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ORIGINAL RESEARCH

OUTCOMES OF A MIND-BODY TREATMENT PROGRAM FOR CHRONIC BACK PAIN WITH NO DISTINCT STRUCTURAL PATHOLOGY—A CASE SERIES OF PATIENTS DIAGNOSED AND TREATED AS TENSION MYOSITIS SYNDROME

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Context • Chronic, nonspecific back pain is a ubiquitous problem that has frustrated both physicians and patients. Some have suggested that it is time for a "paradigm shift" in treating it. One of them is John Sarno, MD, of New York University's Rusk Institute of Rehabilitation, who has argued for this in 4 books and several journal publications. We believe that a mind-body approach is more effective and involves much less risk and expense than conventional approaches in appropriately diagnosed cases.

Objective • To determine if a mind-body treatment program addressing a presumed psychological etiology of persistent back pain merits further research.

Design • Case series outcome study.

Setting • Single physician's office in metropolitan Los Angeles.

Patients • Fifty-one patients with chronic back pain, diagnosed with tension myositis syndrome, a diagnosis for "functional" back pain and treated in the principal investigator's office in 2002 and 2003.

Interventions • A program of office visits, written educational materials, a structured workbook (guided journal), educational audio CDs, and, in some cases, individual psychotherapy.

Main Outcome Measures • Pain intensity (visual analog scale scores), quality of life (RAND SF-12), medication usage, and activity level (questionnaires). Follow-up was at least 3 to 12 months after treatment.

Results • Mean VAS scores decreased 52% for "average" pain ($P<.0001$), 35% for "worst" pain ($P<.0001$), and 65% for "least" pain ($P<.0001$). SF-12 Physical Health scores rose >9 units ($P=.005$). Medication usage decreased ($P=.0008$). Activity levels increased ($P=.03$). Participants aged >47 years and in pain for >3 years benefited most. (*Altern Ther Health Med.* 2007;13(5):26-35.)

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Chronic back pain is one of the most expensive medical problems facing the industrialized world today, costing the US economy alone over $100 billion annually.[1] Moreover, in the majority of cases (up to 85%-90%), it is also idiopathic,[2,3] confronting the physician with the challenge of treating without a clear diagnosis. In fact, British back pain specialist Gordon Waddell called current approaches in both the United States and Britain a "healthcare disaster."[4]

Studies of spinal imaging have shown that many of the typical "abnormal" findings, such as degenerative disc disease, scoliosis, and bulging discs, are equally prevalent in the general asymptomatic population as they are among pain patients.[5-7] Moreover, the incidence of chronic back pain may correlate more closely with psychosocial factors than these structural abnormalities.[8-11] More specifically, chronic pain and poor treatment outcomes may correlate with somatization.[12] Although physicians have suspected that persistent back pain has a psychological component, no clear research-tested treatment program has emerged from this suspicion—for either medical doctors or psychotherapists. Thus Pruitt and Von Korff, among others, have suggested that the time has come for a "paradigm shift" in modern medicine's approach to back pain.[13]

In this study we examined and measured the results of a treatment program derived from a psychosomatic (mind-body) approach to diagnosing and treating chronic (but structurally nonspecific) back pain. This revised conceptualization leads to a differ-

ent treatment and, just as importantly, to different expectations on the part of both patients and caregivers, be they MDs or psychotherapists. The new paradigm is that a significant proportion of nonspecific back pain is psychosomatic, in the sense that its etiology is both psychological and physiological with the original cause being most clearly described at this time in psychological terms. Although research on this model is in the early stages, it is consistent with cutting-edge descriptions of the central modulation of pain, or central hypersensitization, which ascribe a much greater role to the central nervous system than previously believed.[14-16]

This case series study was designed to help evaluate the effectiveness of a treatment program derived from this model, an educational and psychological approach that focuses primarily on developing emotional self-awareness and understanding the relationship between emotions and pain. Patients also learn that their physical condition is actually benign and that any disability they have is a function of pain-related fear and deconditioning, not the actual risk of further "re-injury." Through these concepts, patients learn to identify the emotional causes, release their fears of physical incapacity and re-injury, and, ultimately, heal themselves. This study does not, however, identify which aspects of the program were instrumental in producing the results. This would require a more sophisticated (and perhaps multiple-arm) clinical trial.

This diagnosis and treatment approach was originally developed in the mid- to late 1970s by John Sarno, MD, a physiatrist and clinical rehabilitation specialist at New York University's Rusk Institute. Sarno observed that the most common diagnoses for back pain—such as degenerative discs, bulging discs, and minor curvatures—did not reflect the clinical reality he observed in his patients. Knowing that these structural diagnoses are equally prevalent in the general population, and frustrated by the failure of conventional approaches to provide permanent relief, he began diagnosing and treating back pain as a psychosomatic condition, which he initially described as an "autonomic myoneuralgia."[17-19] Later he called it "tension myositis syndrome" (TMS).[20]

The theory of TMS has both physiological and psychological components. According to the TMS physiological hypothesis,[20,21] the pain is ultimately due not to structural abnormalities in the spine but to a functional pain process in the muscles and nerves. The cascade of events is initiated by emotional repression, which, via neural mechanisms in the limbic and autonomic nervous systems, restricts blood flow to affected tissues. This causes tissue ischemia and buildup of waste products. This, in turn, leads to painful muscle tension that can manifest as local soft tissue pain, sensitive tender points, muscle spasm, and occasionally even distant pain, such as sciatica. On its face, the physiological theory of TMS is certainly plausible. Both persistent muscle tension and vasoconstriction can cause pain, and the brain, in turn, can initiate both processes.

The psychological theory is more controversial. Unlike other diseases believed to be "psychosomatic," TMS is not malingering, hypochondriasis, or even a conversion disorder. Although it falls in no precise category within the *Diagnostic and Statistical Manual of Mental Disorders*, 4th ed (DSM-IV), it could be described simply as a "pain disorder," at least when it is severe enough to warrant professional treatment.[22] It cannot be called a somatization disorder, because a somatization disorder by DSM-IV definition affects at least 4 different physical functions or parts of the body and must also begin prior to age 30. Many TMS cases do not fit this description, although TMS could be comorbid with this more general disorder. Hopefully, future research will result in an appropriate DSM classification.

According to the theory, the brain creates this vasoconstriction and painful muscle tension as a means of distracting or diverting attention away from emotions deemed too disturbing to confront directly, such as anger, rage, grief, anxiety, etc. For this reason, we prefer to call it "distraction pain syndrome" (DPS)[21] instead of TMS, because this term emphasizes the underlying psychological mechanism more clearly. Also, in contemporary pathology, "myositis" connotes muscle inflammation, which is not considered important in this condition. For purposes of consistency with prior publications, however, we will continue to call the condition itself TMS and refer to the psychological distraction theory of TMS as the "distraction pain" theory.

To date, the evidence supporting this theory is still preliminary, most of it being either anecdotal or indirect. The strongest indirect scientific evidence supporting the relationship between chronic pain and repressed emotions is a well-established correlation of chronic pain in general,[23,24] and back pain in particular, with alexithymia (emotional numbness).[25-28] Alexithymia is also linked to somatization.[23] However, the direction of the causal link between alexithymia and chronic pain is still unknown, as there are too few long-term, prospective studies of the relationship.

METHODS

Study Population and Sample

The original study population consisted of patients who were suffering from chronic back pain living in or travelling to the Los Angeles area. The final sample consisted of 51 patients whose back pain had persisted for at least 6 months and who were diagnosed with TMS and treated with an applicable mind-body treatment program.

Patient Recruitment and Selection

Patients were initially contacted pursuant to an initial chart review of all possible TMS patients treated by the principal investigator in his private office in 2002 and 2003. A trained assistant contacted a total of 142 potential participants by telephone and/or e-mail (up to 5 attempts) in early 2004. To help ensure that the patient sample consisted of truly chronic patients as opposed to episodic or periodic ones, we included only patients who had been in pain for at least 6 months and whose visual analog scale (VAS) score for least pain had never dropped to 0. This would tend to exclude patients who were not truly chronic (ie, pain-free for an extended period) and it would almost certainly exclude patients whose pain was only intermittent since the first episode. Fifty-one of the eligible TMS patients were eventually included in the study. The breakdown of how patients were excluded is

shown in Table 1. Although this exclusion process involves some obvious selection bias, it might more accurately be described as counter-bias, as it was done as a means of controlling for the 2 most likely confounders present in this study.

TABLE 1 Patient Selection Process

Total patients attempted contact: 142

Reason for Exclusion	Number Excluded	Remainder
Failed to contact	20	122
Refused to participate	5	117
Not diagnosed as TMS	19	98
Never returned survey materials	21	77
Failed to provide all necessary data*	11	66
Probably acute (in pain <6 mos prior to TMS diagnosis)	8	58
Possibly episodic (VAS score for minimum pain = 0)	7	51

*"Necessary data" here denotes visual analog scale (VAS) scores. See Table 4 for measurements where N<51.

Diagnosing Tension Myositis Syndrome

TMS is very much a clinical diagnosis, and specific criteria are not precisely defined at this time. There is no one lab marker or imaging or exam finding that definitively diagnoses "TMS." The first step in diagnosis is excluding structural etiologies that clearly indicate conventional treatment (ie, ensuring that the pain is physiologically idiopathic or non-specific). In this regard, it shares with other functional or psychosomatic conditions the need to exclude biochemical and other pathological processes, such as nerve impingement, tumors, infections, fractures, systemic arthritis, or severe stenosis, which should be treated conventionally as the structural or inflammatory problems that they are. This is accomplished with a thorough history and physical exam by a qualified physician schooled in the TMS methodology, along with a review of imaging tests. However, patients whose imaging reveals only age-consistent disc degeneration, mild protrusions, minor abnormal curvature, or other conditions that are equally prevalent in the general population, are *not* excluded but categorized as physiologically non-specific.

The physician also attempts to make an affirmative diagnosis of TMS from the symptoms the patient presents (as shown in Table 2). This consists of identifying pain patterns, timing of symptom onset in relation to psychological stressors, exam tender points, failure of other treatments, and personality characteristics that suggest the psychogenic etiology of TMS. A questionnaire has been somewhat helpful in diagnosis (see Figure), but ultimately, the clinician must look, listen, and touch to determine the appropriateness of this diagnosis.

The Tension Myositis Syndrome Mind-Body Treatment Program

The primary goal of the TMS mind-body treatment program is to raise patient awareness of how emotional issues, including repressed emotions, affect their physical pain. It is purely educational and psychological (ie, non-pharmacological), consisting of office visits, educational materials (written and audio formats were available at the time of this study), and sometimes psychotherapy, depending on the needs of the individual patient. It begins with the TMS diagnosis itself. After diagnosis, patients are immediately counseled and educated on how psychological factors can manifest as physical pain and learn to begin "thinking psychologically," not "structurally," about it. They are also encouraged to taper or discontinue medications, gradually be more active, and begin to resume a normal life. As they develop this new understanding of their pain, we believe the dysfunctional processes in the central nervous system (CNS) change, a subject for further planned research.

The typical patient's initial visit with the physician lasts approximately 45 minutes, with 0-3 follow-up visits typically lasting 15 to 20 minutes each. Patients also typically take home an

TABLE 2 Tension Myositis Syndrome Diagnostic Criteria

The "Type T" Personality	Characteristics such as excessive self-criticism, excessive responsibility for others, perfectionism, conscientiousness, and "goodism," a strong need to be good, nice, pleasant, accommodating and helpful."[20,55,56(p102)]
Prior history of other functional disorders	Irritable bowel syndrome, tension headaches, and other conditions that may be linked to tension/stress
Tender points	Characteristic locations,[21] which may or may not be in the vicinity of the pain
Relief with distraction	Clinical improvement on vacation or while otherwise distracted
Symptom substitution or migration of symptoms	Pain moves to other areas of the back, neck, or even other bodily areas that are not tied to any site of injury
Nonspecific structural etiology	No clear structural etiology on review of appropriate imaging and physical examination
Timing of symptom onset	During (or more typically just after) a psychologically traumatic event or events
Failure to respond to other treatments	Designed to correct structural or other organic problems

The following questionnaire has been designed to assist you in evaluating the possibility of your having TMS. It cannot replace a detailed medical history, examination, and review of x-rays and MRI scans. Only a medical doctor with expertise in this condition should make the diagnosis of TMS following an examination in the office.

Please circle your responses and total your points below: **Points**

1. Have you noticed a relationship between your pain and your emotional state/stress level just prior to the onset of pain?

Definitely 2
At times 1
Not really 0

2. Would you describe yourself in general as: very hard on yourself, highly responsible for others, very thorough, orderly, or perfectionistic?

Definitely 2
I've noticed some of these characteristics 1
Not really 0

3. Have you suffered from other tension-related illnesses such as:

- hives, eczema, rashes brought on by tension
- spastic colon, irritable bowel, gastritis, reflux/heartburn
- tension or migraine headaches
- unexplained prostate trouble or pelvic pain
- TMJ, teeth grinding, plantar warts

Definitely, two or more categories 2
Yes, at least one 1
No 0

4. Have you been told regarding the cause of your pain that "there's nothing that can be done surgically," "there's nothing wrong," "it's a soft issue problem," or "the cause is degenerative changes"?

Yes 1
No 0

5. Do you spend a fair amount of time during the day thinking and worrying about your pain, researching an answer, obsessing about its cause?

Yes 1
No 0

6. Have you tried several different treatments or approaches for your pain and received only temporary or limited relief from each of them?

Yes 1
No 0

7. Do you find that massage helps your pain significantly or that you are quite sensitive to massage in several parts of your back or neck?

Yes 1
No 0

Key to total points:

Highly probable for TMS	7-10 points
Possibly TMS	4-6 points
Probably not TMS	0-3 points

Total Points: _____

Additional Questions (don't score these):

8. Does the pain ever move to another location in your body or jump around? ____yes ____no

9. Have you noticed the pain improve when you have another tension-related illness? ____yes ____no

10. Has the pain significantly changed or gone away while you're on vacation, away from home, or while distracted? ____yes ____no

FIGURE Tension Myositis Syndrome Questionnaire

educational program, as described above. One component, the workbook (guided journal), is designed to teach patients how to connect emotional issues with their pain and develop insight into its cause.[29] Approximately 30% of the patients received an additional 6 to 10 psychotherapy sessions. Individuals with longer pain duration, a background of childhood abuse or molestation (a minority), or difficult relationship conflicts were more likely to need referral. Patients were seen in a private doctor's office and typically made the required co-pays, deductible payments, and payments for materials ($15 to $50), which were analogous with payment for their prior treatments for back pain.

Outcome Measurements

The primary endpoint was patient self-assessment of their pre- and post-treatment pain levels using a modified VAS, scored on a scale of 0 (no pain) to 100 (greatest pain). The "triple" VAS included pre- and post-treatment pain levels at their best, worst, and average (typical). In addition, a multiple choice/short answer questionnaire asked questions regarding various components relevant to the TMS treatment program, including duration of pain, medication use (pre- and post-), and activity level (pre- and post-). For the purpose of statistical analyses, medication usage obtained from the retrospective questionnaire was recategorized as regularly (multiple times per day or once daily), occasionally, or rarely/none. Activity levels were recategorized as "participate without hesitation," "mildly restricted," or "moderately/very restricted" due to pain or fear of causing pain.

Data were collected for the answers to these questions seeking correlations with and confirmation of our core VAS results. Data were also collected using the RAND Short-Form 12 (SF-12), from which physical and mental health composite scores were obtained using the scoring algorithm recommended by QualityMetric, Inc, Lincoln, RI.[30] To control for the possibility of brief or temporary responses to treatment, follow-up was at least 3 months after treatment and more typically 6 to 12 months or more.

Outcome measurements included both prospective and retrospective elements. Pain levels pre- and post-therapy were assessed prospectively by the VAS, and quality of life was prospectively measured by the SF-12. Other prospective measurements included demographic data, clinical history, and exam findings. Retrospective components included patient recall of activity and medication levels before treatment, so there may be some recall bias with these measurements.

Statistical Analyses

Baseline characteristics of the study cohort were summarized using descriptive statistics. Post-treatment changes in the VAS and SF-12 were tested for statistical significance using the paired *t*-test. Pre- and post-treatment medication usage and activity levels were compared using the McNemar chi-square test. Logistic regression analyses were conducted to identify prognostic factors of successful treatment (determined by above vs below the median VAS score for average pain). All statistical analyses were conducted at the .05 significance level using SAS (Cary, NC).

RESULTS

Table 3 presents the socio-demographic and clinical description of the study cohort. The majority of participants were male (63%); the average age, 46 years; and the average duration of back pain, 9 years.

TABLE 3 Description of Study Cohort (N=51)

Variable	Summary Statistics*
Gender	
Male	32 (63%)
Female	19 (37%)
Age (years)	46.0 ± 11.1 (24-74)
Duration of pain (years)	9.0 ± 8.35 (0.50-30)

*Frequency (%) for gender; mean ± SD (range) for age and duration of pain.

Table 4 presents the pre- and post-treatment summary statistics for the study endpoints. After TMS mind-body treatment, mean VAS scores (100-point scale) for "average" pain decreased from 64 to 30 ($P<.0001$). Mean scores for "worst" pain decreased from 89 to 58 ($P<.0001$), and for "least" pain from 35 to 12

TABLE 4 Treatment Outcomes (N=51, unless otherwise indicated)

Measure	Pre-treament	Post-treatment	Change Pre-to Post-	*P* value
VAS (mean [SD])				
Average pain	64.4 (17.1)	29.8 (21.6)	34.6 (22.9)	<.0001
Worst pain	89.3 (10.5)	57.7 (24.9)	31.6 (25.6)	<.0001
Best pain	34.5 (19.2)	11.9 (16.2)	22.6 (19.9)	<.0001
SF-12 (mean [SD])*				
Physical health	40.2 (9.6)	50.5 (10.4)	-9.4 (10.2)	.005
Mental health	36.8 (8.9)	42.2 (12.0)	-3.3 (13.6)	.36
Medication Use (N,%)†				.0008
Regularly	19 (38)	6 (12)	—	
Occasionally	23 (46)	17 (34)	—	
Rarely/never	8 (16)	27 (54)	—	
Activity (N, %)†				.03
Moderately/very restricted	35 (70)	8 (16)	—	
Mildly restricted	8 (16)	15 (30)	—	
Without hesitation	7 (14)	27 (54)	—	

* SF-12 data based on sample of N=17. Only 17 patients completed both pre- and post- SF-12 questionnaire.
†Missing data for 1 patient (N=50).

($P<.0001$), representing VAS score reductions of 52%, 35%, and 65%, respectively. In addition, there was significant improvement (average increase = 9 units) in the Physical Health composite score of the SF-12 ($P=.005$).

Somewhat surprisingly, the Mental Health SF-12 composite score did *not* significantly improve ($P<.36$). Further study may be required to understand this result, which is counter-intuitive, given the dramatic improvement in pain and function. One could speculate that, while the pain improves, the increased awareness of repressed emotions may somewhat balance the mood elevation from clinical improvement. We believe this is a worthwhile trade akin to the well-acknowledged discomforts when an alcoholic is sober.[31] Medication usage decreased significantly with treatment ($P=.0008$). Notably, of the 19 participants who regularly took medications pre-treatment, 13 (68%) never or occasionally took medications post-treatment. Of the 23 participants who took medications occasionally pre-treatment, 11 (48%) rarely or never took medications post-treatment. Some recall bias is possible here.

Activity level increased significantly with treatment ($P=.03$). In particular, of the 35 participants who had moderately/very restricted activity levels pre-treatment, 27 (77%) had improved activity levels post-treatment (14 without hesitation, 13 mildly restricted). Of the 8 participants with mildly restricted activity levels pre-treatment, 6 (75%) of them had no restriction post-treatment. Some recall bias is possible here as well.

The age distribution in the TMS case series was similar to the overall population with clinically significant back pain, with a peak in midlife and relatively few patients among young adults (early 20s) or the elderly (80s).[32] Interestingly, this case series had more men than women, which contradicts the popular expectation that more women would be attracted to a psychologically-oriented program. In our sample, the mean VAS score change from pre- to post-treatment for average pain was 33% ($P<.0001$) for men and 38% ($P<.0001$) for women. This corresponded to a 52% improvement in average pain for men and 57% for women. This gender difference was not statistically significant ($P=.47$).

The distribution of the change score in the average VAS pain score was stratified at the median into smaller therapy impact (VAS change <40) and larger therapy impact (VAS change ≥40). Table 5 presents the results of the logistic regression analyses identifying predictors of larger impact of the mind-body treatment program. Although none of these P values is statistically significant, 2 items are at least of clinical interest, in that they seem to contradict the prognoses expected from structurally-induced back pain. As seen in the table, compared to younger participants (<37 years), older participants (>47 years) were 3.3 times as likely to have greater changes in the average pain levels ($P=.09$). Also, participants with more than 3 years of pain were more than twice as likely to achieve larger changes in pain levels ($P>.20$) than participants with shorter pain duration.

DISCUSSION

In this case series of 51 TMS patients with chronic back pain, the TMS mind-body treatment program showed statistically significant reductions in pain and improvements in quality of life, as well as significant reductions in medication use and increased activity levels. Although it is possible that the latter 2 changes were inflated by recall bias, we believe it is far more plausible that they simply resulted from pain relief. With P-coefficients of .00001 for the VAS scores, we can essentially rule out random chance as the cause of the positive results. Clearly, something clinically significant happened during the treatment.

In evaluating the significance of these results, one should bear in mind that this study is intended to be the beginning of a larger research effort that will take years, if not decades. Its main goal was to determine if there was sufficient reason to continue that effort, but it was also to help us determine its direction. The general plan was to begin with relatively inexpensive pilot studies like this one and if the results of these studies were sufficiently promising, seek the outside funding and collaborators needed to perform a proper randomized clinical trial. This study was never intended to substitute for such a trial but rather to make it possible.

Whether the evidence presented here justifies continuing the research is open to debate. Some might argue that the theory of TMS itself, especially the distraction pain theory, is too speculative, being based largely on intellectual constructs that are too abstract and subjective to be studied scientifically. They would prefer that it be ignored and avoided as a form of medical quackery or, at best, as a diagnosis of exclusion. We disagree with this view. If it is possible to measure alexithymia, it should be possible to measure emotional repression, and there are also at least 2 validated psychological tests for levels of emotional sensitivity, the Levels of Emotional Awareness Scale (LEAS)[33] and the Toronto Alexithymia Scale (TAS).[34] Also, emotions are presumed to have physiological correlates both in the brain and elsewhere in the body, eg, galvanic skin response and heart rate variability.

TABLE 5 Results of the Logistic Regression Analysis Predicting Larger Benefits (Change in Average VAS≥40) of the Mind-Body Treatment Program

Predictors	Odds Ratio (95% CI)	*P* value
Gender		
Female	1.0	
Male	1.2 (0.4-3.6)	.80
Age (years)		
<37	1.0	
37-47	1.1 (0.3-4.3)	.89
>47	3.3 (0.8-13.0)	.09
Duration of Pain (years)		
≤3	1.0	
3.1-11	2.4 (0.5-11.0)	.26
>11	2.0 (0.5-8.8)	.36

The variables involved in the theory are in fact becoming increasingly measurable.

Risks and Side Effects

One of the important points to consider here is the extent of the risks involved. The mind-body approach is completely non-invasive and non-pharmacological and carries none of the risks, side effects, or other complications associated with pharmacological and surgical interventions. However, like any other treatment program in the early stages of investigation, the full extent of its risks and side effects cannot be known until it has been studied in numbers of patients and the results documented. Also, there may be a built-in safety control mechanism in the program. Whenever patients find the program too emotionally threatening, their natural response is to reject the diagnosis, which usually means they never start the program in the first place.

Study Limitations, Potential Sources of Bias, and Confounding Variables

The main limitations of this case series stemmed from the budgetary and logistical factors that constrained us to conduct it in the clinical setting of the principal investigator's medical office, resulting in a case series study instead of a randomized clinical trial. We could not use control groups, nor could we precisely standardize the program for all patients.

Like any other case series, the study has several sources of potential bias. One of them is that patients who responded to our follow-up inquiries may have been the more successful ones. Therefore, our results may not reflect outcomes in the treated, non-responder patients. Another is that the principal investigator/attending physician in the study genuinely believes the approach is effective, and we acknowledge that this almost certainly affected the outcomes. We suspect that this, however, will always be a problem, because it is built into the nature of mind-body interventions. (See discussion of the placebo effect, below.) Finally, there is some potential patient recall bias with respect to our retrospective measurement of medication use and activity levels. Although we cannot rule this out, the results were not out of line with the improvements in VAS and SF-12 scores for physical well-being. The fact that participants simply felt better after treatment is sufficient to explain their improvements in activity levels and reduced medication use.

Another potential bias is the fact that the entire sample consisted only of TMS patients and may not represent the larger general population of back pain patients. The reason for this was that the treatment program was designed solely for patients properly diagnosed with TMS, in which the pain is caused by this benign condition. Also, the purpose of the study was not to determine what percentage of the back pain population has TMS but how well the program works for those who do.

Another potential source of bias in patient selection is that all of the patients in our sample had chronic back pain, whereas the vast majority of back pain cases are acute. Table 1 shows that only 8 of the original 66 patients (12%) who fully completed the survey were excluded for being acute (by our definition), a figure that is roughly the reverse of the 80% to 90% ratio of acute cases among back pain patients in general.[35] This "bias" (or, more accurately, counter-bias) was partly by design, to control for the confounder that most back pain episodes typically resolve on their own in a few weeks.[36] Because this confounder precluded any meaningful evaluation of the program for acute patients, we did not attempt it in this study. If we could show that this program has a chance of working with the more difficult chronic cases, we could deal with the easier acute cases in a later study.

Finally, demographics could also have biased the results. The principal investigator's practice is located in the relatively affluent and well-educated West Los Angeles area. Because treatment outcomes could differ across other socio-demographic groups, the TMS approach might require modification to accommodate socio-demographic differences. While we acknowledge that all demographic variables affect an individual's ability to understand and apply this educational and psychological treatment program, we simply were not in a position to control for all of them with the sample size available.

The only demographic biases that we can eliminate are age, for which our sample was typical of back pain patients, and sex, which did not seem to affect the results. Among the 77 TMS patients who originally participated in the survey, 46 (63%) were men and 31 were women, a comparable ratio to the 32 men (60%) to 19 women in our final sample. How well this ratio represents the prevalence of either back pain or TMS in the general population depends on whom (and how) you ask.[1] However, the relative prevalence by sex of back pain per se may be different from the prevalence of TMS in this case series. Many types of chronic pain are listed as more prevalent among women than men in Wall and Melzack's *Textbook of Pain.*[37] However, for purposes of this study, we did not consider the relative prevalence by gender of either back pain or TMS in the general population to be very important because gender did not seem to affect outcomes.

As a case series, this study has several important confounders, only some of which we could control. The ones for which we had some controls (albeit imperfect ones) were the normal prognosis for recovery from a back pain episode and response variability, or the wax-and-wane cycle of back pain. We attempted to control for the former by studying only chronic patients and only the worst cases at that. While these patients sometimes have a spontaneous remission, the probability of it is very low.[37] Although we cannot say it with absolute certainty, it very likely resulted from some aspect of the treatment. Response variability is more problematic, especially because patients are more likely to see their doctor when their pain is at its worst. Although the ideal means of controlling for response variability would have been to take measurements at multiple times both before and after treatment, this method was not feasible at the time. However, we did measure pain at its highest, lowest, and average (or typical) levels, all of which went down at the same level of statistical significance ($P<.00001$). This suggests that the entire fluctuation curve, the high and low points of the cycle, as well as the means had changed significantly. Nevertheless,

the fact that the entire curve shifted does not control for the possibility that patients made their first appointments when their pain was at its very worst. For that reason, post-treatment scores might still have been better even if the treatment did nothing. To mitigate the effects of this bias, we took our post-treatment measurements at least 3 and usually 6 or more months after treatment, allowing the patients to go through the fluctuation cycle at least once and assessing their pain and quality of life from that perspective. Although this would not have controlled for pain cycles of more than 6 months, it would effectively control for cycles shorter than that. Accordingly, the normal recovery response and response variability alone do not explain the results.

Other confounders are within the program itself or at least within the program as it was delivered. Operating in a clinical setting, we could not standardize the treatment for everyone, arbitrarily withholding certain parts from some patients, as in a control group, while making it available to others, just to see which aspects produced the results. The exact program each patient received depended on that patient's individual clinical needs. For some, the visits with the physician were sufficient. Most used all or part of the home study program, and a smaller number of patients had individual psychotherapy. However, every patient learned that TMS was a benign condition and that they need not fear re-injury. For this reason, this study could not serve as a valid test of the distraction theory, because we would never know whether the results were due to the exposure of repressed emotions or another component of the education.

This mind-body healing program does not work for patients who are not at least willing to consider the psychosomatic diagnosis. The principal investigator/attending physician strongly believes in the theory and practice of the TMS approach. This inevitably gives rise to the question of a confounding placebo effect. In this case, we have reason to believe that a placebo effect, as understood in conventional drug trials, was not an important factor here. First, patients in our case series were surveyed at least 3 months and often 6 to 12 months or more after treatment, indicating long-lasting results. Although the duration of placebo cures varies with the conditions they are used to treat and the context in which they are given, the placebo effect is typically more temporary than those of the effective drugs against which the placebo is tested.[38,39] Furthermore, all of the patients had chronic back pain, and nearly all had already failed some or all of the conventional and alternative methods for treatment, such as physical therapy, chiropractic, acupuncture, massage, exercise programs, and injections. This suggests the patients in this cohort were not likely to be placebo responders.

Although the double-blind placebo trial has become the "gold standard" in testing new drugs, its underlying rationale breaks down in the context of mind-body interventions. The purpose of the double-blind placebo trial in testing drugs is to determine whether it is the chemical ingredients or the patient's (and doctor's) belief in the drug that effects the cure. It is a straightforward question of belief vs biochemistry. In mind-body medicine, we already know the effective "ingredient" is belief, along with thoughts, emotions, and attitudes as well. So in one sense, the mind-body intervention itself is a kind of placebo, or more accurately, the placebo is a kind of mind-body intervention.

However, in this study, as well as in virtually all studies of well-delivered mind-body interventions, the concepts taught are also significantly reinforced with the time, care, attention, and encouragement given by both the therapists and the patient, all of which have a placebo effect of their own. Consequently, we do not know whether the results of our program were due to the *content* of the program or the *way in which we delivered it*. For reasons such as these Moerman and Jonas have suggested that, especially in the context of testing mind-body interventions, we dispense with the concept of the classic placebo effect in the strict sense (ie, the therapeutic effect of a false belief in non-existent chemical efficacy) and replace it with the notions of "meaning" and "context" effects,[40,41] of which the placebo effect is but one example.

With respect to the TMS treatment program we are describing, both meaning and context effects are the intended outcome of the program. The practitioner's time, care, attention, and understanding, as well as his confidence in the treatment and assurance that the physical condition is actually benign, are 2 of the "active ingredients" in the program itself. Skeptical or neutral therapists would be less effective than they would be if they strongly believed in the treatment. Therefore, "blinding" either the subjects or those giving the treatment would significantly weaken the treatment itself. To use an extreme example, a "double-blind" psychotherapy program, in which neither the patients nor the therapists knew or understood the content of the program, would border on theater of the absurd. Nevertheless, this does not mean that it is impossible to control for the meaning and context effects. The ideal study would have a control group that received the same amount of time, attention, care, and encouragement as the experimental group but with different content. It would also be a program that has not proven to be very effective (ie, a psychological equivalent of the sugar pill). Such treatments for chronic, nonspecific back pain are easy to find.

Because this case series had no control group, we did the next best thing and compared our results with those of other studies of modalities that we would have used to control for meaning and context effects. As a source for these studies, we referred to the Cochrane Collaboration's 2001[42] and 2005[43] metastudies of randomized controlled trials on behavioral treatments for chronic back pain, "chronic" being defined as pain for at least 12 weeks. (Patients in our case series were in pain for at least 24 weeks.[21]) The results of these studies, along with our own, are shown in Table 6.[44-46] The studies were selected on the basis of their relative quality (according to the Cochrane Collaboration) and the comparability of their outcome measurements (visual analog or numeric rating scales) for pain. To bring this material more up to date, Table 6 also includes a similar but more recent randomized controlled trial (Lang et al 2003) that tested multidisciplinary rehabilitation programs,[47] which, in this case, consisted of a combination of exercise, physiotherapy, cognitive-behavioral psychotherapy, progressive relaxation training,

TABLE 6 Comparison of Outcomes Across Studies With Similar Treatments

Study Author, Year (reference) Approach(es) Tested	Baseline Mean VAS Scores	Improvement in Terms of: Mean VAS Score	Percent of Baseline
Schechter, 2005 (21)			
TMS/Mind-Body	64.0	34.6*	54%
McCauley, 1983 (44)			
Progressive relaxation	56.9	21.0	37%
Self-hypnosis and hypno-analgesic techniques	63.0	19.8	31%
Turner, 1993 (45)			
Cognitive therapy only	56.9	20.0*	35%
Progressive relaxation only	51.3	13.4*	26%
Cognitive and progressive relaxation	60.7	16.4*	27%
Basler, 1997 (46)			
Cognitive-behavioral therapy and medical	45.8	5.0	11%
Lang, 2003 (47)			
Multidisciplinary rehabilitation	44.0	11.0	25%

*Indicates statistical significance at $P<.05$.

and training in "the anatomic, physiologic and movement-related basics of the back and the evidence-based knowledge about the effectiveness of back-related therapies."[47(p272)] Sessions lasted 4 hours per day, 3 days per week for 20 days. The Lang study's control group received "usual care," defined to be non-multidisciplinary (but non-surgical) treatment by physicians and physiotherapists in the community. Patients in this study had also been in pain for at least 6 months.

In all 4 studies, patients received at least as much time, attention, and care as did ours, with some, such as those in the Lang study, receiving much more. Table 6 compares the baseline VAS and change in VAS scores for our TMS group with the other 4 intervention groups. The TMS group improved by 34.6 points (54% improvement) compared to improvements ranging from 5 to 21 points for the other studies (11% to 37% improvement). The unweighted average improvement for the combined comparison groups was 15 points (30% improvement). Thus, in terms of clinical significance, the TMS group improved more than any of the others (54%, as opposed to 30%). Also, the only treatment groups besides the TMS group to show a statistically significant improvement were the 3 groups in the Turner study but at a lower level of statistical significance ($P<.05$) than our results.[45] These groups were also treated with purely psychological interventions. Thus, to the extent that valid comparisons can be made, our TMS group fared relatively well. However, we must acknowledge that the meaning and context effects probably played a significant role in the results of both our study and the ones we used for comparison—in much the same way as the standard placebo effect plays a significant role with drugs that pass double-blind placebo trials.

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