

Addition of Choice of Complementary Therapies to Usual Care for Acute Low Back Pain

A Randomized Controlled Trial

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Study Design.

A randomized controlled trial. **Objective.** To investigate the effectiveness and cost of usual care plus patient choice of acupuncture, chiropractic, or massage therapy (choice) compared with usual care alone in patients with acute low back pain (LBP).

Summary of Background Data. Few studies have evaluated care models with facilitated access to and financial coverage for adjunctive complementary and alternative medicine therapies.

Methods. A total of 444 patients with acute LBP (<21 days) were recruited from 4 clinical sites and randomized into 2 groups: usual care or choice. Outcomes included symptoms (bothersomeness), functional status (Roland), and satisfaction between baseline and 5 weeks, and cost of medical care in the 12 weeks after randomization.

Results. After 5 weeks, providing patients with a choice did not yield clinically important reductions in symptoms (median -4, [interquartile range -7, -2] for usual care, and -5 [-7, -3] for choice; $P = 0.002$) or improvements in functional status (-8 [-13, -2] for usual care, and -9 [-15, -4] for choice; $P = 0.15$). Although there was a significantly greater satisfaction with care in the choice group, this came at a net increase in costs of \$244 per patient. This consisted of a \$99 reduction in the

average cost to the insurer for medical care but an additional cost of \$343, for an average of 6.0 complementary and alternative medicine treatments per patient.

Conclusions. A model of care that offered access to a choice of complementary and alternative medicine therapies for acute LBP did not result in clinically significant improvements in symptom relief or functional restoration. This model was associated with greater patient satisfaction but increased total costs. Future evaluations of this choice model should focus on patients with chronic conditions (including chronic back pain) for which conventional medical care is often costly and of limited benefit.

Key words: acute low back pain, complementary therapies, choice, acupuncture, chiropractic, massage therapy.
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Although low back pain (LBP) is one of the most common conditions for which adults seek medical attention, there are still few therapeutic interventions with proven clinical benefits.^{1,2} Increasingly, patients are seeking complementary and alternative medical therapies in addition to conventional medical care in an effort to relieve their back pain symptoms. Specifically, among individuals reporting LBP and/or neck pain during the previous 12 months, 54% used one or more complementary and alternative medical therapies to treat their LBP.³ Chiropractors, massage therapists, and acupuncturists are licensed complementary and alternative medical practitioners who most commonly treat patients with LBP in the United States.^{3,4} However, the question as to whether these particular therapies are effective or cost effective for LBP when used individually or in combination remains unclear.

LBP is the primary reason for visits to chiropractors, massage therapists, and acupuncturists, and accounts for roughly 40%, 20%, and 15% of all visits, respectively, to each of these professional groups.⁵ Nearly one third of all visits to complementary care practitioners in the United States, 203 million of 269 million visits in 1997, were made specifically for the treatment of back or neck pain.³ While most of these visits involved individuals with chronic LBP, a substantial proportion were suffering from acute LBP.

Over the past 2 decades, each of these therapies has been evaluated in randomized controlled trials involving individuals with acute LBP. A recent Cochrane review,⁶ which could identify only 3 randomized controlled trials evaluating acupuncture, concluded that these studies "did not justify firm conclusions because of small sample

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sizes and low methodological quality.” In spite of numerous randomized controlled trials evaluating spinal manipulation (including chiropractic), it is unclear if spinal manipulation is substantially better than other conventional therapies for acute (or chronic) LBP.⁷ Finally, although initial studies have found massage to be effective for persistent back pain,⁸ it has yet to be evaluated as a treatment for acute LBP.⁹ None of the previous randomized controlled trials evaluating complementary and alternative medical treatments for back pain has allowed patients to select their preferred complementary care option, and few have measured costs.

To fill this gap in knowledge, we designed a randomized trial comparing the clinical effectiveness of usual care with a model that provided facilitated access to a choice of adjunctive acupuncture, chiropractic, or massage (choice) for acute LBP. This pragmatic design reflects the current practices of a large number of patients with LBP who choose to supplement conventional services with complementary and alternative medical therapies.³

Materials and Methods

Study Sites. Recruitment occurred between April 2001 and July 2003 at 4 clinical practice sites of Harvard Vanguard Medical Associates (HVMA), a large multi-specialty group practice in the greater Boston area. Usual care was provided at the HVMA clinics; complementary and alternative medical treatments took place at the private offices of participating credentialed complementary and alternative medical providers. The institutional review boards of Beth Israel Deaconess Medical Center, Harvard Pilgrim Healthcare (the institutional review board of record for HVMA), and Harvard Medical School reviewed and approved the protocol. All participants gave written informed consent.

Participants. Patients were 18 and older, presenting for initial evaluation of back pain. Exclusions included: pain not in the low back; pain lasting longer than 21 days; back or neck surgery in the past 5 years; history of vertebral fracture or dislocation; unexplained fever or weight loss; severe or disabling coexisting problem (*e.g.*, fibromyalgia, substance abuse, rheumatoid arthritis); visceral illness as a cause of back pain (*e.g.*, urolithiasis, endometriosis); history of cancer other than non-melanoma skin cancer; osteoporosis; severe scoliosis or spondylolisthesis; clotting disorders or use of anticoagulant medication; and severe or progressive neurologic signs. Patients who had received systemic corticosteroids, were pregnant, were involved in claims for compensation or litigation because of their back pain, or who had received prior treatment by any clinician for this episode of back pain were also excluded. If there were no exclusions, patients were referred to the study research assistant who did a second screening (requiring: a score ≥ 3 on a 0–10 pain scale [0 = no pain, 10 = worst pain ever],^{10–13} an ability to communicate in English, and availability for treatment during the 5-week treatment period). The research assistant then conducted the informed consent process, administered the baseline questionnaire, and enrolled the patient. This needed to be completed within 24 hours of the baseline screening.

Randomization. Randomization was conducted using sealed, opaque, sequentially numbered envelopes containing treat-

ment assignments generated by computerized stratified permuted-block randomization. One third of participants were assigned to the usual care arm, two thirds to the choice arm. After baseline data collection, the research assistant opened the next, sequentially numbered envelope containing the treatment assignment and informed the patient.

Treatments

Usual Care. Participants randomized to usual care continued to receive treatment at HVMA based on their standard treatment algorithm, which included nonsteroidal anti-inflammatory drugs (NSAID), muscle relaxants, limited bed rest, education, and activity alterations. Further evaluation was recommended based on history, duration of pain, or presence of “red flags.”¹⁴ Physical therapy referrals were not generally made during the acute 3–4-week period, consistent with HVMA algorithms.

Choice of Care. Participants randomized to choice continued to receive usual care but could also select adjunctive acupuncture, chiropractic, or massage therapy. Participants could not add a second complementary and alternative medical modality unless referred by their complementary and alternative medical provider. Treatment included up to 10 sessions at no charge over 5 weeks, and up to 5 additional sessions at 50% co-pay, with the exact number of treatments determined by the treating complementary and alternative medical provider whose goal was to return the participant to their prestudy status. Complementary and alternative medical providers were aware that the number of visits would be tracked.

A credentialing process for complementary and alternative medical providers was developed to identify practitioners in a specified geographic area, with at least 3 years in practice, documentation of licensing and/or certification, documentation of training, and a minimum number of continuing education units.¹⁵ Of 100 complementary and alternative medical practitioners who applied, 59 met credentialing requirements, and 11 acupuncturists, 9 chiropractors, and 12 massage therapists were selected for participation in this study as providers of complementary and alternative medical services.

Follow-up and Documentation of Outcomes. DataStat, a professional data collection company, using standardized questionnaires administered using computer-assisted telephone interview software, conducted follow-up interviews at 2, 5, 12, 26, and 52 weeks. The 4 primary outcomes were changes from baseline to week 5 in symptom relief, functional status, and satisfaction and costs of HVMA care during weeks 0–12. Symptom relief was measured as bothersomeness of the worst symptom (LBP, sciatica, or numbness) over the past 24 hours on a 0–10 scale.^{16,17} Functional status was measured using the modified Roland-Morris Disability Questionnaire^{16,18,19} that includes 23 yes-no questions about daily activities, such as difficulty getting dressed and climbing stairs (23 = maximal dysfunction). Satisfaction with care was measured by asking participants to rate the care received at HVMA for LBP as excellent, very good, good, fair, or poor. Insurance claims data were used to assess costs during the study period.

Additional outcomes included difficulty performing important self-identified activities, worry about one’s back problem, and overall mental and physical health. At baseline, participants were asked to identify 3 activities they felt were important in their daily life that back pain or sciatica had made difficult, and rate their difficulty on a 0–10 scale. Worry was

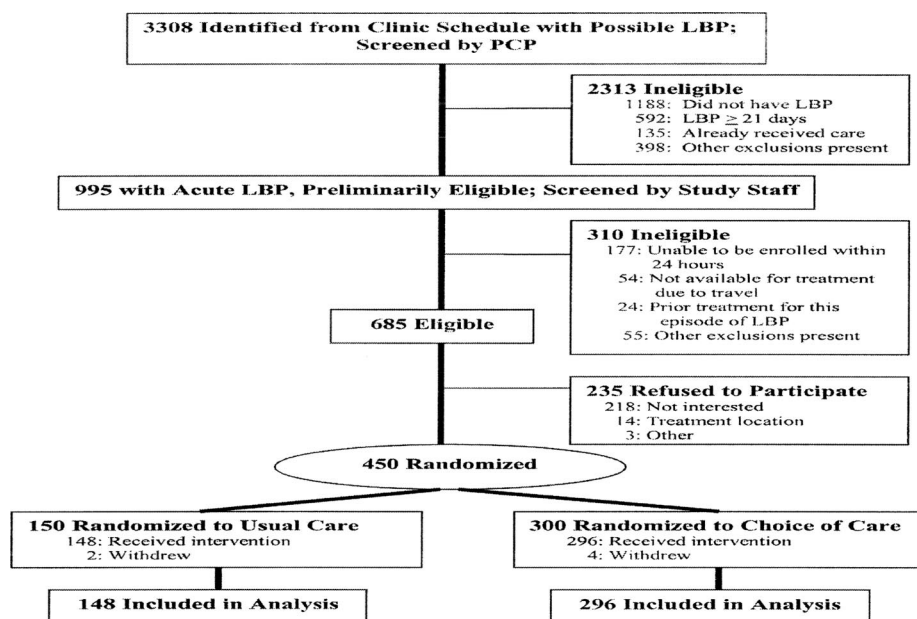


Figure 1. Recruitment and randomization.

measured using a scale from 0 (no worry) to 10 (extremely worried). The Medical Outcomes Study Short-Form (SF-12) was used to measure overall mental and physical health, on subscales ranging from 0 (worst) to 100 (best).²⁰ Patient self-report assessed medication use.

Measurement of Costs. Data on the numbers and types of provider visits, laboratory tests, and prescription drugs were obtained from electronic medical records, pharmacy, and claims databases at HVMA and Harvard Pilgrim Healthcare, the primary insurer for the majority of study subjects. Costs in 2003 dollars were assigned using Medicare reimbursement for encounters and the *Red Book*, which provided average wholesale prices for prescription medications.^{21–23} Because categorizing back pain-specific claims was not reliable using retrospective claims data, the cost analysis was performed on total medical costs. Since acute LBP usually resolves in a few weeks, data were captured for 12 weeks after study enrollment as a marker for costs incurred during the treatment and recovery period, as well as 12 weeks before enrollment for comparison. Analysis of costs was restricted to participants who were continuously enrolled with Harvard Pilgrim Healthcare for these 2 time periods ($n = 276$). Self-reported baseline characteristics were similar between those in the cost analysis and those excluded, except that the group included in the cost analysis was significantly older (45.7 years compared to 38.7 years). Complementary and alternative medical providers were paid \$100 for the first visit and \$50 for subsequent visits, consistent with prevailing fees for comparable services in the Boston area. The first 10 visits were paid in full (no co-pay required); visits 11–15 required a 50% co-pay.

Statistical Methods/Analysis. All statistical analyses were performed using SAS version 9.1 for Windows.²⁴ For the 4 primary outcomes (symptoms, function, satisfaction, and cost), we used a Wilcoxon's rank sum test to compare treatment groups. To preserve a global 5% level of significance, we applied a Bonferroni procedure and required a P value below 0.0125 to consider a difference statistically significant. This analytic plan was developed before the initiation of the trial.

We report medians and interquartile ranges for changes in clinical outcomes from baseline to week 5. Data were analyzed according to intention-to-treat assignments. Sample size calculations were based on an assumption that a minimal clinically important difference on the Roland scale was 2.5 points.¹⁶ Based on the 2:1 randomization and the Bonferroni correction, we estimated that 444 patients would provide 80% power to detect a 2.5 point difference⁸ between treatment groups in change from baseline in Roland-Morris scores.

To compare proportions of participants using each class of medications we used Fisher exact tests. We also fit an exploratory longitudinal logistic regression model for patient satisfaction. We used generalized estimating equations methods^{25,26} assuming an autoregressive correlation structure. To examine costs further, we fit a 2-stage model, separately modeling the log odds of incurring any costs and the logarithm of costs among those who incurred any cost, adjusting for the patients' prestudy costs.²⁷ We used Duan's smearing estimator²⁸ to calculate appropriate error estimates when the data were retransformed from the logarithmic scale.

■ Results

Recruitment and Randomization

In order to identify patients with acute LBP, we reviewed daily clinic schedules that recorded patients' self-reported reasons for upcoming appointments. All visits that were possibly LBP (*e.g.*, back, hip, leg pain, or sciatica) were flagged to be screened by the evaluating clinician for eligibility. As shown in Figure 1, 3308 patients were identified from the clinic schedules and underwent an initial screening. Of these, 2313 (69.9%) were ineligible primarily due to pain not in the low back ($n = 1188$, 51.4%), LBP present for more than 3 weeks ($n = 592$, 25.6%), or the patient had already received care for this episode ($n = 135$, 5.8%). Of the remaining 995 patients with acute LBP, an additional 310 (31.2%) were found to be ineligible when screened by study staff. Reasons for ineligibility included the inability to be enrolled within 24 hours ($n = 177$), those not available for treatment due to planned travel ($n = 54$), prior treat-

ment for this episode ($n = 24$), and other exclusions ($n = 55$). Of the remaining 685 eligible patients, 235 declined to participate, primarily because they were not interested in the study ($n = 218$), or complementary and alternative medical provider offices were too distant for travel ($n = 14$). The 450 participants who remained eligible and willing to enroll were then randomized in a ratio of 1:2 to usual care *versus* choice. Six participants (2 from usual care and 4 from choice) withdrew, leaving 444 participants for analysis (148 in the usual care arm and 296 in the choice arm).

Baseline Characteristics

There were no significant differences at baseline between the 2 groups with regard to self-reported demographic characteristics, history of LBP, history of complementary and alternative medical use, clinical measures, disability, use of medication, and satisfaction (Table 1). Race was self-reported by the participants using categories defined by the National Institutes of Health and was included because it was a potential confounder of the effect of choice on the outcome variables. There was a signifi-

Table 1. Self-Reported Baseline Characteristics of Randomized Participants by Group

	Usual Care ($n = 148$)	Choice of Care ($n = 296$)
Demographics		
Mean age \pm SD	42.7 \pm 12.7	43.2 \pm 12.7
Female gender	50%	54.7%
Race		
White	62.8%	65.2%
Black/African American	20.3%	19.3%
Other	15.5%	14.2%
Hispanic	8.1%	10.5%
Marital status (married or partner)	67.6%	63.5%
Employed for pay or self-employed	82.4%	86.5%
Education (college or greater)	75.7%	81.8%
LBP history		
First time to seek care for LBP	34.5%	33.8%
First episode of LBP in past 12 mo	39.2%	40.9%
Mean No. episodes of LBP in past 12 mo for those with more than the current episode \pm SD	5.4 \pm 11.1	4.0 \pm 7.1
CAM use and preference		
Prior CAM treatment for any reason		
Acupuncture	12.2%	12.8%
Chiropractic	34.5%	36.5%
Massage therapy	35.1%	31.1%
Stated first choice of therapy preferred (prior to randomization)		
Acupuncture	23.0%	16.9%
Chiropractic	27.7%	27.0%
Massage	41.2%	53.4%
Usual care	7.4%	2.7%
Expectations		
Expectation of improvement in 6 wk for this episode of LBP (0 [no improvement] to 10 [complete recovery]) (mean \pm SD)	8.3 \pm 1.9	8.7 \pm 1.6
Clinical measures		
Modified Roland Disability Questionnaire (0–23 scale, 23 = worst) (mean \pm SD)	16.2 \pm 4.7	16.5 \pm 4.7
Bothersomeness of worst symptom (LBP, sciatica, numbness) (0 [not bothersome] to 10 [extremely bothersome]) (mean \pm SD)	7.7 \pm 1.7	7.9 \pm 1.8
Difficulty with the worst of 3 self-reported activities (0 [no difficulty] to 10 [extreme difficulty]) (mean \pm SD)*	8.6 \pm 1.5	8.6 \pm 1.7
Physical SF-12 (0–100) (higher score indicates better function) (mean \pm SD)	36.9 \pm 7.3	36.5 \pm 7.5
Worry or concern about LBP (0 [no worry] to 10 [extremely worried]) (mean \pm SD)	6.8 \pm 2.3	7.1 \pm 2.6
Mental SF-12 (0–100) (higher score indicates better function) (mean \pm SD)	48.9 \pm 11.2	49.6 \pm 11.2
Severity of LBP (0 [no pain] to 10 [worst pain ever]) (mean \pm SD)	7.0 \pm 2.0	7.1 \pm 2.3
Disability		
Mean No. days in bed in the last week \pm SD	0.86 \pm 1.33	0.97 \pm 1.55
Mean No. days work/school missed in the last week \pm SD	0.69 \pm .98	0.80 \pm 1.28
Mean No. days' activities reduced in the last week \pm SD	2.94 \pm 2.32	2.74 \pm 2.28
Medications prescribed or recommended at index visit (self-report)†		
Use of non-narcotic analgesics	6.1%	5.4%
Use of NSAID	69.6%	64.5%
Use of muscle relaxants/sedatives	39.9%	45.3%
Use of narcotic analgesics	5.4%	7.1%
Baseline rating of care for LBP		
Percent rating care for LBP on index visit as "Excellent"	49%	46%

*All participants were asked, "Your (first/sec/third) activity was _____. Using a scale from 0 to 10, where 0 is not at all difficult and 10 is extremely difficult, please rate how difficult this activity is to perform."

†All participants were asked, "Were any medications prescribed or suggested by your practitioner today for your back pain or sciatica? (yes/no) What medicines were you prescribed?"

CAM indicates complementary and alternative medical; SD, standard deviation.

Table 2. Distribution of Complementary and Alternative Medical Treatment Visits By Those in the Choice of Care Arm Who Chose Complementary and Alternative Medical Treatment (n = 286)

	No. Visits				
	0	1-4	5-7	8-10	11-15
Acupuncture (n = 58)	5 (9%)	13 (22%)	9 (16%)	20 (33%)	11 (19%)
Chiropractic (n = 76)	4 (5%)	15 (20%)	25 (33%)	20 (26%)	12 (16%)
Massage (n = 152)	16 (11%)	51 (34%)	39 (26%)	35 (23%)	11 (7%)
Total (n = 286)	25 (9%)	79 (28%)	73 (26%)	75 (26%)	34 (12%)

cantly higher expectation of improvement in 6 weeks for those assigned to choice for this episode of acute LBP ($P = 0.04$). In addition, the stated first choice of complementary and alternative medical therapy, before randomization, was different for the 2 groups ($P = 0.02$).

This was the first episode of LBP in the past 12 months for approximately 40%, and for 34% it was the first time they sought medical care for LBP (Table 1). Two thirds of participants were using NSAID at baseline. Over half of all study participants (58.8%) had previously used one or more of the complementary and alternative medical treatments offered in the choice arm. Average Roland scores over 16 and symptom bothersomeness scores of almost 8 indicate moderate-to-high levels of pain and dysfunction.

Study Treatments and Follow-up

Of the 296 participants randomized to choice, 51.4% selected massage therapy, 25.7% chiropractic, 19.6% acupuncture, and 3.4% usual care only. The average number of treatments of all 296, including those who received no treatments, was 6.0 (5.5 for massage, 7.0 for chiropractic, and 7.2 for acupuncture). For the 261 (88.2%) participants who had at least one treatment, the average number was 6.8 treatments (6.1 for massage, 7.4 for chiropractic, and 7.9 for acupuncture). Table 2 summarizes the distribution of complementary and alternative medical treatment visits by participants in the choice arm of the study.

During the treatment period, 18 (12%) participants in the usual care arm reported seeing a complementary and alternative medical provider out of study: 4 acupuncture, 9 chiropractic, 4 massage therapy, and one both chiro-

practic and massage. In the choice arm, 14 (5%) reported seeing an additional complementary and alternative medical provider out of study: one acupuncture, 5 chiropractic, 6 massage, one both chiropractic and massage, and one all 3 methods.

Participants were interviewed by telephone at 2, 5, 12, 26, and 52 weeks. Response rates were high, with interviews completed for 92.1%, 90.8%, 87.4%, 82.4%, and 80.4%, respectively, at these time points, with no significant differences between the 2 randomized groups. Telephone interviewers were not blind to randomization assignment group as different skip logic was required for questionnaires for each group. However, interviewers were contractors (as opposed to coinvestigators) and had no role in data analysis or interpretation.

Outcomes

Adverse Effects. At each complementary and alternative medical treatment follow-up visit, participants were asked, "Did you have any problems after your last treatment visit? (1) Yes, (2) No – If 'Yes,' describe." Responses from 1492 follow-up treatment forms revealed minor discomfort or soreness among 5% of those receiving acupuncture, 8% receiving chiropractic, and 7% receiving massage. No clinically significant adverse events were reported to study staff among 1778 treatment encounters during the trial.

The effects of the study interventions on acute LBP outcomes at 5 and 12 weeks are summarized in Figures 2 and 3.

Outcomes. At 5 weeks, compared to those in the usual care arm, those in the choice arm had a statistically, but not clinically significant, one point greater improvement in bothersomeness^{16,29} of worst symptom (median change from baseline -4 [interquartile range $-7, -2$] for usual care, and -5 [$-7, -3$] for choice; $P = 0.002$), but no significant improvement in functional status as measured by the Roland score (-8 [$-13, -2$] for usual care, and -9 [$-15, -4$] for choice; $P = 0.15$). By week 12, there were no significant differences for either endpoint.

Despite similar scores at baseline, choice participants were significantly more likely to rate their back pain care at HVMA as excellent compared with usual care participants at each time point throughout the trial. (Figure 4) This effect was further modified by the baseline ratings of

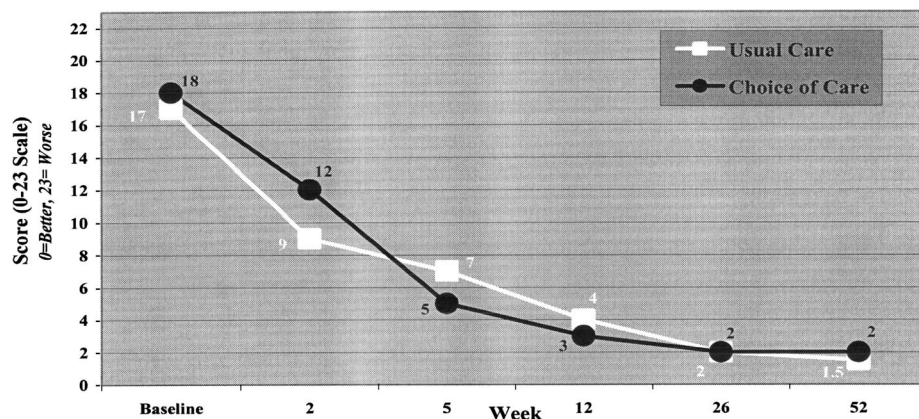


Figure 2. Median bothersomeness of worst symptom (LBP, sciatica, or numbness).

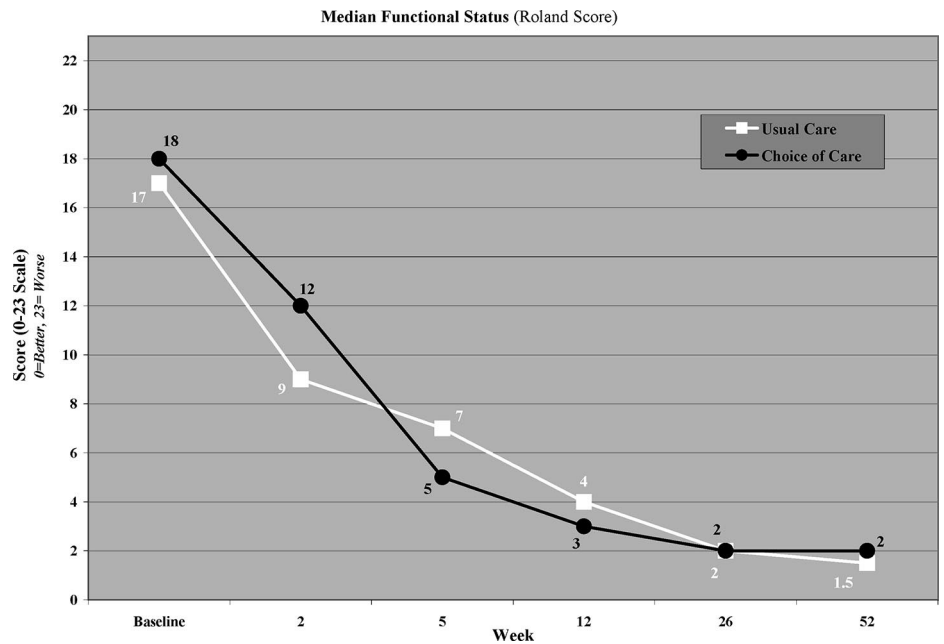


Figure 3. Median functional status (Roland score).

satisfaction. Among those who had baseline ratings of less than excellent, choice participants were more likely to report their care as excellent through 52 weeks (odds ratio 14.9, 95% confidence interval 6.11, 36.5; $P = 0.0001$). There were no differences for those with and without sciatica (data not shown).

Participants in the choice group were significantly more likely to experience a decrease in worry (median change from baseline -2 [interquartile range $-5, -2$] for usual care, and -4 [$-6, -1$] for choice; $P = 0.004$) at 5 weeks but had nonsignificant improvements in difficulty with the worst of 3 self-reported activities (-4 [$-7, -1$] for usual care, and -5 [$-8, -2$] for choice; $P = 0.05$), as well as in both the SF-12 physical function (10.1 [0.5, 18.1] for usual care, and 10.9 [2.9, 17.7] for choice; $P = 0.32$), and mental function scales (1.7 [$-3.1, 7.2$] for usual care, and 2.6 [$-2.4, 9.8$] for choice; $P = 0.39$). At 12 weeks, those in the choice arm continued to report a greater degree of improvement than the usual care arm for each outcome, but none of these was statistically significant.

Costs of Care

In the 12 weeks before study entry, the average total cost of care for the usual care arm was \$393 (median \$126,

interquartile range [\$30, \$373]) and for the choice arm, \$247 (median \$131 [\$19, \$333], $P = 0.68$). In the 12 weeks post-study entry, those in the usual care group had average total costs of \$521 (median \$207 [\$62, \$727]), and the choice arm, excluding the complementary and alternative medical treatment costs, \$476 (median \$185 [\$37, \$599], $P = 0.20$). After controlling for average prestudy costs, the choice group average total costs were \$99 lower, primarily due to a reduction in costs for conventional medical encounters and procedures. The mean reimbursement to providers for the complementary treatments in the 12 weeks post-study entry was \$343 (range \$0 to \$675, median \$300), which resulted in a net cost of \$244 per person for those offered a choice of complementary and alternative medical treatment.

Discussion

This was the first controlled trial to evaluate the effects of patient's choice of facilitated access to licensed complementary and alternative medical practitioners as an adjunct to conventional care for adults with acute LBP. This trial failed to identify any clinically significant ben-

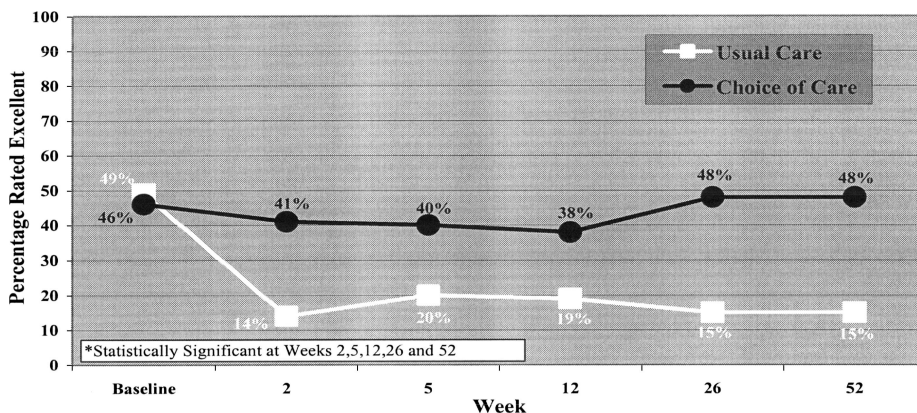


Figure 4. Participant satisfaction with LBP care at HVMA.

efits of “choice” for either of the primary outcomes: symptoms or function.

Although providing patients with acute LBP access to a choice of complementary and alternative medical therapies boosted satisfaction with back care, there was a net increase in costs in the choice group of \$244 per patient from baseline to week 12. Thus, despite increased satisfaction, the model tested in this study design did not result in superior clinical outcomes and resulted in increased costs of care.

In retrospect, these results are not entirely surprising given that the vast majority of patients with acute LBP experience significant and rapid improvement in pain and function, even in the absence of treatment. As Deyo³⁰ has commented, “It is hard to prove that any treatments (for acute LBP) result in greater improvement than the nonspecific effects of natural history, placebo and regression to the mean.” Giving patients a choice of complementary and alternative medical treatments did not improve outcomes substantially over the natural history of acute LBP.

Although we did not observe a significant difference in symptoms or function, we did observe a persistent, significant difference in perceived satisfaction with care for LBP in the choice group. These observed differences are difficult to interpret since it remains unclear whether access to complementary and alternative medical therapies directly enhanced overall satisfaction, or disappointment in not receiving additional benefits (due to randomization to usual care) led to a decrease in satisfaction. Either way, the differences in satisfaction may be of interest to third-party payers to the extent that higher levels of satisfaction may translate to member retention, health plan marketing to expand membership, or an ability to compete within a market of health plans with more conservative benefit options. Furthermore, it is noteworthy that adults with LBP selected massage over acupuncture or chiropractic by a factor of 2 to 1.

The absence of clinically significant adverse events in any of the 1778 complementary and alternative medical treatment sessions within this trial is consistent with previous reports documenting the overall safety of chiropractic, acupuncture, and massage therapy as applied to adults with LBP.⁹

We suggest that future evaluations of a choice of care model focus on conditions with less favorable natural histories and higher costs (*e.g.*, chronic, instead of acute LBP). With medical costs associated with the care of LBP estimated to exceed \$91 billion per year (1% of the gross domestic product),³¹ even a modest improvement in clinical outcome with a concurrent modest decrease in medical, surgical, or prescription drug costs could have a significant impact on standard treatment algorithms as well as the national economy.

This study had several noteworthy limitations. First, the choice model did not incorporate all complementary and alternative medical therapies as potential adjuncts to conventional care (*e.g.*, yoga, tai chi, or mindfulness-

based stress reduction). Second, the complementary and alternative medical therapies that were included may not have been the most effective subset of complementary and alternative medical therapies available. Third, this trial evaluated a single financial model (*i.e.*, full reimbursement for the first 10 treatments, 50% for treatments 11–15) patterned after existing medical benefits for dental or mental health services. Other reimbursement models can and should be tested in future health service studies.

Another limitation is that this trial was not designed to test for any additive or synergistic effects of multiple complementary and alternative medical therapies, an approach that is common among individuals with LBP.³² This would have required randomization of subjects to a group who receive a coordinated “bundle of care,” a research strategy recommended in a recent Institute of Medicine report “Complementary and Alternative Medicine in the United States.”³³

Finally, this trial was conducted within a health care system that closely manages referrals and prescriptions. This may have underestimated costs to the insurer for medical care in the choice group compared with costs in other health care settings. In addition, the greater use of complementary and alternative medical treatments outside of the study by participants in the usual care group may have led to underestimates of the benefits of adjunctive complementary and alternative medical therapy.

Although providing a choice of adjunctive complementary and alternative medical treatments was not more effective for acute LBP, the approach used in this trial may serve as a prototype for future studies evaluating the effectiveness and costs of models of care delivery. Such trials should focus on common chronic conditions that are costly and for which conventional medical care is of limited effectiveness. In light of the high prevalence of use of complementary and alternative medical therapies for such problems, such research is essential if we are to responsibly advise patients, medical caregivers, and benefits administrators about the judicious use or avoidance of complementary and integrative care models.

■ Key Points

Providing patients with facilitated access to their choice of adjunctive complementary and alternative medical therapies:

- Did not result in clinically significant improvement for patients with acute LBP.
- Resulted in high patient satisfaction but at increased total cost.
- Should be evaluated for chronic conditions, including chronic back pain, for which conventional medical care is often costly and of limited benefit.

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- Acupuncture: Kwok Lap Wong; Joseph Kay; Wenfei Xie; Richard Wallace; James Doyle, DO; Ellen Highfield; Zhi Ping Li; Weidong Lu; Grant Guan Hou; and Yan Jennifer Cao.
- Doctors of Chiropractic: Megan Tabor; David Sherman; Wayne London; Harlan Rieur; Deborah Wu; Otto Todorov; JoAnne Cancro; Thomas Gorman; and Michael Costa.
- Massage therapists: Sharon Brennan; Arun Jain; Dorea D'Agostino; Tony Adomaitis; Tanya McCloskey; Karen Buck-Gilbert; Jann Cobb; Cynthia Ann Gillan; Nancy Wilde; Arthur Madore; Randall Brubaker; and Lauren Schofield.

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HVMA

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