RANDOMIZED, CONTROLLED TRIAL OF BREATH THERAPY FOR PATIENTS WITH CHRONIC LOW-BACK PAIN

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Context • Patients suffering from chronic low back pain (cLBP) are often unsatisfied with conventional medical care and seek alternative therapies. Many mind-body techniques are said to help patients with low back pain by enhancing body awareness, which includes proprioception deficit in cLBP, but have not been rigorously studied in cLBP.

Breath therapy is a western mind-body therapy integrating body awareness, breathing, meditation, and movement. Preliminary data suggest benefits from breath therapy for proprioception and low back pain.

Objective • To assess the effect of breath therapy on cLBP.

Design • Randomized, controlled trial.

Setting • Academic medical center.

Participants • Thirty-six patients with cLBP.

Interventions • Six to eight weeks (12 sessions) of breath therapy versus physical therapy.

Main Outcome Measures • Pain by visual analog scale (VAS), function by Roland Scale, overall health by Short Form 36 (SF-36) at baseline, six to eight weeks, and six months. Balance as a potential surrogate for proprioception and body-awareness measured at the beginning and end of treatment.

Results • Pre- to post-intervention, patients in both groups improved in pain (VAS: -2.7 with breath therapy, -2.4 with physical therapy; SF-36: +14.9 with breath therapy and +21.0 with physical therapy). Breath therapy recipients improved in function (Roland: –4.8) and in the physical and emotional role (SF-36: +15.5 and 14.3). Physical therapy recipients improved in vitality (SF-36: +15.0). Average improvements were not different between groups. At six to eight weeks, results showed a trend favoring breath therapy; at six-months, a trend favoring physical therapy. Balance measures showed no improvements and no correlations with other outcomes.

Conclusions • Patients suffering from cLBP improved significantly with breath therapy. Changes in standard low back pain measures of pain and disability were comparable to those resulting from high-quality, extended physical therapy. Breath therapy was safe. Qualitative data suggested improved coping skills and new insight into the effect of stress on the body as a result of breath therapy. Balance measures did not seem to be valid measures of clinical change in patients' cLBP.

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With its significant economical burden to society[1,2] and few proven treatment options,[3,4] chronic low back pain (cLBP) continues to be challenging to treat. Patients are often unsatisfied with conventional medical care[5] and seek alternative or complementary therapies, such as massage, chiropractic, and mind-body techniques.[6-8] Unfortunately, clinicians can provide only limited informed medical advice on these complementary therapies because of a lack of rigorous research.[9,10] Mind-body techniques, such as yoga; tai chi; the Alexander, Feldenkraïs, Rolfing, and Trager methods; eutony; sensory awareness; body awareness therapy; and breath therapy, are said to help patients with low back pain by enhancing body awareness.[11,12] This has been defined as refining and differentiating perceptions of physical sensations previously ignored by the patient or overwhelmed by nociceptive input. Despite an abundance of anecdotal information,[13-15] only a few controlled research studies have explicitly explored the effects of training to increase body awareness in patients with musculoskeletal pain.[16-19] Most of these studies are of limited rigor and have not provided conclusive evidence.[20]

Recent studies report that patients with cLBP suffer from a deficit of trunk proprioception.[21-26] Proprioception is the integration of the afferent inputs from joints, muscles, ligaments, and tendons. Proprioception is the central process "by which the body attains a neuromuscular awareness of posture, movement, and equilibrium changes as well as knowledge of position, weight, and resistance to objects in relation to the body."[27] Interventions specifically designed to improve proprioception have been studied in patients with knee and ankle injuries and elderly patients who are at risk for falls. To date, there have been no systematic mind-body or traditional studies of proprioception and intervention strategies for patients with cLBP.

Breath therapy is a Western mind-body therapy developed in Germany in the 1920s that integrates body awareness, breathing, meditation, and movement. It is similar to physical therapy in that it includes exercises and skilled touch with soft tissue interventions.[28,29] It differs from physical therapy in that it minimizes biomechanical and neuromotor control issues and adds a mind-body element of awareness training by focusing the patients' interoceptive attention on their physical sensations.

Both proprioception, studied in physiological and clinical research,[27] and interoception, studied in neurology[30] and psychology,[31,32] constitute body awareness. A descriptive study conducted in Germany in 2001 suggested that breath therapy improves body-awareness and might be particularly helpful in patients with LBP.[28,29] If mind-body approaches improve body-awareness, then they also might improve proprioception. Postural control, including balance, depends on visual, vestibular and proprioceptive information.[23,26] Measuring balance control by dynamic posturography, which challenges visual, vestibular, and somatosensory input, has been proposed as a potential, albeit not yet validated, measure of effectiveness of proprioceptive balance training[33] or spine rehabilitation.[34] Two small studies by the same investigator used force plate analyses to document improved postural control after breath therapy.[35]

The causal relationship between low back pain and poor proprioception is unclear. Is lack of proprioception a byproduct of chronic pain following an injury, or is lack of body awareness and proprioception a risk factor for low back pain, particularly cLBP? It is intriguing to hypothesize that an improvement in low back pain could be paralleled by a measurable improvement in proprioception and that a therapeutic approach focusing primarily on body awareness and proprioception could be as effective as a neuromuscular-biomechanical approach. Although preliminary data suggest benefits from breath therapy for both postural control and low back pain, no rigorous clinical trials of breath therapy and cLBP were identified in a literature review.[20] Therefore, we conducted a randomized, controlled study of breath therapy on patients suffering from cLBP and included a measure of postural control as a secondary outcome and a potential surrogate measure for proprioception and body awareness. Physical therapy was selected as the control intervention because it is considered the standard of care for patients with cLBP and is known to be effective.[4,36,37]

METHODS

Participants

Inclusion criteria for the study were as follows: 20 to 70 years of age; continuous cLBP of three to 24 months' duration; seeking help from primary care providers for low back pain; and fluent in English. Patients with prior spinal surgery, compensation for back-pain related problems, active alcohol or drug dependency, cognitive or psychological impairment, or other pain-related disease were excluded. Patients with sciatica, or pain radiating below the knee, were included if they did not suffer motor deficits.

Participants were recruited using flyers posted in university-based primary care clinics, by referral from primary care providers in the same clinics, and through notices posted in the university employee newsletter. Several individuals responded to flyers posted in a local medical center advertising a study of yoga for low back pain and were referred to the breath therapy study after the yoga study had been filled. In addition, the university medical center database was checked for potentially eligible patients, and letters, which were signed by primary care physicians, were mailed to patients with cLBP informing them about the study.

Interested participants were prescreened over the telephone for eligibility. A baseline visit was arranged, and participants were informed about study details and underwent a physical examination. Once eligibility was confirmed, the patients gave signed informed consent. The study was approved by the institutional review board of the University of California, San Francisco.

Randomization

Using blocked, stratified randomization that was performed after completion of all baseline assessments, participants were randomly assigned to the breath therapy or physical therapy group. Four strata were formed according to pain severity (pain score <7 or ≥ 7 cm on a VAS of 0 to 10) and pain duration (continuous pain for <6 or ≥ 6 months). Randomized, permuted blocks of four were generated for each stratum using a computer-generated random-sequence table. Group assignments were made using opaque, sequentially-numbered, sealed envelopes that contained the group assignment.

Intervention

Both the intervention and control groups received one introductory evaluation session (60 minutes) and 12 individual therapy sessions of equal duration (45 minutes) over six to eight weeks. Breath therapy was provided by five certified breath therapists on faculty at the Middendorf Breath Institute in Berkeley, California. Physical therapy was provided by experienced physical therapy faculty members in the Department of Physical Therapy and Rehabilitation Science. To control for setting, both interventions were provided in the same building of the academic medical center.

Breath therapists followed a study protocol prepared by the Director of the Middendorf Breath Institute. The protocol included a general outline of the treatment, allowing for individual variations. The breath therapy sessions were structured as follows: patients remained clothed during all sessions and were instructed to lie down on a massage table. Through verbal intervention and skillful touch, the breath therapist guided the participant's awareness to the subtle physical sensations of breath movements in the patient's back. Skillful touch involved touching the patient with gentle pressure, holding, or gentle stretching at the back, neck, and legs with the goal of enhancing attention allocation. By teaching a meditative kind of attention to the patient, the therapist aimed to facilitate the emergence of a spontaneous pattern of subtle, unmanipulated breath movements. Skillful touch mediated a non-verbal dialogue between therapist and patient while both sensed breathing movements at the point of contact. The therapist provided verbal and non-verbal cues to allow for less restricted breath movements in the body regions where breathing was restricted in conjunction with the patient's experience of low back pain. A more detailed description of breath therapy is published elsewhere.[28,29]

Physical therapists followed a study protocol recommended by an experienced physical therapist clinician and educator. The intervention began after a thorough evaluation of the patient and consisted of individualized strategies, including soft-tissue mobilization; joint mobilization; and exercises for postural righting, flexibility, pain relief, stabilization, strengthening, functional task performance, and back-related education. The physical therapy sessions used the same structure as usual practice but had a longer duration to match the breath therapy intervention. Therapists were licensed, experienced clinicians who specialize in the management of patients with chronic pain, musculoskeletal problems, and balance. Strategies included a limited degree of attention to diaphragmatic breathing and proprioception.

Both breath therapists and physical therapists instructed the patient in daily exercises to do at home. This home program was expected to last 20 to 30 minutes. The investigator met with both groups of therapists several times separately and once jointly to clarify the operational guidelines for the interventions.

Measurements

Participants underwent a baseline clinical examination, including history and physical, by the primary investigator (WM). Demographics and medical history data were assessed by questionnaire. At baseline and after six weeks and six months, pain intensity was assessed as "bothersomeness" by a 10 cm VAS,[38] low back pain–specific functional disability by a modified 16-item Roland Morris Scale,[39] and functional overall health status by the Short Form-36 (SF-36) version 2.[40] The shortened Roland Morris Scale scores were transformed to the 24-item score equivalents to permit comparison with other low back pain research. At follow-up, a six-point ordinal perceived recovery scale ranging from "much worse" to "completely recovered" was added. This scale has been used previously to compare the effect of manual therapy to traditional physical therapy in patients with neck pain.[41]

To provide a potential surrogate measure for whole-body proprioception and body awareness, postural stability was measured at baseline and immediately after therapy with computerized dynamic posturography (sensory organization test [SOT], NeuroCom Smart Balance Master; NeuroCom, Clackamas, Oregon) and a traditional static force plate (Type 9286, Kistler Instrument Corporation, Amherst, New York). In both tests, patients stand on a force platform in a neutral position and attempt to maintain balance.

The SOT systematically assessed each patient's ability to integrate visual, vestibular, and proprioceptive components of balance. It consisted of six different test conditions in which the patient stood, feet slightly apart, on a platform that is initially static and then compliant, first with eyes open and then with eyes closed. For "eyes open" the visual surround is either static or moving. The outcome measure of the SOT is the composite Equilibrium Score (ES) and ranges from 0 (exceeded limits of stability) to 100 (perfect stability), a weighted average of the scores under each condition.

Traditional static measures of balance were assessed under five different conditions while the participant stood on the Kistler force plate. Ground reaction force data were sampled at 100 Hz. Center of pressure velocities were calculated from the ground reaction force data using a custom Matlab program. The conditions were presented in a progression of increasing difficulty from eyes open, standing in a stable position, to eyes closed, standing in an unstable position with head movements. By isolating the three sensory inputs (visual, vestibular, and proprioceptive) necessary to control balance, this program was designed to increase the demands on the somatosensory system. All tests were practiced before the actual data collection began.

During the six to eight weeks of intervention, patients kept a diary. Each participant received the following instructions:

> *What was important for you today? Please, feel free to share in your own words any commentaries about your treatment experience. Do not feel obligated to write something every day! Also, the themes can be very different with different entries. But we would like to know your thoughts and feelings related to your therapy and therapist, whether you think any differently about your body, your back, your pain, or life in general.*

Analyses

Baseline measures were compared between groups by *t*-test (continuous variables) and χ^2 test or Fisher exact test (categorical and ordinal variables). Overall outcomes (three time points) were compared within and between groups by repeated measures analysis of variance (ANOVA). Pre- and post intervention changes (two time points) were compared within groups by paired *t*-tests and between groups by *t*-tests or Mann-Whitney Tests. Additional pain ratings at the 12 treatment sessions were used to calculate the area under the curve of each individual's scores over the duration of the intervention. The average areas were compared between groups. Correlations between different outcome variables were calculated using the Pearson correlation coefficient.

RESULTS

Thirty-six patients were randomized to either breath therapy (18) or physical therapy (18). Eight of the 36 randomized subjects (two in breath therapy, six in physical therapy) did not receive any intervention. Most commonly, subjects did not show up for the first scheduled appointment despite repeated efforts to reschedule. One subject assigned to the physical therapy group experienced a severe recurrence of low back pain between randomization and intervention, was referred to neurosurgery, and did not begin physical therapy. Compared to study participants, the eight subjects who were randomized but did not participate were somewhat younger (average 39 versus 49 years, P=.07) and were slightly more likely to be randomized to physical therapy (6/18 versus 2/18, P=.11).

The baseline characteristics of the 28 study subjects are summarized in Table 1. Stratified randomization resulted in comparable distributions of pain (intensity and duration) and other baseline variables, with the exception of postural sway. Three out of five postural sway measures were significantly worse in the physical therapy group at the start of the study. Across groups, subjects were more frequently female and, on average, approximately 49 years old. Participants had suffered from moderate low back pain for an average of one year, of which 44% in the breath therapy group and 25% in the physical therapy group also had sciatica during this episode. Only one patient in each group had lost one day of work due to low back pain during the week before the baseline assessment. In the breath therapy group, two patients had spent two days in bed, and one patient had spent five days in bed during the week before baseline assessment, whereas in the physical therapy group, none of the subjects stayed in bed the week before the study. Most patients had received physical therapy for back pain in the past (breath therapy: 75%; physical therapy: 92%).

Analyses were performed on all available data in an intention-to-treat fashion for 14 subjects in the breath therapy group and 12 subjects in the physical therapy group. Of the 16 subjects undergoing breath therapy, one dropped out after two sessions and was lost to follow-up. This patient reported the emergence of old memories that were emotionally too uncomfortable to confront. Of the remaining 15 subjects, one did not go to the post-intervention measurements in the motion laboratory (scheduling problem) and one did not complete the six-week questionnaire (unexplained). These two were not lost to further follow-up and reduced the number of subjects with completed questionnaires or motion laboratory measures at six weeks (n=14). Of the 12 subjects undergoing physical therapy, one dropped out (unexplained) after six sessions, completed the six-week follow-up questionnaire, but was lost to the follow-up motion laboratory testing and the six-month assessment. Two subjects did not complete all 12 therapy sessions; one participant in the physical therapy arm stopped after 10 sessions due to worsening pain. One participant in the breath therapy arm missed four sessions after using up the allowed period of six to eight weeks for the intervention. Subjects performed their home exercises on average 11±9 (breath therapy) and 17±9 (physical therapy) minutes per day (P=.12).

The change scores for the outcome measures for both groups are summarized in Table 2. From baseline to the end of the intervention, patients in both groups experienced a statistically and clinically significant improvement in pain intensity as measured by the VAS (-2.71±2.23 with breath therapy; -2.43±2.05

TABLE 1 Patient Baseline Characteristics (N=28)

Variable	BT	PT	P
n	16	12	
Mean Pain Intensity in cm on VAS (± SD)	5.15 (±2.04)	4.37 (±2.36)	.36
Pain Duration in months (± SD)	11.6 (±5.9)	13.7 (±5.9)	.36
Age in years (± SD)	49.7 (±12.1)	48.7 (±12.5)	.83
Male	31.3%	41.7%	.57
Sciatic pain this episode	43.8%	25.0%	.31
Education (median level)	College Degree	College Degree	.69
On pain medication at baseline	87.5%	83.3%	.76
Previous PT	75.0%	91.7%	.27
Days/week of reduced activity	1.5 (±1.9)	1.2 (±2.2)	.71
Ethnicity			.45
Caucasian-American	75.0%	83.3%	
Asian-American	18.8%	8.3%	
African-American	6.3%	0%	
SF-36 bodily pain score	50.1 (±16.6)	42.3 (±16.0)	.23
SF-36 general health score	76.0 (±19.3)	71.7(±23.5)	.53
Modified Roland Morris score (range 0-16)	6.7 (±3.3)	6.6 (±4.0)	.94
Transformed Roland Morris score (range 0-24)	10.0 (±5.0)	9.9 (±6.0)	.94
Balance master score	76.2 (±3.7)	79.0 (±6.2)	.18
Force plate velocity eyes open (cm/s)	0.99 (±0.30)	1.02 (±0.21)	.78
Force plate velocity EC (cm/s)	1.23 (±0.24)	1.54 (±0.42)	.03
Force plate velocity one leg stand (cm/s)	4.10 (±1.27)	4.82 (±1.23)	.02
Force plate velocity EC head back (cm/s)	1.15 (±0.29)	1.49 (±0.39)	.02
Force plate velocity EC lean forward (cm/s)	1.70 (±0.58)	2.01 (±0.62)	.20

Abbreviations: BT=Breath therapy; PT = Physical therapy; VAS=Visual analogue scale; SD=Standard deviation; SF-36 =Short form 36; EC=Eyes closed

TABLE 2 Outcome Changes From Baseline to After Intervention and to Six-Month Follow-Up (n = 26)

	BT (n = 14) pre-post*	**BT (n = 15) baseline to 6 months†**	**PT (n = 12) pre-post***	**PT (n = 11) baseline to 6 months†**	**Between-Group Difference pre-post* *P***	**Between-Group Difference incl. 6-Month Follow-up† *P***
Pain Intensity	-2.71 (±2.23)¶	-1.71 (±2.12)¶	-2.43 (±2.05)¶	-2.45 (±2.55)¶	.74	.56
Roland Morris (RM) score	-4.82 (±5.92)‖	-3.72 (±6.03)§	-3.13 (±6.90)	-5.18 (±5.90)§	.51	.53
Days/week of reduced activity	-0.69 (±1.97)	-0.86 (±2.07)	+0.08 (±2.97)	-0.45 (±2.21)		
SF-36 bodily pain	+14.9 (±1.5)¶	+14.6 (±19.5)‖	+21.0 (±2.48)§	+27.0 (±22.6)¶	.45	.27
SF-36 physical functioning	+8 .9 (±5.4)§	+10.0 (±15.7)	+13.6 (±7.2)§	+18.9 (±22.6)	.60	.58
SF-36 role physical	+15.5 (±23.8)§	+13.2 (±20.8)§	+16.7 (±33.5)	+20.5 (±30.9)	.92	.69
SF-36 role emotional	+14.3 (±28.2)§	+12.8 (±21.1)§	+15.3 (±36.4)	+18.9 (±31.6)	.94	.76
SF-36 general health	-0.6 (±4.6)	-1.0 (±15.3)	+ 0.8 (±4.7)	-2.1 (±7.8)		
SF-36 vitality	+8.2 (±4.4)	+6.4 (±21.3)	+15.0 (±5.1)§	+17.3 (±16.9)¶	.32	.45
SF-36 social functioning	+2.7 (±4.9)	-1.7 (±22.1)	+6.3 (±7.3)	+17.0 (±21.1)	.68	.08
SF-36 mental health	+5.0 (±4.1)	-1.7 (±14.6)	+4.0 (±3.6)	+11.3 (±14.5)§	.83	.12
Balance master equilibrium Score	+2.36 (±4.45)		+3.64 (±5.54)‡		.53	
Force plate eyes open (cm/s)	- 0.08 (±0.24)		+0.14 (±0.23)‡		.04	
Force plate eyes closed (cm/s)	+0.01 (±0.04)		+0.10 (±0.07)‡			
Force plate on one leg (cm/s)	+0.36 (±0.82)		+0.49 (±0.74)‡		.70	
Improvement rating #	2.6 (±0.7)	2.5 (±0.7)	2.8 (±1.4)	2.5 (±1.2)	.91**	.61**
Proportion of patients that improved pain score by >2††	10/14 (71%)	6/15 (40%)	6/12 (50%)	5/11 (45%)	.42	.84*
Proportion of patients that improved RM score by >3††	10/14 (71%)	10/15 (67%)*	6/12 (50%)	8/11 (73%)*	.42	.76

(Standard deviation in parenthesis; BT = Breath Therapy, PT = Physical Therapy)
* By *t*-test; †By Repeated Measures ANOVA for the three time points (baseline, after six to eight weeks of intervention, after six-month follow-up; ‡ Two subjects in the physical therapy group did not undergo the motion laboratory measures reducing the balance observations in this group to n = 10; § *P*<.05; ‖ *P* <.01 ¶ *P*<.005;
\# Improvement Rating Scale: one to six for "completely recovered" to "much worse," Mann-Whitney test, ** Kruskal-Wallis or ‡‡Fisher's exact test

with physical therapy; see also Figure 1) and the SF-36 (+14.9±1.5 with breath therapy; +21.0±2.5 with physical therapy). Individual pain scores varied strongly between therapy sessions, and average areas under the curve of pain, which included the pain scores assessed at each therapy session, were not different between groups (not shown in Figure 1). The breath therapy group improved significantly in low back pain–related functional disability (Roland Morris score; Figure 2) and in the physical and emotional role components of the SF-36. The physical therapy group improved significantly in the vitality component of the SF-36. Average change scores at baseline, six to eight weeks and six months were similar in both groups, but the standard deviations for all outcomes were generally larger in the physical therapy group.

There were improvements in balance in both groups as measured by computerized dynamic posturography SOT (balance master), but the gains were neither statistically nor clinically significant. Traditional force plate measures (velocity of center of pressure) did not show significant changes in both groups when examined with eyes open, eyes closed, standing on one leg only, bent, or leaning forward. Comparison of change scores between the two groups yielded no significant differences.

Considering a change of two points or more on the VAS for pain or three points or more on the Roland Morris Scale for function clinically significant, 10 of 14 participants improved in the breath therapy group and six of 12 improved in the physical therapy group (between-group difference: *P*=.42). Using logistic regression models, the crude odds ratio (OR) for a clinically significant improvement in the breath therapy group versus the physical therapy group was 2.5 (95% confidence interval [CI] .5-12.6). Adjustment for demographic and clinical variables, such as sex, age, baseline pain or functional score, neurological symptoms, months of pain, and presence of sciatica, consistently provided ORs above one favoring the breath therapy group (for Roland Morris score: OR 8.6; 95% CI .7-101.4; for VAS 1.4; 95% CI .1-26.4); however, none of these differences was statistically significant.

Changes in disability in terms of (1) reducing usual activities for more than half of the day (pre- and post-intervention changes in days: breath therapy –.7 ±2; physical therapy +.1 ±3), (2) staying in bed for more than half a day (breath therapy –.5 ±1; physical therapy +.2 ±1), or (3) losing days from work or school for more than half the day (breath therapy –.1 ±.3; physical therapy –.1 ±0.3) did not reach statistical significance in either group. None of the participants missed any days of work in the last week of the intervention. In the breath therapy group, none of the three originally partially bedridden patients remained bedridden. In the physical therapy group, one patient had to stay in bed due to low back pain for two days in the last week of the intervention.

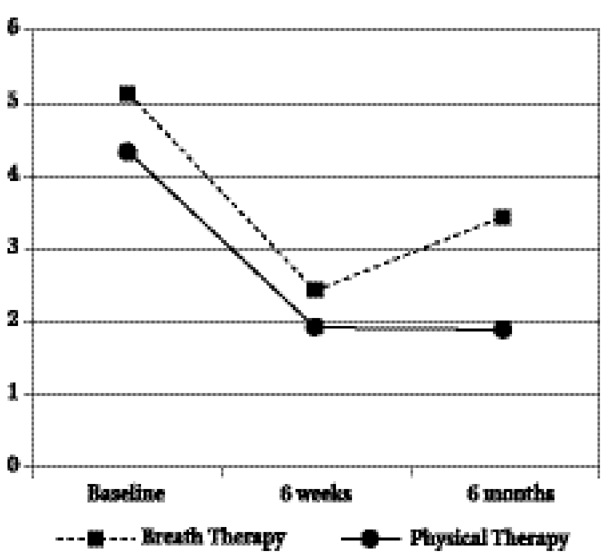
There were no differences between groups with regard to average number of low back pain–related doctor visits during the intervention (breath therapy .5 ±.89; physical therapy .58 ±.79; *P*=.80). The duration of self-reported home exercises was not correlated with improvement in pain or function for either group (for pain and Roland Morris scores: r=–.23 and –.24 with breath therapy; r=.07 and –.38 with physical therapy; all *P* values >.2).

The various balance measures did not show a significant correlation among themselves nor with baseline or change scores of other outcome variables when assessed for all participants or by treatment group. There was no correlation between change in balance (ie, balance master equilibrium score) and change in pain intensity (–.065; *P*=.76), Roland score (–.085; *P*=.69) or change in any of the various SF-36 function scores (–.262 to .140; *P*=.19 to .78). Force plate center of pressure velocity measures showed no clinically or statistically significant improvements (velocity was expected to decrease with improved balance) and no correlations among the various velocity measures or between these measures and main outcome measures.

No significant adverse effects were reported in the breath therapy group or the physical therapy group. Breath therapy provoked the emergence of painful emotional memories in one patient, however. The subject explicitly preferred to avoid these and, consequently, dropped out of the study.

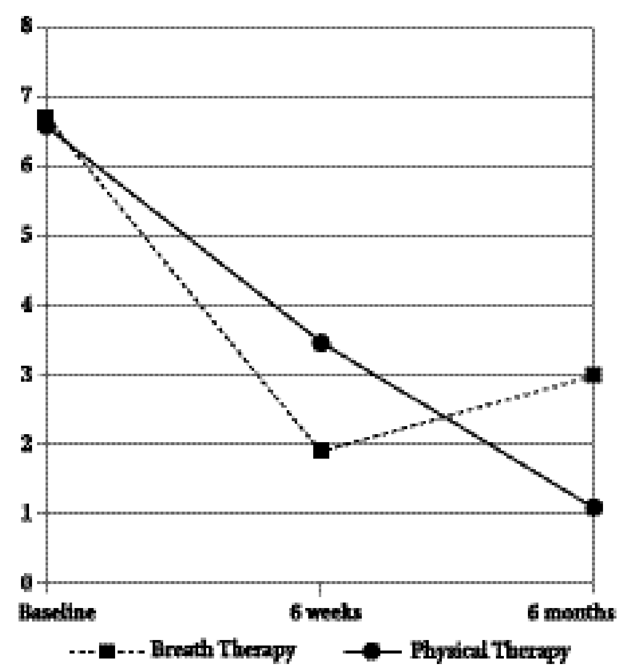
At the follow-up assessment six months after the last therapy session, more patients in the breath therapy group were experiencing a relapse or exacerbation of low back pain than in the physical therapy group (5/15 in the breath therapy versus 1/11 in the physical therapy group). A relapse was defined as any increase of three or more over the lowest previous point value on the VAS for pain. Using the monthly self-reported pain scales during follow-up, the number of recurrences or exacerbations of low back pain (as defined above) at any time after the last therapy session was similar in both treatment groups: 6/15 (40%) in the breath therapy and 5/11 (45%) in the physical therapy group (Figure 3). At six months, patients in both groups had statistically significant improvements in the main outcome measures (Figures 1 and 2). During the six to eight weeks of intervention, 71% of participants in the breath therapy group demonstrated clinically meaningful (as defined above) improvement (VAS, Roland Morris) compared to 50% in the physical therapy group. After six months, 40% (VAS) or 66.7% (Roland Morris) of the BT group were still clinically meaningful improved compared to 45% (VAS) or 72.7% (Roland Morris) in the PT group.

Entries in patient diaries were coded under five emerging themes: a) functioning in daily activities, b) exercise related experiences, c) effect on emotions, d) insights about pain and coping with stress, e) relation to body and self. There were no differences between groups in statements of functioning in daily activities (a) or exercise-related experience (b). The gentler the



Legend: Y-axis is VAS change score; X-axis for time points.

FIGURE 1 Change in Pain (VAS 10 cm)



Legend: Y-axis is Roland-Morris change score; X-axis for time points.

FIGURE 2 Change in Disability (Roland Morris score, range 0-24) physical therapy (eg, focusing on breathing), the more similar to breath therapy the emotional statements were: "calmness," "less anxiety," "sense of emotional strength," "encouraged," "uplifting," "more emotional awareness." Major differences between groups appeared for emotional effects (d) and insights about pain and coping with stress (e) with few (d) or no (e) entries in the physical therapy group's diaries and rather rich entries in the breath therapy group's diaries. The following are examples from the diaries of five different breath therapy patients: "I look at my body a little more friendly and understanding." "With this chronic low back pain, my goal has been to isolate the pain, to separate it from the rest of my body and life ... through breath therapy I am trying to incorporate the painful part into the rest of my body. It feels opposite of what I've been doing." "I think I have to change my attitude toward my body and the pain. I feel angry at my body to give me such trouble and pain. Maybe instead I should be grateful and have compassion for it ... my body seems to be very cooperative and not this troublemaker." "Breath Therapy has taught me how to relax and be in touch with my own being." "It's like a boat that used to drift aimlessly in the ocean now has a direction to go."

DISCUSSION

In our study, patients with cLBP undergoing individual breath therapy alone or physical therapy alone over a period of six to eight weeks improved significantly. Improvements of breath therapy and physical therapy were not significantly different. Previous research has shown that the natural course of cLBP of this duration is rather stable, with spontaneous improvements being the exception[42,43] and that a highly credible placebo can improve cLBP by 1.4 on a VAS in a comparable patient population.[44] The average improvements in pain of 2.7 with breath therapy and 2.4 with physical therapy on the VAS were comparable to a prior study of physical therapy and low back pain[44] and confirm suggestions from a prior descriptive study of breath therapy.[28]

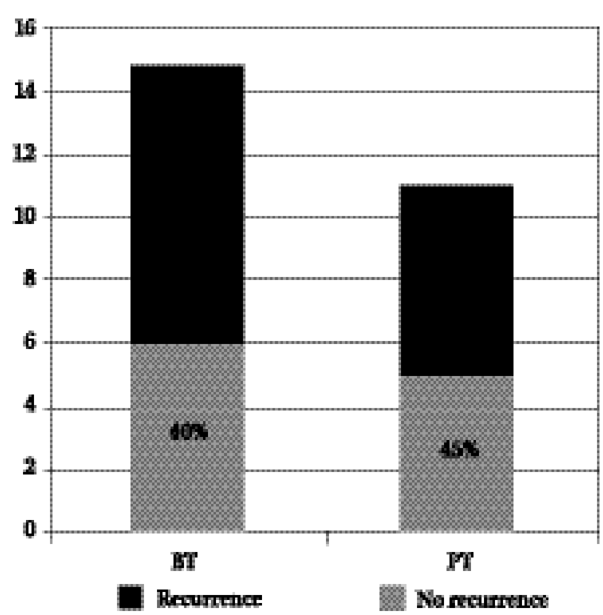
Breath therapy appears to be as good as but not better than physical therapy, the gold-standard therapy for patients with cLBP.[4,37] Both approaches use hands-on touch and are provided by highly motivated and empathic practitioners, but they differ greatly in practitioner training, treatment goals and philosophy, and in their degree of pathology-oriented treatment individualization. Breath therapy is not designed to specifically target low back pain. Considering both interventions as equally effective, two interpretations are possible: (1) any individual, hands-on, highly motivated or empathic attention is able to improve pain and function in patients with cLBP irrespective of the methods applied, the qualification of the practitioners involved, or the degree of pathology orientation of the approach; and (2) each method provides equally valuable elements to the therapy for patients with cLBP, and a combination of both approaches might enhance the educational potential and be worth studying for benefits potentially superior to any single approach.

Immediately after the interventions, there was a trend toward greater improvement in pain and function in the breath therapy group. That trend reversed at six-month follow-up, reaching marginal statistical significance favoring physical therapy for two of eight SF-36 scores, "social functioning" and "mental health."

The lack of statistically significant differences in the main outcomes between the two interventions may be due to insufficient statistical power. Our sample size was only powered to detect a between-group difference of at least 2.3 in the average changes of pain scores and of 6.6 in the average changes of Roland Morris scores for each group assuming a two-sided α of 0.05 and β of 0.20. Standard effect sizes for therapies of chronic low back pain generally are small because of between-session variance in pain scores from influences independent of the interventions. Given that the trends were not consistent (breath therapy gain scores were better immediately after treatment, but physical therapy gain scores were better at six months after treatment), however, the sample size is probably not a sufficient explanation.

The control intervention was provided by physical therapists who are experienced in treating patients with chronic pain, provide clinical services, and teach in an academic setting. Physical therapists adapted their intervention to each patient. In patients with chronic pain, it is not uncommon for physical therapists to teach patients diaphragmatic breathing and use mental imagery techniques to decrease tension and pain (confirmed by our qualitative data). For these reasons, the chances of finding a difference in benefits between the experimental and control interventions may have been reduced.

Patients had clinically significant improvements with both



(Legend: Y-axis is number of patients)

FIGURE 3 Low Back Pain Relapses During 6-Month Follow-Up (Defined as a ≥3-point Increase Over Any Previous Value on a 10-Point Pain Scale in Monthly Questionnaires) therapies, despite the high percentage of patients who had previous experience with physical therapy (92%) and other interventions for the same problem. Either previous physical therapy exercises were not remembered or practiced or needed structured refreshing, or both interventions in our study provided superior therapy compared to previous interventions.

Our qualitative data suggested a different kind of learning in the breath therapy group that involved a new and improved relationship to the body. In the breath therapy group, there was greater experiential insight into the connection between daily stress and back pain. New and improved coping strategies were reported mostly from participants in the breath therapy group.

Unexpectedly, the duration of self-reported home exercising did not correlate with differences in outcome for either group. Duration of exercise was measured with limited accuracy, however. Some subjects reported the time for any kind of exercise added to the exercises taught with the intervention. In addition, no compliance meters or pedometers were used in the study. Limited compliance for home exercises in both groups potentially reduced the effects of the interventions. Furthermore, both breath therapy and physical therapy might be more beneficial if applied over a longer period of time. We limited our intervention to a six- to eight-week course with up to 12 sessions, as is commonly prescribed in medical care.

The relapse rate at the six-month follow-up point seemed to be highest in the breath therapy group (Figures 1 and 2). When monthly follow-up pain scores were taken into account, however, the number of relapses during the six months after the interventions was not different between the two groups (Figure 3). It is possible that the follow-up measures happened to fall into a higher number of relapse episodes prevalent by chance alone at the six-month time point in the breath therapy group. Low-frequency refresher sessions after completion of a treatment series might help to prevent some of the relapses in all patients.

Relapse rate as well as responsiveness of treatment for cLBP is dependent on psychosocial as much as musculoskeletal, biomechanical, and neuro-motor predictors. One limitation of our study is that these factors were not independently assessed. Future studies are needed to determine whether the responses to breath therapy and physical therapy are specifically associated with psychosocial, cultural, or functional patient characteristics.

Participants were not blinded to which intervention they received. Careful attention was given to control for setting, time spent with patient, and motivation of therapists to reduce bias, however. Subjects in the breath therapy group did not interact with subjects in the physical therapy group.

The inclusion of objective balance measures was unique to our study. These balance measures (computerized dynamic posturography and a traditional force plate) captured measurements of postural control. The goal was to objectively document postural responses in patients with low back pain. Also, it was postulated that improvements in postural control could be a measurable surrogate for improvements in whole-body proprioception and body awareness. Previous studies have shown an improvement of similar balance measures with breath therapy in healthy volunteers when measured before and immediately after group breath therapy sessions.[35] We could not replicate these findings when measures were taken up to one week after the last therapy session in patients suffering from cLBP who are expected to have deficits in balance control.[26] The previously reported beneficial effect of breath therapy on balance measures in healthy volunteers might have reflected short-lasting effects and may not have been sufficient to have a significant long-term effect.

Moreover, we could not find any association between objective measures of postural control and the clinical course of low back pain. It is possible that our measures were not sensitive enough to capture changes in patients' postural control with clinical performance gains in patients with low back pain. The low correlation between our various balance measures and between these measures and other independent variables casts doubt upon the validity of these balance measures for research on cLBP and complementary or traditional therapies.[34]

In summary, this is the first study providing evidence that patients suffering from chronic low back pain can clinically improve with breath therapy. Changes in standard self-reported low back pain measures of pain and disability appear to be comparable to changes measured following high-quality, extended physical therapy. Breath therapy is generally safe in patients with cLBP. Qualitative data suggest that breath therapy might teach improved coping skills and provide new insight into the effect of stress on the body and low back pain. A future study should determine whether an approach combining or integrating breath therapy and physical therapy would render more benefits than breath therapy or physical therapy alone. Objective force-plate balance measures may not be a valid measure of clinical change in patients with cLBP.

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