

# Lessons from a Trial of Acupuncture and Massage for Low Back Pain

## Patient Expectations and Treatment Effects

Donna Kalauokalani, MD, MPH,\* Daniel C. Cherkin, PhD,† Karen J. Sherman, PhD,‡  
Thomas D. Koepsell, MD, MPH,§ and Richard A. Deyo, MD, MPH||

**Study Design.** A subanalysis of data derived from a randomized clinical trial was performed.

**Objective.** To evaluate the association of a patient's expectation for benefit from a specific treatment with improved functional outcome.

**Summary of Background Data.** Psychosocial factors, ambiguous diagnoses, and lack of a clearly superior treatment have complicated the management of patients with chronic low back pain. The authors hypothesized that patient expectation for benefit from a specific treatment is associated with improved functional outcomes when that treatment is administered.

**Methods.** In a randomized trial, 135 patients with chronic low back pain who received acupuncture or massage were studied. Before randomization, study participants were asked to describe their expectations regarding the helpfulness of each treatment on a scale of 0 to 10. The primary outcome was level of function at 10 weeks as measured by the modified Roland Disability scale.

**Results.** After adjustment for baseline characteristics, improved function was observed for 86% of the participants with higher expectations for the treatment they received, as compared with 68% of those with lower expectations ( $P = 0.01$ ). Furthermore, patients who expected greater benefit from massage than from acupuncture were more likely to experience better outcomes with massage than with acupuncture, and *vice versa* ( $P = 0.03$ ).

**Conclusions.** The results of this study suggest that patient expectations may influence clinical outcome independently of the treatment itself. In contrast, general optimism about treatment, divorced from a specific treatment, is not strongly associated with outcome. These results may have important implications for clinical trial design and recruitment, and may help to explain the apparent success of some conventional and alternative therapies in trials that do not control for patient expectations. The findings also may be important for therapy choices made in the clinical setting. [Key words: acupuncture,

alternative therapies, low back pain, massage, patient expectations, placebo, Roland scale, treatment effectiveness] **Spine 2001;26:1418-1424**

Patients differ substantially in the way they experience pain and pain-related distress, and in the way they respond to pain treatments.<sup>13,23</sup> For patients with low back pain, the importance of psychological factors and an ambiguous relation between anatomic findings and symptoms are characteristic. Therefore, many treatments coexist without any considered as clearly superior.<sup>1,8,14,29,32</sup>

Many studies have assessed patient expectations regarding delivery of health care services (*e.g.*, fulfillment of expectations for a certain type of service, provider interaction, or overall satisfaction with care),<sup>12,16,24,31,34</sup> but few have assessed expectations about specific treatment benefit or its association with clinical outcomes.<sup>17</sup> Studies seeking to understand placebo effects have inferred that patient expectations are partly responsible for "nonspecific" effects of treatment.<sup>9,19</sup> Other nonspecific effects may result from physician attention, interest, and concern; the reputation, expense, and impressiveness of the treatment; and the characteristics of the setting.<sup>30</sup>

A complex array of factors also may influence outcomes from studies on the efficacy of alternative therapies.<sup>18</sup> Multiple theories often exist about the mechanism responsible for a specific effect, complicating the choice of a placebo that effectively simulates therapy.<sup>21</sup> Meanwhile, consumer demand is motivating more managed care systems, insurance carriers, and hospital providers to cover alternative treatments,<sup>26</sup> and back pain is a leading reason why patients seek alternative forms of treatment.<sup>10,11</sup>

This study sought to determine whether patient expectation about the helpfulness of a specific treatment is associated with outcomes independently of any specific treatment effect. Because expectations may be especially important for alternative therapies, this study focused on patients with chronic low back pain enrolled a randomized trial evaluating acupuncture and massage.

### ■ Methods

#### Setting.

This study was a secondary analysis of data from a randomized clinical trial comparing massage, acupuncture, and self-care material (control group) used for patients with chronic low back pain.<sup>5</sup> The study was conducted at the Group Health

From the \*Washington University Pain Center, St. Louis, Missouri, the †Center for Health Studies, Group Health Cooperative of Puget Sound, Seattle, Washington, the ‡Northwest Institute of Acupuncture and Oriental Medicine, Seattle, Washington, and the University of Washington, the §Departments of Epidemiology and Health Services and ||Departments of Medicine and Health Services, Seattle, Washington. Supported by grants from the Group Health Cooperative of Puget Sound, the Group Health Foundation, from the Agency for Health Care Policy and Research (Grant #HS09351), and the John E. Fetzer Institute, and by the Robert Wood Johnson Clinical Scholars Program. The views, opinions, and conclusions in this article are those of the authors and do not necessarily reflect those of any of the funding organizations.

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Cooperative of Puget Sound, a large staff-model health maintenance organization (HMO). Acupuncture and massage were provided in private office practices near the Group Health primary care clinics. The Group Health Cooperative Human Subjects Review Committee approved the study protocol, and all the participants gave written informed consent.

### Participants.

The Group Health Cooperative enrollees, ages 20 to 70 years, who saw a primary care physician for low back pain between March and September 1997 were identified using computerized visit data. These patients were invited to participate 6 weeks after their initial visit if they still had low back pain, and 262 were enrolled. Patients were excluded if they had sciatica, cardiac pacemakers, clotting disorders, anticoagulant therapy, evidence of severe or progressive neurologic deficits, a recent history of vertebral fractures, serious comorbid conditions, inability to speak or read English, or acupuncture or massage treatment for low back pain within the preceding year.

At the end of a 10-week treatment period, 249 subjects (95%) completed a follow-up telephone interview. The current analysis was restricted to patients who completed the 10-week follow-up questionnaire, and who had been randomized to acupuncture or massage ( $n = 166$ ). The self-care patients were excluded from this analysis because, although they served as a nonphysical treatment control for the effectiveness trial, the aim of this study was to examine the influence of patient expectations on outcomes of physical treatments. In addition, subjects were excluded if data were missing on patient expectations for either acupuncture or massage ( $n = 29$ ) or on follow-up functional status scores ( $n = 2$ ). As a result, 135 (81%) of all the patients randomized to acupuncture or massage were studied.

### Intervention.

The participants were allocated randomly by computer to receive acupuncture or massage. In each group, the participants received up to 10 treatments within 10 weeks. The treatments were provided by 7 licensed acupuncturists and 12 licensed massage therapists, all having practiced a minimum of 3 years, whose approaches to low back pain represented those commonly used in the region. In consultation with each group of providers, protocols for acceptable and proscribed treatments as well as standardized clinical encounter forms were developed.

The acupuncture treatment protocol allowed standard traditional Chinese medical body needling, adjuvant electrical stimulation with needles, induction of a vacuum on the skin surface using a small glass cup ("cupping") to increase local circulation, and exercise prescription. Permitted also was heat applied to the inserted needles and near the surface of the body by an infrared heat lamp or a burning dried mugwort plant (*Artemisia vulgaris*) in a process called "moxibustion." Proscribed treatments for acupuncturists included massage, magnets, acupressure, herbal therapy, liniments, vitamins, dietary counseling, homeopathy, bloodletting, and unusual forms of needling.

The massage treatment protocol allowed basic Swedish techniques, active and passive range-of-motion exercises, and hydrotherapy. Other permitted massage techniques included "deep tissue," "neuromuscular," "trigger point" massage and "myofascial release." Reflexology, nutritional counseling, acu-

pressure, Rolting, unusual forms of massage, and techniques lacking physical contact with the patient were proscribed.

### Data Collection.

Telephone interviews were conducted to determine eligibility and collect baseline data. To reduce bias, patient expectations about the therapeutic benefit from each of the treatments were assessed before randomization. The participants were asked to rate how helpful they believed each treatment would be for their current back problems on a scale with choices ranging from 0 (not at all helpful) to 10 (extremely helpful). They also were asked to describe their expectations for improvement of their back pain without regard to treatment using a 7-point Likert scale with choices ranging from "completely gone," to "much worse." Outcomes were assessed by telephone interview after a 10-week treatment period.

### Construction of Expectation Variables.

Before initiation of the trial, in an attempt to ensure that the various aspects of this concept were examined, the following four measures of expectation were defined: 1) expectation for treatment benefit, 2) relative expectation, 3) average expectation for treatment benefit, and 4) general expectation regarding prognosis.

The first measure, expectation for treatment benefit, was the main predictor variable, designated as  $E_m$  or  $E_a$  to reflect expectations for massage and acupuncture, respectively. This score, used for each participant's randomly assigned treatment, was the participant's rating of how helpful they believed massage ( $E_m$ ) and acupuncture ( $E_a$ ) would be for their current back problem, as indicated on a scale of 0 to 10. After the frequency distribution of expectation-for-benefit scores was examined, the sample was dichotomized into equal size groups defined as having either a "higher" or "lower" expectation for treatment benefit. Thus, ratings of 8 to 10 were considered "higher" expectations for benefit, and ratings of 0 to 7 were considered "lower" expectations.

The second measure, relative expectation for treatment benefit, indicated the relative strength of expected benefit from a specific treatment, as compared with the alternative treatment. This variable was calculated as the difference between the two treatment ratings ( $E_m - E_a$ ). A positive difference indicated higher expectations for benefit from massage than from acupuncture, whereas a negative difference indicated higher expectations for benefit from acupuncture than from massage.

The third measure, average expectation for treatment benefit, in contrast to relative expectation ( $E_m - E_a$ ), is sensitive to actual expectation ratings. Calculated as the average of the expectation ratings for massage and acupuncture  $(E_m + E_a)/2$ , it reflected the general level of expectancy for treatment benefit averaged across treatments.

The fourth measure, general expectations regarding prognosis, represented participants' general optimism about improvement without regard to specific treatment received. General expectation was assessed with the following question: "One month from now, do you expect your back or leg pain to be 1 (completely gone), 2 (much better), 3 (moderately better), 4 (a little better), 5 (about the same), 6 (a little worse), or 7 (much worse)?" The responses to this 7-point Likert scale were dichotomized into those that expected their back pain to be at least moderately better in 1 month and those that did not.

**Table 1. Baseline Characteristics of Subjects by Level of Expectation for Treatment Received**

Sociodemographic Characteristics	All Patients	Expectations about the Helpfulness of the Randomly Assigned Treatment		P
		Higher (n = 66)	Lower (n = 69)	
Age, mean years (SD)	44 (11)	45 (12)	43 (10)	0.43
Women (%)	63	70	57	0.11
Attended some college (%)	79	71	87	0.11
Caucasian (%)	81	83	78	0.46
Family income >\$35,000 (%)	53	48	58	0.45
Employed/self-employed (%)	87	83	91	0.16
Married (%)	64	64	64	0.99
Smoke cigarettes (%)	20	24	16	0.23
SF-12 Physical Health Scale, mean (SD)	37.3 (9)	35.7 (9)	38.8 (9)	0.05
SF-12 Mental Health Scale, mean (SD)	49.8 (10.2)	49.5 (11)	50.2 (10)	0.68
Low Back Pain History				
Previous Low Back Surgery (%)	4	3	6	0.44
Previous injection for Back/Leg Pain (%)	17	18	16	0.70
Prior use of Acupuncture (%)	2	2	3	0.59
Prior use of Massage (%)	16	23	10	0.05
Current Back Symptoms				
>7 days restricted activity due to LBP in past month (%)	41.5	43.9	39.1	0.48
Limited regular daily activities or accomplishments in past month (%)	77.8	83.3	72.5	0.13
Mean symptom bothersomeness past week (0–10 scale) (SD)	6.14 (1.9)	6.36 (1.9)	5.93 (1.8)	0.17
Mean Roland Score (0–23 scale) (SD)	12.1 (4.9)	13.2 (4.6)	11.1 (4.9)	0.01
Expect LBP to be at least moderately better in one month (%)	31.9	27.3	36.2	0.26
LBP symptoms more than a year (%)	79.3	83.3	75.4	0.25
Assigned Study Treatment				
Acupuncture (%)	55	48	61	0.15

### Outcome Measures.

The primary outcome measure was the modified Roland scale, a back pain–specific functional status questionnaire adapted from the generic Sickness Impact Profile.<sup>3,25,27</sup> Each of the 23 items requires a yes or no response to questions such as “Because of my back problem, I am doing less of the daily work around the house than I would usually do.” The overall score, ranging from 0 to 23, is a sum of all positive responses, so a higher score indicates more disability. This instrument, validated extensively among patients with low back pain, is responsive to changes over time.<sup>7,25</sup> A change of at least 2 points on the Roland scale is considered clinically important.<sup>25</sup>

Other outcome measures described the effect of the assigned treatment on symptoms and on general physical and mental health status. At baseline and at follow-up assessment, participants rated how “bothersome” back and leg pain symptoms had been during the preceding week using a scale ranging from 0 (not at all bothersome) to 10 (extremely bothersome). The score for the most bothersome symptom was used. In prior studies of low back pain, this question appeared to have substantial construct validity.<sup>4,25</sup>

Three types of potential confounding variables were examined: sociodemographic factors, health status, and back pain–specific history. Sociodemographic variables assessed included age, gender, race, household income, education, marital status, employment status, and type of employment (*i.e.*, work that involved lifting). General health was evaluated with the Physical and Mental Health summary scores of the Medical Outcomes Study Short Form Health Survey (SF-12).<sup>33</sup> The SF-12 scales are scored so that a high score indicates better physical or

mental health, respectively. Back pain–related data included history of prior back surgery, history of injection therapy, and medications used.

### Analysis.

The analysis was designed to determine whether patient expectations regarding benefit from a specific treatment were associated with functional improvement. With the size of the available sample, the study was determined to have at least 80% power to detect a baseline-adjusted difference of 2.1 points on the Roland score at 10 weeks, given a correlation of 0.7 between baseline and follow-up Roland scores at the  $P = 0.05$  level. For all the baseline characteristics listed in Table 1, analysis of variance (ANOVA) and Pearson  $\chi^2$  were used to test for significant differences between participants with higher expectations for acupuncture and those with higher expectations for massage.

Linear regression was used with the 10-week Roland score as the outcome variable. In multivariate analysis, potential confounders were retained in the regression model if their inclusion produced a change of at least 10% in the estimated coefficient for the expectation variable of interest. All models adjusted for baseline Roland scores, and all analyses were performed using Stata 6.0 (Stata Corp., College Station, Texas).<sup>28</sup> Each of the four measures of patient expectations was tested for independent effects and for interaction with treatment. Logistic regression also was used to calculate the adjusted odds ratio for functional improvement (defined by a minimum 2-point decrease in Roland score at 10 weeks) as a function of a participant's expectation level.

**Table 2. 10-week Outcomes According to Treatment Expectations**

Functional Outcome	All Patients	Baseline Expectations for Benefit from the Treatment Received		P
		Higher (n = 66)	Lower (n = 69)	
Mean Baseline Roland score (SD)	12.1 (4.9)	13.2 (4.6)	11.1 (4.9)	0.01
Mean 10-week Roland score (SD)	6.8 (6.2)	6.4 (6.2)	7.1 (6.2)	0.50
Mean Change from Baseline Roland score (SD)	-5.3 (5.3)	-6.8 (5.9)	-4.0 (4.3)	0.002
Improved Roland score (at least 2-points) (%)	77	86	68	0.01
<b>Symptoms</b>				
Mean 10-week symptom bothersomeness score past week (0–10 scale) (SD)	3.7 (3.0)	3.5 (2.8)	3.8 (3.2)	0.50
Mean change from baseline symptom bothersomeness score (SD)	-2.5 (2.9)	-2.9 (2.9)	-2.1 (3.0)	0.12
<b>Satisfaction</b>				
Mostly or very satisfied with care (%)	77	83	71	0.09
<b>Health Status</b>				
SF-12 Physical Health Scale, mean (SD)	44.2 (10.8)	44.0 (11.2)	44.3 (10.4)	0.87
Mean Change from baseline SF-12 Physical Health Scale	6.9 (9.7)	8.5 (9.7)	5.5 (9.5)	0.08
SF-12 Mental Health Scale, mean (SD)	51.5 (10.4)	52.9 (9.4)	50.2 (11.1)	0.14
Mean Change from baseline SF-12 Mental Health Scale	1.7 (9.9)	3.9 (10.5)	-0.35 (8.87)	0.01

## ■ Results

### **Baseline Characteristics**

Of the 135 subjects included in the analysis, most were white (79%), employed (87%) women (63%) with at least some college education (79%). Most had first received treatment for back problems more than a year earlier. On the basis of the dichotomous categorization used in this study, 49% (66) of participants had higher expectations for benefit from their assigned treatment. Correlates of higher expectations for massage were not significantly different from those for acupuncture (data not shown). Therefore, the results were pooled across treatment groups. Within higher and lower expectation categories, participants were similar with regard to most sociodemographic, illness, and treatment characteristics (Table 1). The participants with higher expectations had greater baseline functional disability than those with lower expectations, as measured by baseline Roland score (mean, 13.2 *vs* 11.1,  $P = 0.01$ ) and by the mean summary of the SF-12 Physical Health score (35.7 *vs* 38.8,  $P = 0.05$ ), but no significant difference in the mean summary of the SF-12 Mental Health scores (49.8 *vs* 49.5,  $P = 0.68$ ).

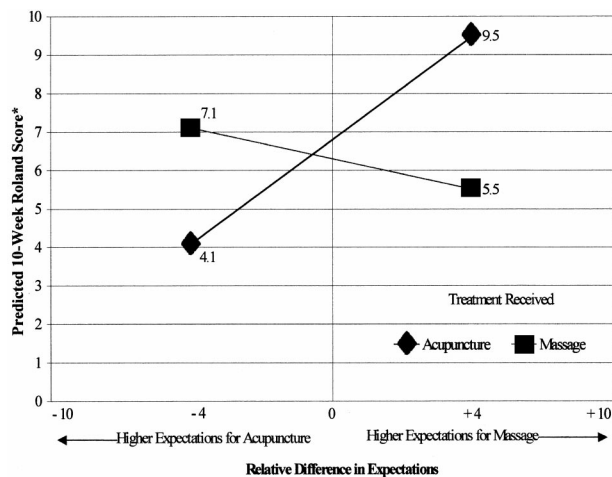
### **Expectation for Treatment Benefit**

In the primary analysis of data from the randomized trial, comparisons of mean Roland scores adjusted for baseline values and other covariates found massage to be superior to acupuncture at 10 weeks.<sup>5</sup> In the current analysis, which excluded 29 subjects with missing expectation ratings, 104 of 135 participants (77%) had improved their Roland scores by at least 2 points after the 10-week treatment period. There was no significant difference in the proportion of participants with improved Roland scores between the acupuncture (77%) and massage (77%) treatment groups.

However, more improved Roland scores were found among participants with higher expectations for benefit from their assigned treatment (86%) than among those with lower expectations (68%) ( $P < 0.01$ ). This difference remained significant even when the threshold for improvement was raised to a minimum of 3 points (79% *vs* 62%,  $P < 0.04$ ). The improvement in Roland disability scores from baseline to follow-up assessment also was significantly greater in the higher expectations group than in the lower expectation group (-6.8 points *vs* -4.0 points, respectively,  $P < 0.002$ )(Table 2).

The mean mental health status scores on the SF-12 did not differ significantly between higher and lower expectation groups at 10 weeks. However, the magnitude of change in the mental health status scores was significantly greater among the participants with higher expectations than among the participants with lower expectations (3.9 *vs* -0.35,  $P < 0.01$ ). Greater magnitudes of change favorable to the higher expectation group also were observed for physical health status, symptom severity, and satisfaction with care, although these differences did not reach statistical significance (Table 2).

In a linear regression model adjusted for baseline Roland score, four covariates were retained in the model for their confounding effects on the 10-week Roland score: gender, education, physical health status, and prior use of massage. After adjustment for these covariates and for age and treatment, the model yielded a coefficient estimate for higher expectations (-3.43,  $P < 0.001$ ), indicating that patients with higher expectations showed more than a 3-point improvement on the Roland scale over those with lower expectations. Using logistic regression and adjusting for potential confounders (baseline Roland score, treatment, age, gender, education, physical health status, and prior use of massage), the relative



\* Lower Roland scores indicate better functional status.

Figure 1. Effect of expectation for benefit on the predicted outcome based on a linear regression model.

odds of improvement for a participant with higher expectations as compared with a participant who had lower expectations was 5.3 (95% confidence interval [CI] 1.9–15.4,  $P = 0.002$ ).

#### Relative Strength of Expectation

The relative strength of expectation for a specific treatment was represented by the difference between the expectation scores for acupuncture and massage. Although scores could range from  $-10$  to  $10$ , the observed scores varied between  $-7$  and  $6$ . There was no significant main effect of relative expectations on the 10-week Roland score, but a significant interaction existed between relative expectations and the effect of treatment actually received ( $P = 0.03$ ;  $R^2 = 0.35$ ). To illustrate this interaction, two lines, each representing a specific treatment, were plotted from the fitted regression model. All the plotted estimates used the sample mean baseline Roland score (12.1) (Figure 1).

Among the participants with higher relative expectations for massage (e.g., a relative expectation score of  $+4$ ), estimates of 10-week Roland scores were better (lower) if the participants had received massage than if they had received acupuncture. Alternatively, the 10-week Roland score estimates for the participants with higher relative expectations for acupuncture (e.g., a relative expectation score of  $-4$ ) were better if the participants had received acupuncture than if they had received massage. Thus, regardless of the treatment received, the effect of the treatment depended on the magnitude of relative expectations.

#### General Treatment and Prognosis Expectations

In contrast, neither average expectations for treatment benefit nor general expectations regarding prognosis had a significant association with the 10-week functional outcome as measured by the Roland score. This was true even after control had been used for age, gender, educa-

tion, physical health status, baseline Roland score, prior use of massage, and treatment received.

#### Discussion

For patients with low back pain who received acupuncture or massage, patient expectation regarding treatment benefit was found to be associated significantly with clinical outcome. As compared with participants who had lower expectations, those with higher expectation ratings for the specific treatment received had a fivefold greater likelihood of substantial improvement after adjustment for sociodemographics, health status, and physical factors. Furthermore, the analyses suggest that the strength of expectation for benefit from one treatment *versus* another treatment modified the effect of the treatment received. Thus, the participants with strong relative expectations for a specific treatment had significantly better functional outcomes if they received that treatment.

The influence of patient expectations may help to explain the “nonspecific” effects of treatments.<sup>30</sup> That is, expectation about the benefit from a specific treatment may be an important part of what is labeled the “placebo” or “nonspecific” effect. Patient expectation thus may account for some of the variability in the results of clinical trials of low back pain treatment.<sup>2,15</sup> In the current study, the differences in outcomes observed between patients with higher and those with lower expectations exceeded the differences reported between the treatment groups in several other clinical trials.<sup>6,22</sup> Therefore, the influence of expectations may partly explain the apparent success of some therapies.

The current findings suggest a role for assessment of patient expectations in the design and interpretation of clinical trials. This role may be especially important in studies of chronic pain conditions for which the clinical state before and after treatment is, in large measure, subjectively defined. The results suggest that recruitment strategies may affect the results of a clinical trial. For example, a British study comparing National Health Service physiotherapy with chiropractic care for patients with low back pain found that the benefit from chiropractic care was restricted to patients recruited from chiropractic practices.<sup>20</sup> Similarly, in a trial assessing the efficacy of surgical interventions, patients recruited from a surgeon’s office would, on this basis alone, have a higher expectation of benefit from surgery, and likely would experience better results from surgery than from nonsurgical treatment. If patients in the current study had been recruited from acupuncture clinics instead of primary care clinics, greater treatment benefit may have been expected from acupuncture than from massage because such patients likely would have relatively high expectations for acupuncture.

These results also highlight the importance of effectively masking the treatment received in clinical trials. This masking is relatively easy in some drug trials, but more difficult in trials of physical treatments, devices, or procedures. Nonetheless, control treatments not only should mimic the active treatment as closely as possible, but also should seek to mimic levels of expectations. Innovation and pilot testing

may be required to determine appropriate control conditions for nondrug treatments.

Neither average expectation for treatment benefit nor general optimism about improvement for a back condition was an important predictor of better functional outcome. This finding may highlight the importance of assessing a patient's expectation regarding benefit from a specific treatment, and suggests that patient preferences for treatment should be considered in clinical decision making when there are multiple reasonable options. The results from this study can be generalized only to patients who are able and willing to express their expectations for treatment benefit on a numerical scale. Moreover, it is not known to what extent a patient's expectations change over time, perhaps in response to interactions with providers.

Interestingly, the duration of symptoms did not appear to be associated with either expectations for treatment benefit or functional outcome. Little also is known about the extent to which providers can influence patients' expectations about a treatment and thereby affect the outcome of that treatment. Nevertheless, besides the potential for enhancing patient autonomy and satisfaction, the current findings support shared decision making by patients and providers as a basis for improving clinical outcomes, particularly when the safety and costs of each treatment are similar.

### ■ Key Points

- Patient expectation for benefit from a specific treatment correlates significantly with improved clinical outcome and may help to explain the non-specific effects of many treatments.
- The relative odds of improvement are five times greater among those with high expectations for treatment benefit compared with those with low expectations for benefit after adjusting for sociodemographic, health status, and physical factors.
- General optimism regarding prognosis does not appear to have an important influence on outcomes.
- These findings may have implications for both physicians and patients regarding treatment choice, particularly when no treatment is clearly superior and when the relative safety and costs of each treatment are similar.
- These findings may also indicate a role of assessing patient expectations in the interpretation and design of clinical trials aimed at determining the effectiveness of specific therapies, especially in situations in which blinding of treatment is difficult or impossible, or in trials in which expectation of one treatment is generally likely to be higher than the comparison treatment.

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*Address reprint requests to*

Donna Kalauokalani, MD, MPH  
 Department of Anesthesiology  
 Washington University Pain Center  
 660 So. Euclid Avenue  
 Campus Box 8054  
 St. Louis, MO 63110  
 E-mail: Kalauokalani@notes.wustl.edu

## Point of View

Jon D. Lurie, MD, MS  
 SPORT at the Spine Center  
 DHMC—One Medical Center Drive  
 Lebanon, New Hampshire

Using data from a randomized trial of acupuncture and massage therapy, Kalauokalani and colleagues examined the relationship between patients' expectations from treatment and their self-reported functional outcomes. They demonstrated improved outcomes when patients had higher expectations of benefit from the treatment they received, independent of which treatment that was. Previous studies have shown similar results for patients undergoing lumbar discectomy.<sup>1</sup> Importantly, in the current study general optimism about improvement was not associated with improved outcomes; the effect appears to be specific to expectations about the treatment received.

While there is growing evidence that patient expectations can have important effects on outcomes, the mechanism or mechanisms of these effects are not well understood. It may be that patients' expectations of benefit from a treatment generate a placebo effect when that treatment is given. It may also be that patients' expectations affect their reports of their health status more than their actual health itself. Alternatively, it may be that patients know what is likely to work for them. Patients

may be able to perceive subtle differences, of which clinicians or researchers are less aware, that make them better candidates for one treatment than another.

Whatever the reason, the fact that patients with higher expectations of a specific treatment have better outcomes with that treatment has important implications for both research and clinical care of patients with low back pain. Researchers need to pay attention to the potential confounding effects of patient expectations; these effects should be minimized by adequate masking of control treatments whenever possible. When adequate masking is not possible, patient expectations should at least be measured and controlled for in the analysis. For clinicians, actively engaging patients in a process of shared decision-making about treatment options offers the potential for better matching patients' expectations with their treatments, thereby improving outcomes.

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