|-------------------------------------|-----------------|-----------|-----------|-----|
| | Acupuncture | Massage | Self-care | |
| Provider visits, No.‡ | 1.9 (3.7) | 1.0 (2.1) | 1.5 (4.0) | .17 |
| Low back pain medication fills, No. | 4.4 (8.9) | 2.5 (3.6) | 4.0 (8.6) | .69 |
| Imaging studies, No. | 0.2 (0.4) | 0.1 (0.4) | 0.1 (0.4) | .43 |
| Cost of services, 1998 \$ | 252 (46) | 139 (25) | 200 (45) | .15 |

*Data are given as mean (SD). HMO indicates health maintenance organization. Mean duration of HMO enrollment during the year after randomization was about 5% shorter in the acupuncture group (10.9 mo) than in the massage and self-care groups (11.5 and 11.4 mo, respectively).

†Based on Kruskal-Wallis nonparametric test.

‡Excludes intervention visits.

group, 12%; adjusted $P=.04$). The proportion of patients who missed work or school was similar in the 3 groups (8%-14%).

Secondary Outcomes

Differences among the groups on the SF-12 Physical Health Scale were significant at 10 weeks ($P=.006$). The only significant pairwise comparison found massage to be superior to self-care ($P=.004$). Differences among the treatments on the SF-12 Mental Health Scale were not significant at 10 weeks, but at 4 weeks the scores for the massage group were superior to those for the acupuncture ($P=.003$) and self-care ($P=.03$) groups.

At baseline, less than 10% of patients in all 3 groups were very satisfied with the care they had received for their back problem. By 10 weeks, patients in the massage and acupuncture groups were more likely to be very satisfied than those in the self-care group (50%, 37%, and 13%, respectively; adjusted $P<.001$).

Between baseline and 10 weeks, the percentages of patients reporting medication use decreased substantially in the acupuncture group (from 69% to 51%) and the massage group (from 73% to 47%) but little in the self-care group (from 63% to 62%). Controlling for baseline values, medication use by the acupuncture and massage groups did not differ from each other but was significantly below that in the self-care group ($P<.05$).

At the end of the treatment period, approximately 25% of patients in all 3 groups reported more than 3 days of aerobic exercise in the previous week.

OUTCOMES AFTER 1 YEAR

Outcomes observed for massage and acupuncture at 10 weeks remained relatively unchanged at 1 year (Table 2 and Figures 2 and 3). Massage was superior to acupuncture in its effect on symptoms ($P=.002$) and function ($P=.051$). However, there were substantial improvements in the self-care group during this period such that patients in this group had better outcomes than those in the acupuncture group, although these differences were not statistically significant.

By 1 year, differences among groups in disability days, SF-12 Physical and Mental Health scale scores, and satisfaction were no longer significant. However, use of

medications (primarily nonsteroidal anti-inflammatory drugs) remained lower in the massage group than in both other groups (adjusted $P<.05$).

At 1 year, there were no significant differences among the treatment groups in the proportions of patients (1) with a recurrence or continuation of back pain in the previous 6 months (almost 80%), (2) seeking back care (about 40%), or (3) visiting an acupuncturist (about 6%) or a massage therapist (about 15%). The benefit of massage did not seem to be due to greater exercise by patients in that group because we found that patients in the massage group were less likely than those in the acupuncture and self-care groups to report more than 3 days of regular back exercises in the previous week (18%, 26%, and 37%, respectively; $P=.03$) and about equally likely to report use of aerobic exercise.

During the year after randomization, the mean number of provider visits (excluding intervention visits), number of filled pain medication prescriptions, and costs of outpatient HMO back care services were about 40% lower in the massage group than in other groups (Table 3). However, because of large SDs, these differences were not statistically significant. Two patients in the self-care group and 1 in the acupuncture group had back surgery (decompressive lumbar laminectomies for spinal stenosis). Similar percentages of patients (15%-20%) in the 3 groups reported use of non-HMO providers for back care during the previous 6 months, and they averaged similar numbers of visits (about 2).

CLINICAL SIGNIFICANCE OF FINDINGS

Group differences identified in this study exceeded suggested values for the smallest clinically relevant differences (2.5 points on the Roland Disability Scale and 1.5 points on the symptom bothersomeness scale). The adjusted Roland Disability Scale score for the massage group at 10 weeks was 3.0 points lower than that for the self-care group and 2.4 points below that for acupuncture. Symptom bothersomeness for the massage group at 1 year was 1.7 points lower than in the acupuncture group. The magnitude of the benefit of massage in this study (3.0 points on the Roland Disability Scale at 10 weeks) is double that found by other studies using the Roland Disability Scale and reporting significant effects of exercise¹⁹ and cognitive-behavioral interventions^{20,21} for chronic low back pain.

The results of this study suggest that massage is an effective short-term treatment for chronic low back pain, with benefits that persist for at least 1 year. Self-care educational materials had little early effect but, by 1 year, were almost as effective as massage. We were unable to identify any subgroups that were especially likely to benefit from one or both of these therapies. The persistent effects and substantially lower (but not statistically significant) utilization and costs of care for the massage group suggest that the initial costs (approximately \$375 in this study) might be offset by reductions in subsequent care. Although the cost of self-care materials is low, it is not clear that their use will result in cost savings. However, the combination of massage and self-care materials might prove to be particularly cost-effective.

Because we did not include a “no treatment” or “standard care only” control group, the results might underestimate the value of all 3 treatments. However, if acupuncture has a positive effect, it seems to be concentrated during the first 4 weeks because there was little improvement thereafter. During the first 4 weeks, all 3 groups improved by similar amounts, reflecting either the natural course of back pain, equivalent early effectiveness of all 3 treatments, or both.

The reasons for superior outcomes in the massage group are unclear but do not seem attributable to more favorable baseline characteristics or greater use of back care or exercise. In fact, back care visits, medication use, and back exercise were lowest in the massage group. The findings of this study are congruent with those of a recent consumer survey, which found deep-tissue massage to be the most helpful treatment for back pain and acupuncture to be among the least helpful.²²

Several related aspects of the massage therapy experience could explain its effectiveness: (1) spending an hour in a relaxed environment, (2) being touched in a therapeutic context, (3) receiving ongoing attention, (4) specific effects of soft-tissue manipulations on the structure and/or function of the tissues and on pain sensation, (5) education about exercise or other lifestyle changes, and (6) increased body awareness (as described in the “Study Treatments” subsection). It is unclear which, if any, of these explanations is most important. Better mental health status in the massage group during the first few weeks of treatment suggests that massage might enhance mental health independent of its effect on physical health, as has been reported in previous controlled studies evaluating the effects of massage for various conditions.²³

The relative ineffectiveness of the educational materials in the short term, coupled with evidence for effectiveness at 1 year, suggests a delayed benefit of viewing the materials or a benefit of reviewing the materials during the remainder of the year. Previous studies of educational booklets alone²⁴ or combined with nurse education^{25,26} showed no significant effect on back pain or function. More sophisticated educational materials (identical to those used in this study) supplemented by classes^{20,21} have modest short-term effects on function and symptoms compared with a popular book on back pain.²⁷

This study demonstrates that HMO patients with back pain are willing to participate in trials evaluating CAM therapies and to comply with assigned treatments. Although only 17% of patients invited to participate returned consent forms, a large fraction of the nonrespondents were likely ineligible (eg, no longer experiencing significant pain, workers compensation claimants, or experiencing sciatica). We previously found that two thirds of patients seen for back pain by primary care providers no longer had significant pain or dysfunction 7 weeks after their visits.²⁸ This suggests that a substantial proportion of patients with persisting pain or dysfunction volunteered to participate in this study. Furthermore, participants resembled patients with back pain commonly seen in primary care in terms of their demographic and clinical characteristics and were not persons who normally visited acupuncturists or massage therapists for their back pain. Finally, few patients reported significant discomfort or pain associated with the treatments, and there were no serious adverse effects.

Major strengths of this study were the randomized design, involvement of massage therapists and acupuncturists in developing treatment protocols, minimal “contamination” or “co-interventions,” high compliance rates, adequate sample size, high follow-up rates, and short- and long-term follow-up. The study’s primary limitations are use of a single study site, the absence of a “no treatment” or “usual care” control group, restriction of the study to a single form of acupuncture (TCM), the possibility that acupuncturists and massage therapists were atypical, and use of protocols that excluded treatments often used by some TCM acupuncturists (eg, herbs and oriental massage).

Few conventional or CAM treatments have been found by rigorous randomized trials to be effective treatments for chronic low back pain. The results of this study suggest that therapeutic massage is effective for chronic or subacute low back pain and raise doubts about the effectiveness of TCM acupuncture. It remains unclear whether a more comprehensive TCM approach including herbs and oriental massage would be effective for persistent back pain. Studies of the effectiveness of other forms of acupuncture are also needed because these vary in the location and depth of needling. The finding that benefits of massage persist well beyond the last treatment and the suggestion of possible reductions in subsequent health care utilization make massage a high priority for further study. Finally, future research should attempt to determine which components of the massage therapy experience contribute to its effectiveness.

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REFERENCES

- Eisenberg DM, Kessler RC, Foster CF, et al. Unconventional medicine in the United States. *N Engl J Med*. 1993;328:246-252.
- Eisenberg DM, Davis RB, Ettner SL, et al. Trends in alternative medicine use in the United States, 1990-1997: results of a follow-up national survey. *JAMA*. 1998;280:1569-1575.
- Ernst E. Massage therapy for low back pain: a systematic review. *J Pain Symptom Manage*. 1999;17:65-69.
- NIH Consensus Conference: acupuncture. *JAMA*. 1998;280:1518-1524.
- Ernst E, White AR. Acupuncture for low back pain: a meta-analysis of randomized controlled trials. *Arch Intern Med*. 1998;158:2235-2241.
- Van Tulder MW, Assendelft WJJ, Koes BW, Bouter LM, and the Editorial Board of the Cochrane Collaboration Back Review Group. The effectiveness of acupuncture in the management of acute and chronic low back pain: a systematic review within the framework of the Cochrane Collaboration Back Review Group. *Spine*. 1999;24:1113-1123.
- Bigos S, Bowyer O, Braen G, et al. *Acute Low Back Problems in Adults: Clinical Practice Guideline No. 14*. Rockville, Md: Public Health Service, US Dept of Health and Human Services; 1994. AHCPR publication 95-0642.
- Moore J, Lorig K, Minor M, et al. *Back Pain (Recurrent): Self-care Companion for Better Living*. New York, NY: Patient Education Media; 1996.
- Back Pain (Recurrent): Self-care* [videotape 1] and *Follow-Along Exercises* [videotape 2]. New York, NY: Patient Education Media; 1996.
- Moore JE, Lorig K, von Korff M, Gonzalez VM, Laurent DD. *The Back Pain Help-book*. Reading, Mass: Perseus Books; 1999.
- Patrick DL, Deyo RA, Atlas SJ, Singer DE, Chapin A, Keller RB. Assessing health-related quality of life in patients with sciatica. *Spine*. 1995;20:1899-1909.
- Cherkin DC, Deyo RA, Battie M, Street JH, Barlow W. A comparison of physical therapy, chiropractic manipulation, and provision of an educational booklet for the treatment of patients with low back pain. *N Engl J Med*. 1998;339:1021-1029.
- Roland M, Morris R. A study of the natural history of low-back pain, part I: development of a reliable and sensitive measure of disability in low back pain. *Spine*. 1983;8:141-144.
- Roland M, Morris R. A study of the natural history of low-back pain, part II: development of guidelines for trials of treatment in primary care. *Spine*. 1983;8:145-150.
- Deyo RA. Measuring the functional status of patients with low back pain. *Arch Phys Med Rehabil*. 1988;69:1044-1053.
- Riess PW. *Current Estimates From the National Health Interview Survey: United States, 1984*. Hyattsville, Md: National Center for Health Statistics; 1986. DHHS publication PHS 86-1584.
- Ware JE Jr, Kosinski M, Keller SD. A 12-item short-short survey: construction of scales and preliminary tests of reliability and validity. *Med Care*. 1996;34:220-233.
- Sidak Z. Rectangular confidence regions for the means of multivariate normal distributions. *J Am Stat Assoc*. 1967;62:626-633.
- Kluber Moffett J, Torgerson D, Bell-Syer D, et al. Randomized controlled trial of exercise for low back pain: clinical outcomes, costs, and preferences. *BMJ*. 1999;319:279-283.
- Von Korff M, Moore JE, Lorig K, et al. A randomized trial of a lay person-led self-management group intervention for back pain patients in primary care. *Spine*. 1998;23:2608-2615.
- Moore JE, von Korff M, Cherkin D, Saunders K, Lorig K. A randomized trial of a cognitive-behavioral program for enhancing back pain self-care in a primary care setting. *Pain*. 2000;88:145-153.
- Consumer's Union. The mainstreaming of alternative medicine. *Consumer Reports*. May 2000:17-25.
- Field TM. Massage therapy effects. *Am Psychol*. 1998;53:1270-1281.
- Roland M, Dixon M. Randomized controlled trial of an educational booklet for patients presenting with back pain in general practice. *J R Coll Gen Pract*. 1989;39:244-246.
- Berwick DM, Budman S, Feldstein M. No clinical effect of back schools in an HMO: a randomized prospective trial. *Spine*. 1989;14:338-344.
- Cherkin DC, Deyo RA, Street JH, Hunt M, Barlow W. Pitfalls of patient education: limited success of a program for back pain in primary care. *Spine*. 1996;21:345-355.
- White AA. *Your Aching Back: A Doctor's Guide to Relief*. New York, NY: Simon & Schuster; 1990.
- Cherkin DC, Deyo RA, Street JH, Barlow W. Predicting poor outcomes for back pain seen in primary care using patients' own criteria. *Spine*. 1996;21:2900-2907.