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The impact of treatment confidence on pain and related disability among patients with low-back pain: results from the University of California, Los Angeles, low-back pain study

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Abstract

Background context: Although many researchers and practitioners believe that patients' positive expectations of their treatment favorably influence clinical outcomes, there is little scientific evidence to support this belief.

Purpose: To describe the level of patients' initial confidence in the success of their assigned treatment, by treatment group and other factors; and to estimate the effects of treatment confidence on subsequent changes in low-back pain and related disability.

Study design and patient sample: Randomized clinical trial involving 681 patients treated for low-back pain in a managed-care facility in Southern California.

Outcome measures: Treatment confidence; and changes in three clinical measures of low-back pain: average pain, most severe pain and back-pain–related disability.

Methods: Patients were randomly assigned to one of four treatment groups: medical care with and without physical therapy, and chiropractic care with and without physical modalities. Information was collected by questionnaires at baseline, 2 weeks, 6 weeks and 6 months. Treatment confidence was measured just after randomization on a scale of 0 to10.

Results: Treatment confidence was lowest, on average, for patients assigned to medical care only and highest for patients assigned to medical care plus physical therapy. Other predictors of high treatment confidence were having acute pain and being older, female and nonwhite. Although treatment confidence was only weakly associated with subsequent changes in low-back pain or disability in the total sample, high treatment confidence was associated with greater improvement among patients assigned to medical care plus physical therapy.

Conclusions: Initial confidence in treatment for low-back pain varies by type of care and other factors. Higher confidence may have some beneficial effect on the course of low-back pain in certain patients, but this effect may depend on the type of interaction between client and provider.

Keywords: Low-back pain; Medical care; Chiropractic; Physical therapy; Treatment confidence

Introduction

Variation in treatment outcomes for such conditions as chronic low-back pain, which do not have clear causal mechanisms or uniformly efficacious treatments, are commonly related to the beliefs of patients and the characteristics of the healing situation. When such factors as beliefs have an impact, they are often considered to be dimensions of the "placebo effect."

Although there are some commentators who deny the reality of the placebo effect [1], it is generally accepted as a

FDA device/drug status: not applicable.

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true, if poorly understood, factor in almost all therapeutic contexts [2–5]. The placebo effect is usually described as encompassing the nonspecific impact of treatment, excluding the direct effect of therapy and any naturally occurring remission and healing. This would include the attention and interest shown to the patient by the physician or other therapists, aspects of the treatment setting, the patient's feeling that he or she has received a coherent explanation for his or her illness or problem, the initial level of confidence that the patient has in the physician and therapy, the reputation of the physician or institution, the extent or degree of commitment to the process shown by the patient and the patient's enhanced sense of control or mastery over his or her symptoms. Clinical researchers have often claimed that these factors are responsible for approximately 33% of all clinical improvement [6]. In fact, although researchers have found the placebo effect to be omnipresent, its impact varies considerably. For example, studies by Deyo et al. [7,8] and Marchand et al. [9] found that the frequency and severity of pain, along with improvements in functional status, improved by 20% to 40% in patients with histories of chronic back pain after sham electrical treatments. Other researchers have found placebo responses among considerably smaller proportions of patients [10], whereas yet others [11] have found that over 90% of patients with chronic low-back pain respond to placebos. Reviews encompassing a wide range of chronic conditions have consistently found that, despite its variable strength, the placebo effect is omnipresent [2,3,5,12,13]. In particular, pain is an outcome affected by the placebo effect. In fact, because pain reflects an individual's reaction to a wide array of biological, psychological and social factors, it has been called the "ideal" outcome measure for assessing the impact of the placebo effect [14].

Despite the expectations of many researchers and clinicians, a constellation of psychological traits associated with an individual being particularly susceptible to the placebo effect has yet to be found [2,15–18]. However, two factors have been identified as associated with the placebo effect. Positive expectations on the part of the patient (as well as the provider) that the treatment will be effective have consistently been found to influence clinical outcomes. A recent review of studies attempting to ascertain the role of patient expectations on outcomes found almost all reporting positive findings [19]. In addition, certain characteristics of the healing situation have been shown to foster these expectations [2,20–23]. Examples include spending more time with patients, educating patients to anticipate specifically what they will experience in the future and recommending how patients might best react [2,4,20,24,25].

Assessing how confident the patient is in the efficacy of treatment before its initiation is one way of measuring positive expectations. Treatment confidence has long been recognized by many observers as a crucial aspect in the determination of positive outcomes. For example, Antonovsky [26,27] believed that the "dynamic feeling of confidence in a favorable outcome" is the key to staying healthy and responding favorably to most any treatment. Little is known about whether treatment confidence is equally important for all types of therapy used in treating the same condition. Recently, a study comparing patients with low-back pain randomly assigned to acupuncture or massage found that whereas favorable expectations about therapy in general did not influence outcomes, positive expectations about specific forms of treatment did have a clear impact on outcomes [28]. Our research offers an opportunity to examine the impact of the patient's initial confidence in treatment on subsequent pain and functioning for individuals with low-back pain. The primary research questions for this article are 1) Does treatment confidence, measured after randomization but before treatment, differ among patients randomly assigned to the four treatment groups? 2) What are other predictors of having a high level of confidence that treatment will be successful? 3) Does treatment confidence have an impact on low-back pain and related disability, and does this impact vary among the treatment groups?

Methods

The analyses reported in this article are derived from a randomized clinical trial designed to assess the effectiveness and cost-effectiveness of medical versus chiropractic care for treating low-back pain in a managed-care setting. The source population is approximately 100,000 members of a managed-care organization, formerly based in Orange County, California. The health-care network was primarily a prepaid group practice, where all providers were on salaries largely derived from capitation payments. The study was conducted at the organization's main ambulatory care facility in La Habra and at its satellite clinics in Brea and Buena Park.

Subjects were eligible for the study if they were health maintenance organization members who had selected the managed-care network as their medical provider and 1) sought care at one of the three study sites between October 30, 1995, and November 9, 1998; 2) presented with a complaint of low-back pain (defined as pain in the region of the lumbrosacral spine and its surrounding musculature, with or without leg pain); 3) had not received treatment for low-back pain in the previous 1 month and 4) were at least 18 years old. Potential subjects were excluded if 1) their low-back pain was the result of any nonmechanical cause (fracture, tumor, infection and so forth); 2) they had severe coexisting disease that would threaten 18-month survival; 3) they were being treated by electrical devices, such as pacemakers; 4) they had blood coagulation disorders or were using corticosteroids or anticoagulant medication; 5) they had plans to move within the next 18 months; 6) they were not easily accessible by telephone; 7) they lacked the ability to read English or 8) they were involved in any third-party liability or workers compensation action.

Patients meeting the eligibility criteria were asked by the field coordinator if they would be willing to participate in a study to assess the effectiveness of various treatments for their condition. They received an information sheet explaining that participants would be randomly assigned to one of four treatment protocols, that it is not known which protocol is most effective and that they would be required to complete five sets of questionnaires over an 18-month period. Study participants were not blinded to their assigned treatment group or to treatment alternatives. Those agreeing read and signed an informed consent form that had been approved by the institutional review boards of both the University of California, Los Angeles, and the managed-care organization. Random assignment was based on an off-site computer-generated code that was placed in sealed envelopes, put in blocks of 12 and stratified by site. After consent was obtained, the coordinator opened the envelope and documented the assignment for the patient. After completing the baseline questionnaire, the subject was assigned to and seen by the physician or the chiropractor on the same day. Subjects received a token payment of $10 on enrollment and $10 after completing the last follow-up questionnaire.

Subjects were assigned to one of four treatment protocols: medical care only (MD group)—instruction in proper back care and strengthening and flexibility exercises, bed rest, pain killers, muscle relaxants, anti-inflammatory agents and other medications used to reduce or eliminate sensation at the discretion of the provider; chiropractic care only (DC group)—spinal manipulation or other spinal adjusting techniques, instruction in proper back care and strengthening and flexibility exercises; medical care with physical therapy (MDPt group)—medical care, as described above, instruction in proper back care from the physical therapist, plus one or more of the following at the discretion of the physical therapist: heat, cold, ultrasound, electrical muscle stimulation, soft tissue and joint mobilization, traction, supervised therapeutic exercise and strengthening and flexibility exercises; chiropractic care with physical modalities (DCPm group)–chiropractic care as described above, plus one or more of the following, at the discretion of the chiropractor: heat, cold, ultrasound and electrical muscle stimulation.

Medical care was provided by 33 family medicine practitioners. Chiropractic care was provided by four chiropractors, each with at least 5 years of clinical chiropractic experience. The group's chiropractors routinely used the diversified technique, the most frequently used type of spinal manipulation, taught in almost all US chiropractic schools [29]. Physical therapy was administered in the physical therapy department of the managed-care group and supervised by a licensed physical therapist. The group employs four physical therapists (each with over 5 years of clinical experience), three assistant physical therapists and four physical therapy aides. All these personnel work at a site within a 15-minute drive of the three study sites. Because the goal of the study was to assess care as it is actually delivered in a managed care setting, the frequency of follow-up visits with physicians, physical therapists and chiropractors, as well as the specific treatments received by each patient were at the discretion of the provider.

Sources of data for the analyses reported in this article include a baseline questionnaire and follow-up questionnaires at 2 weeks, 6 weeks and 6 months. Follow-up questionnaires addressed low-back-pain severity, frequency, improvement, disability and employment status. In addition, a 5- to 10-minute telephone interview was conducted with all participants 4 weeks after their initial visit. This interview dealt with aspects of the patient's care: amount of time spent with each provider at each visit and the advice given by the provider on posture, exercise, ergonomics and so forth.

Of 1,469 eligible patients screened for this study, 681 (46.4%) were enrolled. The major reasons patients gave for refusing to participate were "not interested" (n=345), "inconvenient" (n=137), "prefer medical care" (n=116) and "prefer chiropractic care" (n=105). Less than 2% (n=46) of the eligible patients were excluded from the study because of an inability to read English. This very low rate was expected and was the basis of our decision to offer the interview in English only. Whereas the mean age of those who refused to participate was not appreciably different from those who did, nonparticipants were more likely to be female (63% vs. 52% of the participants). The 2- and 6-week follow-up questionnaires were completed by 680 (99.9%) and 676 (99.3%) subjects, respectively, whereas 652 (95.7%) completed the 6-month follow-up questionnaire. Disability resulting from low-back pain was assessed by the 24-item Roland-Morris Disability Questionnaire [30,31]. Patients respond by answering "yes" or "no" to indicate whether each statement applies to them on the day of the interview. Possible scores range from 0 (indicating no disability) to 24 (indicating severe disability). The Roland-Morris scale is widely used in clinical studies and has been shown to be reliable, valid and sensitive to change [32,33]. Numerical rating scales were used at baseline and each follow-up to assess intensity of pain (most severe pain and average level of pain for the past week), where 0=no pain and 10=unbearable pain. These scales have been shown to have excellent reliability and validity for measuring back pain [34]. Specific questions addressed the duration of the current and longest episodes of low-back pain.

There is no standard scale for the measurement of treatment confidence. We used a straightforward numerical scale of 0 to 10 in which 0 represents no confidence and 10 represents complete confidence. The scale was based on a single item: "Circle below on the scale from 0 [not confident] to 10 [confident] how confident you are that the treatment you will be receiving will be successful at reducing your low-back pain." This question was included in the baseline questionnaire after subjects knew their assigned group but before treatment began. For descriptive purposes, the treatment confidence score was categorized into four levels: high (9 or 10), moderate (7 or 8), modest (5 or 6) and minimal (0 to 4).

Table 1
Frequency distribution (numbers and percents of each treatment group) and/or means and standard deviations of selected baseline variables, by treatment group

Variable	Treatment group DC (n=169)	DCPm (n=172)	MD (n=170)	MDPt (n=170)
Age (years)				
Under 30	15 (8.9%)	14 (8.1%)	16 (9.4%)	19 (11.2%)
30–39	34 (20.1%)	38 (22.1%)	39 (22.9%)	39 (22.9%)
40–49	28 (16.6%)	22 (12.8%)	39 (22.9%)	35 (20.6%)
50–59	33 (19.5%)	32 (18.6%)	29 (17.1%)	29 (17.1%)
60–69	28 (16.6%)	25 (14.5%)	19 (11.2%)	24 (14.1%)
70+	31 (18.3%)	41 (23.8%)	28 (16.5%)	24 (14.1%)
Mean (SD)	51.8 (16.5)	53.4 (16.8)	49.4 (16.5)	49.3 (16.7)
Sex				
Male	86 (50.9%)	73 (42.4%)	90 (52.9%)	78 (45.9%)
Female	83 (49.1%)	99 (57.6%)	80 (47.1%)	92 (54.1%)
Race/ethnicity				
White non-Hispanic	105 (62.1%)	113 (65.7%)	102 (60.0%)	91 (53.5%)
Hispanic	46 (27.2%)	44 (25.6%)	54 (31.8%)	59 (34.7%)
Other	18 (10.7%)	15 (8.7%)	14 (8.2%)	20 (11.8%)
Education				
High school or less	54 (32.0%)	54 (31.4%)	41 (24.1%)	53 (31.2%)
Some college	78 (46.2%)	66 (38.4%)	66 (38.8%)	59 (34.7%)
College or above	37 (21.9%)	52 (30.2%)	63 (37.1%)	58 (34.1%)
Income (N = 663)				
<$40K	82 (49.7%)	73 (44.5%)	58 (34.9%)	76 (45.2%)
$40K–$59K	45 (27.3%)	39 (23.8%)	54 (32.5%)	44 (26.2%)
≥$60K	38 (23.0%)	52 (31.7%)	54 (32.5%)	48 (28.6%)
Marital status				
Married	117 (69.2%)	128 (74.4%)	120 (70.6%)	110 (64.7%)
Other	52 (30.8%)	44 (25.6%)	50 (29.4%)	60 (35.3%)
Current employment status				
Full time	98 (58.0%)	88 (51.2%)	103 (60.6%)	104 (61.2%)
Retired	42 (24.8%)	52 (30.2%)	39 (22.9%)	39 (22.9%)
Other	29 (17.2%)	32 (18.6%)	28 (16.5%)	27 (15.9%)
Duration of low-back pain episode				
Acute (<3 weeks)	37 (21.9%)	52 (30.2%)	46 (27.1%)	43 (25.3%)
Subacute (3 weeks–1 year)	55 (32.5%)	45 (26.2%)	41 (24.1%)	44 (25.9%)
Chronic (>1 year)	77 (45.6%)	75 (43.6%)	83 (48.8%)	83 (48.8%)
Roland-Morris disability score (past week)				
0–5	38 (22.5%)	23 (13.4%)	34 (20.0%)	24 (14.1%)
6–10	56 (33.1%)	61 (35.5%)	53 (31.2%)	45 (26.5%)
11–15	40 (23.7%)	49 (28.5%)	47 (27.6%)	54 (31.8%)
16–24	35 (20.7%)	39 (22/7%)	36 (21.2%)	47 (27.6%)
Mean (SD)	10.3 (5.6)	11.3 (5.0)	10.5 (5.6)	11.7 (5.4)
Most severe low-back pain (past week)				
Mean (SD)	6.5 (2.0)	6.7 (2.1)	6.5 (2.2)	7.0 (2.1)
Average low-back pain (past week)				
Mean (SD)	4.5 (1.9)	4.7 (1.8)	4.4 (1.9)	4.9 (2.0)
Confidence in treatment success (N = 679)				
Minimal (0–4)	22 (13.0%)	22 (12.9%)	41 (24.1%)	19 (11.2%)
Modest (5–6)	49 (29.0%)	48 (28.1%)	45 (26.5%)	39 (23.1%)
Moderate (7–8)	50 (29.6%)	50 (29.2%)	50 (29.4%)	50 (29.6%)
High (9–10)	48 (28.4%)	51 (29.8%)	34 (20.0%)	61 (36.1%)
Mean (SD)	6.9 (2.4)	7.0 (2.3)	6.1 (2.7)	7.3 (2.4)
Mean SF-36 score (SD)				
Physical Function	65.8 (25.1)	59.7 (24.1)	63.9 (22.8)	59.4 (25.9)
Role Physical	43.9 (41.0)	36.3 (39.1)	43.8 (39.8)	41.2 (40.5)
Role Emotional	75.4 (38.5)	66.1 (40.7)	68.4 (38.4)	70.0 (39.0)
Mental Health	72.1 (16.6)	72.8 (15.8)	70.6 (17.1)	69.3 (16.7)
General Health	68.1 (17.3)	69.0 (17.2)	67.6 (18.3)	66.6 (19.1)

DC=chiropractic care alone; DCPm=chiropractic care with physical modalities; MD=medical care alone; MDPt=medical care with physical therapy.

In conducting the statistical analysis of the data, we first identified baseline predictors of high treatment confidence using logistic regression with modified stepwise variable selection. “Treatment-group” variables were forced into the model. The effects of the predictors, adjusted for other predictors, were estimated with odds ratios (and 95% confidence intervals [CI] derived from the results of the logistic regression analyses. The outcome variable was high treatment confidence (score of 9 or 10 on an 11-point scale) versus less treatment confidence (score less than 9). The potential baseline predictors included age, gender, race/ethnicity, education, income, marital status, treatment group, duration of the current episode of low-back pain, recency of treatment using the same modality as the one randomly assigned, baseline value of average low-back pain, most severe pain, disability score (Roland-Morris scale) and the 36-item Short-Form Health Survey [35] score on the scales measuring 1) limitations in physical activities because of physical or emotional problems; 2) limitations in usual role activities because of physical health problems; 3) limitations in usual role activities because of emotional health problems; 4) general health perceptions and 5) general mental health. To account for the uncertainty of variable selection, we used a conservative approach. Variables were retained in the model if they had a p value less than 0.15 or if they changed the estimated effect of assigned treatment group on treatment confidence by 10% or more. Qualitatively similar results were obtained when treatment confidence was treated as an interval outcome.

Next we examined the change in low-back pain between baseline and 6 months by level of treatment confidence (where a negative change represents improvement). To assess the impact of high treatment confidence on the change in low-back pain, we estimated crude and adjusted effects of high treatment confidence by fitting linear regression models. The main predictor variable in these analyses was high treatment confidence (score of 9 or 10) versus those with lower treatment confidence (score less than 9). The estimated effect of high treatment confidence was adjusted for the baseline value of the outcome variable, age, gender, race/ethnicity, employment status, treatment group and the duration of the current episode of low-back pain.

Finally, to better understand how treatment confidence influences the improvement of low-back pain, we applied separate linear regression models on changes in average low-back pain, most severe pain and disability score measured at three follow-up assessments (2 weeks, 6 weeks and 6 months) within each treatment group. Separate models were fit with treatment confidence treated as an interval variable and as a dichotomous variable (9 or 10 vs. 0 to 8).

Results

Selected characteristics of the sample are shown in Table 1. The demographic characteristics of the 681 subjects across the four treatment groups were similar. The patients were generally in their early fifties, married, equally divided among males and females and about 60% non-Hispanic white. Just under 30% of the patients were Latino/Hispanic, with African Americans under 3%, Asian/Pacific Islanders under 5% and other minorities comprising the remainder of the sample. Subjects were relatively well educated, with about 70% having at least some college. The group was also reasonably affluent, with almost 3 in 10 having family incomes of over $60,000 a year. Over 80% were employed at least part-time. Differences among the four treatment groups on these demographic variables were small.

Clinically, the four treatment groups were also generally comparable at baseline. The duration of the current episode of low-back pain was more than a year for almost 50% of the subjects, whereas about 25% reported the episode as acute (less than 3 weeks duration). Each of the treatment groups reported comparable levels of disability (approximately 11 points on the 0 to 24 Roland-Morris scale) and similar levels of pain (both average and most severe) over the week just before entering the study. However, the Roland-Morris scores do indicate that those in the MD group had somewhat lower levels of disability during the week before baseline, whereas those in the MDPt group were the most disabled. Overall, patients in the study appear to be reasonably confident about each of the treatments (mean score=6.8, SD=2.5). Mean and median scores for confidence in the outcome of treatment were lowest for those in

Table 2
Estimated effects adjusted odds ratios* and 95% confidence intervals of baseline predictors on high treatment cofidence (score 9 or 10) after randomization: results derived from logistic regression analysis (N = 679)†

Predictor/category	OR*	95%CI	p Value
Age (per 10 years)	1.33	(1.14, 1.56)	<.001
Female vs. male	1.99	(1.36, 2.91)	<.001
Race/ethnicity			
White	1.00	—	—
Hispanic	1.80	(1.20, 2.71)	.005
Other	2.80	(1.55, 5.05)	<.001
Current employment status			
Full time	1.00	—	—
Retired	0.94	(0.52, 1.73)	.849
Other‡	1.60	(0.97, 2.63)	.065
Treatment group			
MD	1.00	—	—
DC	1.54	(0.91, 2.62)	.109
DCPm	1.45	(0.85, 2.45)	.171
MDPt	2.10	(1.25, 3.52)	.005
Duration of current low-back pain episode			
Chronic (>1 year)	1.00	—	—
Subacute (3 weeks–1 year)	1.58	(1.03, 2.44)	.038
Acute (>3 weeks)	1.97	(1.26, 3.08)	.003
Baseline most severe pain (per point)	1.16	(1.06, 1.27)	.001

*Each effect is adjusted for other predictors presented in the table.

†Patients who had missing values of treatment confidence were excluded from logistic regression analyses.

‡Includes employed part-time, on leave, and unemployed.

CI = confidence interval; DC = chiropractic care alone; DCPm = chiropractic care with physical modalities; MD = medical care alone; MDPt = medical care with physical therapy; OR = odds ratio.

Table 3
Mean 6-month changes* (and standard deviations) in average low-back pain, most severe pain, and disability score, by level of baseline treatment confidence after randomization (N = 650)†

Level of treatment confidence	N	Average pain	Most severe pain	Disability score
High (9–10)	190	−2.31 (2.65)	−3.17 (3.38)	−5.34 (5.83)
Moderate (7–8)	189	−1.69 (2.66)	−2.47 (3.38)	−4.16 (6.34)
Modest (5–6)	172	−1.58 (2.39)	−2.32 (2.93)	−4.35 (5.30)
Minimal (0–4)	99	−1.02 (2.18)	−1.58 (2.97)	−2.80 (5.78)
Total	650	−1.74 (2.55)	−2.50 (3.24)	−4.35 (5.89)
p Value‡		<.001	<.001	.001

*6-month changes in outcome = outcome measured at 6 months – outcome measured at baseline.

†Patients who were lost to follow-up at 6 months or had missing values of treatment confidence were excluded in the analyses.

‡P values reflect tests for linear trends, where treatment confidence is treated as an interval variable in a simple linear regression model.

the MD group (mean score=6.1, SD=2.7) and highest for those in the MDPt group (mean score=7.3, SD=2.4). The mean score for the DC group was 6.9 (SD=2.4), and the mean score for the DCPm group was 7.0 (SD=2.3; p<.001 for difference in mean levels of treatment confidence among the four groups).

Table 2 shows which factors predicted high confidence (score of 9 or 10). The duration of one's current episode of low-back pain at baseline was inversely associated with treatment confidence. Thus, patients with acute pain (less than 3 weeks) were most likely to report high treatment confidence, and patients with chronic pain (more than 1year) were least likely to report high treatment confidence. High treatment confidence was also positively associated with being older, female and nonwhite. In addition, treatment assignment affected treatment confidence; subjects in the MDPt group reported the highest level of treatment confidence, and subjects in the MD group reported the least confidence.

As shown in Tables 3 and 4, there is a crude (unadjusted) association between treatment confidence and subsequent change in each outcome between baseline and 6 months. Improvement in average pain, most severe pain and disability score are greatest for patients who reported high treatment confidence after randomization. Nevertheless, when controlling for the effects of age, gender, race/ethnicity, baseline value of the outcome, treatment group and duration of current episode, the estimated effects of treatment confidence weakened appreciably (see Table 4). For example, the adjusted mean 6-month improvement in average and most severe pain was only 0.28 point greater in patients initially reporting high treatment confidence than in patients reporting less confidence.

The estimated effects of treatment confidence (treated as an interval variable) on changes from baseline in low-back pain and disability for each treatment group at each follow-up assessment are shown in Table 5. The effect estimates in this table are adjusted for the same covariates used in Table 4. Although treatment confidence appears to have little or no effect on any of the outcomes in any treatment group during the first 6 weeks of follow-up, consistent associations are observed after 6 months in one treatment group. Specifically, high treatment confidence was associated with greater improvement in mean levels of most severe pain and disability among patients in the MDPt group. For example, a one-point increase in treatment confidence was associated with a 0.45-point reduction in the disability score. These associations were not observed in the other treatment groups. Furthermore, in the MDPt group, there is an increasing trend in the estimated effect of treatment confidence on disability change over time. The estimated regression coefficient changes from −0.04 (95% CI=−0.37, 0.29) at the 2-week follow-up, to −0.18 (95% CI=−0.54, 0.18) at the 6-week follow-up, to −0.45 (95% CI=−0.83, −0.07) at the 6-month follow-up.

Table 4
Estimated crude and adjusted* effects (regression coefficients [β]† and 95% confidence intervals) of high treatment confidence on 6-month changes in average low-back pain, most severe pain, and disability score: results of linear regression analyses (N = 650)‡

	Crude effect estimates			Adjusted* effect estimates		
Outcome	†β	95%CI	p Value	†β	95%CI	p Value
Average pain	−0.80	(−1.23, −0.37)	<.001	−0.28	(−0.66, 0.10)	.151
Most severe pain	−0.95	(−1.49, −0.41)	<.001	−0.35	(−0.84, 0.14)	.165
Disability score	−1.40	(−2.39, −0.41)	.006	−0.65	(−1.50, 0.20)	.134

*The effect of high treatment confidence is adjusted for the baseline value of the outcome variable, age, gender, race/ethnicity, treatment group, and duration of the current episode of low-back pain.

†The estimated regression coefficient (β) may be interpreted as the crude (unadjusted) or adjusted difference in mean 6-month change in outcome between patients with high treatment confidence (score 9 or 10) after randomization and those with less treatment confidence (score less than 9). Thus, a negative value of the estimated coefficients means that patients with high treatment confidence improved more during follow-up

‡Patients who were lost to follow-up at 6 months or had missing values of treatment confidence were excluded from linear regression analyses.

CI=confidence interval.

Table 5
Estimated adjusted* effects (regression coefficients [β] and 95% confidence intervals) of treatment confidence on 2-week, 6-week and 6-month changes in average low-back pain, most severe pain and disability score by treatment group: results of linear regression analyses

Treatment group	Outcome	N		95%CI	p Value
DC	2-week follow-up				
	Change in average pain	169	−0.07	(−0.17, 0.03)	.147
	Change in most severe pain	169	−0.05	(−0.18, 0.07)	.389
	Change in disability score	169	−0.16	(−0.42, 0.09)	.208
	6 -week follow-up				
	Change in average pain	168	0.00	(−0.12, 0.13)	.956
	Change in most severe pain	168	−0.02	(−0.17, 0.12)	.755
	Change in disability score	168	−0.13	(−0.44, 0.17)	.393
	6-month follow-up				
	Change in average pain	165	−0.04	(−0.19, 0.10)	.560
	Change in most severe pain	165	−0.04	(−0.23, 0.14)	.639
	Change in disability score	165	−0.12	(−0.42, 0.18)	.432
DCPm	2-week follow-up				
	Change in average pain	169	−0.05	(−0.18, 0.08)	.476
	Change in most severe pain	169	−0.05	(−0.19, 0.10)	.546
	Change in disability score	169	−0.05	(−0.35, 0.24)	.714
	6-week follow-up				
	Change in average pain	168	−0.05	(−0.19, 0.10)	.507
	Change in most severe pain	168	−0.11	(−0.29, 0.06)	.206
	Change in disability score	168	−0.25	(−0.56, 0.07)	.121
	6-month follow-up				
	Change in average pain	162	−0.03	(−0.17, 0.11)	.679
	Change in most severe pain	162	−0.02	(−0.21, 0.16)	.835
	Change in disability score	162	0.01	(−0.33, 0.35)	.945
MD	2-week follow-up				
	Change in average pain	170	0.09	(−0.01, 0.19)	.067
	Change in most severe pain	170	0.17	(0.05, 0.29)	.005
	Change in disability score	170	0.21	(−0.03, 0.44)	.081
	6-week follow-up				
	Change in average pain	170	0.04	(−0.07, 0.16)	.435
	Change in most severe pain	169	0.08	(−0.06, 0.22)	.256
	Change in disability score	169	0.06	(−0.19, 0.32)	.635
	6-month follow-up				
	Change in average pain	165	−0.06	(−0.18, 0.06)	.293
	Change in most severe pain	165	−0.08	(−0.24, 0.08)	.305
	Change in disability score	165	−0.13	(−0.39, 0.13)	.323
MDPt	2-week follow-up				
	Change in average pain	168	0.12	(−0.00, 0.24)	.056
	Change in most severe pain	168	0.02	(−0.13, 0.18)	.770
	Change in disability score	168	−0.04	(−0.37, 0.29)	.811
	6-week follow-up				
	Change in average pain	167	0.06	(−0.08, 0.21)	.389
	Change in most severe pain	167	0.08	(−0.10, 0.26)	.375
	Change in disability score	167	−0.18	(−0.54, 0.18)	.331
	6-month follow-up				
	Change in average pain	158	−0.12	(−0.28, 0.03)	.123
	Change in most severe pain	158	−0.25	(−0.46, −0.04)	.018
	Change in disability score	158	−0.45	(−0.83, −0.07)	.022

Treatment-confidence score is treated as a continuous variable, and the effect of a one-point difference in treatment confidence is adjusted for the baseline value of the outcome variable, age, gender, race/ethnicity, treatment group and duration of the current episode of low-back pain.

CI=confidence interval; DC=chiropractic care alone; DCPm=chiropractic care with physical modalities; MD=medical care alone; MDPt=medical care with physical therapy.

Discussion

Our findings show that treatment confidence, measured after randomization but before treatment, does vary by treatment group. Perhaps not surprisingly, we also found that the more chronic the symptoms, the less likely patients were to express a high level of confidence in the outcome of treatment. Older patients, women and nonwhites were also relatively more likely to express high levels of confidence in treatment outcomes. This may be because of the fact that such individuals are more likely to accept the authority of a physician or other healer [5].

We found a moderate association between the patient's initial confidence in treatment and clinical outcomes 6 months later, but only among those subjects assigned to be treated by both medical doctors and physical therapists. Although differences in the estimated treatment-confidence effect across assigned treatment groups may be a chance finding, the association observed in the MDPt group supports our hypothesis that high treatment confidence has a beneficial effect on the course of low-back pain. Our results for the MDPt group are also consistent with those of Kalauokalani et al. [28], who found a positive association between expectation of benefit from acupuncture or massage and improved back-pain–related disability. In that study, however, the investigators measured patient expectations for each treatment before their randomization. We measured patient expectations after subjects had been randomly assigned and knew which treatment they were to receive. Because we observed an association between assigned treatment group and treatment confidence, we controlled for treatment group in the analysis when estimating the effect of treatment confidence on clinical outcome.

If our findings do indicate a true effect of treatment confidence on the course of low-back pain, two characteristics of the study participants may be helpful in explaining why the association was observed only in the MDPt group. One explanation is simply the amount of time that the provider spends with the patient. According to patient reports, the medical doctors and chiropractors spent about 14 minutes on average with our subjects at each clinical visit, and the physical therapists spent 31 minutes per visit. Thus, it is reasonable to assume that those patients assigned to the MDPt group did, in fact, spend more time in direct contact with a care giver. There is reason to expect that the amount of time the providers spent with the patients might be associated with more favorable outcomes [4,13,25]. Another possible explanation of a favorable effect of treatment confidence in the MDPt group is the greater emphasis on behavioral changes (eg, back-exercise education and instruction) by physical therapists and a positive association between treatment confidence and the level of adherence to such behaviors. Thus, MDPt patients with more confidence in their treatment may be more likely to exercise outside the therapeutic setting, which produces better clinical outcomes.

A limitation of this study is our reliance on a single item to measure treatment confidence, which may have increased the amount of measurement error (ie, less reliability). Because we have no reason for believing that such error was associated with other key variables or errors, it is likely that the net result would be to underestimate associations with treatment confidence. Thus, for example, the true effect of treatment confidence on low-back pain outcome in the MDPt group might actually be larger than our reported estimate of that effect.

We conclude that confidence in treatment among those with low-back pain does vary among patients seeking care. Furthermore, higher treatment confidence may have some beneficial effect on the course of low-back pain. This effect, however, does not appear consistent across all types and periods of treatment; it was observed only in the MDPt group after several weeks of follow-up. Thus, our findings need to be replicated in other populations, and alternative explanations for these effects should be explored. It is noteworthy that the sole treatment group in which the hypothesized relation was observed is the one that offered the longest and most sustained contact with the health-care providers, as well as the greatest likelihood that patients would include education about long-term back care. If providers of care to those with chronic low-back pain wish to mobilize the power of confidence in treatment among their clients, it is likely that they will need to do so within a clinical environment that allows it to emerge. Confidence in treatment is not merely an attribute that individuals bring to a clinical encounter. It is the product of a “therapeutic alliance of belief” [36] that arises from the interaction of patient, provider and the clinical environment.

References

[1] Kienle GS, Kienle H. The powerful placebo effect: fact or fiction? J Clin Epidemiol 1997;50:1311–8.

[2] Turner JA, Deyo RA, Loesser JD, Von Korff M, Fordice WE. The importance of placebo effects in pain treatment and research. JAMA1994;271:1609–14.

[3] Biller N. The placebo effect: mocking or mirroring medicine? Pers Bio and Med 1999;42:398–401.

[4] Brody H. The placebo response: recent research and implications for family medicine. J Fam Pract 2000;49:649–54.

[5] Thompson WG. Placebos: a review of the placebo response. Am J Gastroentrol 2000;95:1637–43.

[6] Beecher HK. The powerful placebo. JAMA 1955;159:1602–6.

[7] Deyo RA, Walsh NE, Martin DC, Schoenfeld LS, Ramanurthy S. A controlled trial of transcutaneous electrical nerve stimulation (TENS) and exercise for chronic low back pain. N Engl J Med 1990;322:1627–34.

[8] Deyo RA. Practice variations, treatment fads, and rising disability: do we need a new clinical research paradigm? Spine 1993;18:2153–62.

[9] Marchand S, Charest J, Li JX, Chenard JR, Lavignolle B, Laurencelle L. Is TENS purely a placebo effect—a controlled study on chronic low-back pain. Pain 1993;54:99–106.

[10] North R, Han M, Zahurak M, Kidd DH. Radiofrequency lumbar facet denervation—analysis of prognostic factors. Pain 1994;57:77–83.

[11] Jacobson L, Chabal C, Mariano AJ, Chaney EF. Persistent low-back pain is real—however, diagnostic spinal injections are not helpful in its evaluation. Clin J Pain 1992;8:237–41.

[12] Harrington A. The placebo effect: an interdisciplinary exploration. Cambridge, MA: Harvard University Press, 1997.

[13] Vickers AJ, de Craen AJ. Why use placebos in clinical trials? A narrative review of the methodological literature. J Clin Epidemiol 2000; 53:157–61.

[14] Spiegel H. Nocebo: the power of suggestibility. Prev Med 1997;26: 616–21.

[15] Lasagna L, Mosteller F, von Felsinger JM, Beecher HK. A study of the placebo response. Am J Med 1954;16:770–9.

[16] Lieberman R. An experimental study of the placebo response under three different situations of pain. J Psychiatr Res 1964;2:223–46.

[17] Price L. Art, science, faith and medicine: the implications of the placebo effect. Soc Health Ill 1984;6:61–73.

[18] Shapiro AK, Shapiro E. Patient-provider relationships and the placebo effect. In: Matarazzo JD, Weiss SM, Herd JA, Miller NE, editors. Behavioral health: a handbook of health enhancement and disease prevention. New York: Wiley-Interscience, 1984:371–83.

[19] Mondloch MV, Cole DC, Frank JW. Does how you’ll do depend on how you think you’ll do? A systematic review of the evidence for a relation between patients’ expectations and health outcomes. Can Med Assoc J 2001;165:174–9.

[20] Frank J. Persuasion and healing. Baltimore, MD: Johns Hopkins University Press, 1974.
[21] Evans FJ. Expectancy, therapeutic instructions, and the placebo response. In: White L, Tursky B, Schwartz GE, editors. Placebo: theory, research and mechanisms. New York: Guilford Press, 1985:215–28.
[22] Gracely RH. Verbal descriptor measures of pain clarify mechanisms of analgesia due to narcotics, brain stimulation and placebo. Anesth Prog 1987;34:113–27.
[23] Price D, Milling LS, Kirsch I, Duff A, Montgomery GH, Nicholls SS. An analysis of factors that contribute to the magnitude of placebo analgesia in an experimental paradigm. Pain 1999;83:147–56.
[24] Lowinger P, Dobie S. What makes the placebo work? A study of placebo response rates. Arch Gen Psych 1969;20:84–8.
[25] Lin CT, Albertson GA, Schilling LM, et al. Is patients' perception of time spent with the physician a determinant of ambulatory patient satisfaction? Arch Intern Med 2001;161:1437–42.
[26] Antonovsky A. Health, stress, and coping. San Francisco: Jossey-Bass, 1979.
[27] Antonovsky A. Unraveling the mystery of health. San Francisco: Jossey-Bass, 1987.
[28] Kalauokalani D, Cherkin DC, Sherman KJ, Koepsell TD, Deyo RA. Lessons from a trial of acupuncture and massage for low-back pain. Spine 2001;26:1418–24.
[29] Cherkin DC, Mootz RD. Chiropractic in the United States: training, practice, and research. AHCPR Pub. No. 98-N002. Rockville, MD: Agency for health Care Policy and Research, Public Health Service, U.S. Department of Health and Human Services, 1997:74–6.
[30] Roland M, Morris R. A study of the natural history of back pain—part I: development of a reliable and sensitive measure of disability in low-back pain. Spine 1983;8:141–50.
[31] Deyo RA. Comparative validity of Sickness Impact Profile and shorter scales for functional assessment in low-back pain. Spine 1986;11:951–4.
[32] Deyo RA, Battie M, Beurskens AJHM, et al. Outcome measures for low back pain research: a proposal for standardized use. Spine 1998; 23:2003–13.
[33] Roland M, Fairbank J. The Roland-Morris Disability Questionnaire and the Oswestry Disability Questionnaire. Spine 2000;25:3115–24.
[34] Cherkin DC, Deyo RA, Battie M, Street J, 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;339:1021–9.
[35] Ware JE, Sherbourne CD. The MOS 36-item Short Form Health Survey (SF-36): I. Conceptual framework and item selection. Med Care 1992;30:473–83.
[36] Noon JM. Placebo to credebo: the missing link in the healing process. Pain Reviews 1999;6:133–42.

COMMENTARY

Modeling is, perhaps, the most fundamental yet sophisticated technique available to the investigator. Models provide substantial insight into the behavior of systems yet always oversimplify the real world. In order to make models fit more closely to actual experience, they must be made increasingly complex. Ideally, we would like to have models that provide more than a broad understanding of population responses. We would like to be able to predict individual behaviors and, in medicine, select accurate diagnoses that predict responsiveness to treatment on an individual basis.

The authors have conducted a nicely crafted study seeking to examine the effects of patients' positive expectations of treatment outcomes. They have drawn their evaluation from a randomized, controlled clinical trial of a sample of 681 patients representing a subpopulation of patients with low-back pain with or without leg pain receiving one of four care approaches. Outcomes were based on questionnaires performed at baseline and by telephone follow-up at 2, 6 and 26 weeks. Linear regression models, in a stepwise process, were used to evaluate how patient confidence influences improvement from low-back pain.

Stepwise regression is a method that permits an investigator to narrow the range and rank order the importance of specific parameters in a model. With each step, the model fits more and more tightly to the sample from which it is derived. Therein lies the rub. The problem is that every sample of a population is just that, a sample. By itself, it may be skewed and misrepresent the population as a whole on one or more of its important parameters. As a result, the more tightly the model fits the sample data mathematically, the more the model can diverge from the intended goal of representing either the population as a whole or the individual specifically. The problem has been identified for years, because those modeling data inadvertently exploit chance and overfit their data.

The problem has been discussed explicitly by Tabchnik and Fidell [1]: "In stepwise logistic regression, inclusion and removal of predictors from the equation are based on statistical criteria. Thus, stepwise logistic regressions are best seen as a screening or hypothesis-generating technique, as it suffers from the same problems as statistical multiple regression and discriminate function analysis" (page 592). "The procedures' controversy lies primarily in capitalization on chance and over fitting the data....In this way, the technique capitalizes on chance differences within a single sample and may not generalize well to the population" (page 153).

If an investigator is lucky enough to obtain a sample for a study that legitimately represents the population as a whole, then the methodology, like that used by Goldstein et al., is adequate. However, unless one has data that can show that the sample characteristics are the same as the population as a whole, the model must be verified regarding its accuracy and predictive values before it can be used with confidence. It is important to verify that the model has not crossed the threshold into overfitting the data. The observation by Goldstein et al., that their model and data are closely matched, should not create confidence in the accuracy of its use and generalizing to the population. In fact, the nature of the stepwise regression, done properly, increases the expectation of such close fit.