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ORIGINAL RESEARCH

# Change in Pain-Related Anxiety Mediates the Effects of Psychophysiologic Symptom Relief Therapy (PSRT) on Pain Disability for Chronic Back Pain: Secondary Results from a Randomized Controlled Trial

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**Purpose:** Widely used therapeutic approaches, such as cognitive-behavioral and mindfulness-based therapies, can improve pain and functioning in people with chronic back pain, but the magnitude and duration of their effects are limited. Our team developed a novel 12-week program, psychophysiologic symptom relief therapy (PSRT), to substantially reduce or eliminate pain and disability. This study examined whether PSRT helped more patients achieve large-magnitude (≥30%, ≥50%, ≥75%) reductions in back pain-related disability compared to mindfulness-based stress reduction (MBSR) and usual care (UC), and if the beneficial effects of PSRT were explained by reductions in pain-related anxiety following treatment.

**Patients and Methods:** Data from a three-armed randomized controlled trial were used (N=35 adults with chronic back pain). Change scores (baseline to 4-, 8-, 13-, and 26-weeks post-enrollment) were computed for back pain disability (RDQ) and pain-related anxiety (PASS-20). Fisher's exact tests and mediation analyses were conducted.

**Results:** Compared to MBSR and UC, PSRT helped significantly more patients achieve ≥75% reductions in back pain disability at all timepoints and in pain anxiety at all timepoints except 13-weeks. Change in pain anxiety significantly mediated the relationship between treatment group and change in back pain disability from baseline to 26-weeks.

**Conclusion:** PSRT helped more patients achieve substantial reductions in disability than an established treatment (MBSR) and usual care. Findings indicate reduced pain anxiety may be a mechanism by which PSRT confers long-term benefits on disability. Importantly, this work aims to move the field toward more precise and effective treatment for chronic back pain.

**Keywords:** chronic back pain, mind-body therapies, back pain disability, pain-related anxiety

## Introduction

Chronic back pain (CBP) is the leading cause of disability worldwide.[1] Approximately 8% of the global population experience CBP, with rates continually growing as the age distribution shifts with increased life expectancy.[1] The burden of CBP is well-documented and far-reaching—from reduced quality of life to major economic consequences.[2,3] In most cases, CBP is not associated with a specific identifiable pathoanatomical cause,[4] suggesting that it may be largely generated by central factors such as psychosocial processes.[5] As such, psychological or mind-body interventions have emerged to treat CBP. The most commonly studied mind-body treatments for chronic pain—cognitive-behavioral therapy, acceptance and commitment therapy, and mindfulness-based stress reduction (MBSR)—teach patients to manage their symptoms using cognitive-behavioral techniques such as psychoeducation, activity pacing, sleep hygiene, values-based behavioral activation, pain

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acceptance, and mindfulness. Although these therapeutic approaches have been shown to improve pain and functioning in people with CBP, the magnitude and duration of their effects are limited.[6–8]

Novel mind-body approaches for chronic pain are being developed with aims of achieving greater and longer-lasting effects.[7,9,10] Psychophysiologic symptom relief therapy (PSRT)[11] is a pain treatment approach informed by the work of John Sarno, whose interventions focused on educating patients that emotional processes (eg, chronic stress and avoidance of negative affective states) rather than physiological damage are causing their pain.[12] This approach aims to substantially reduce or eliminate pain, thereby deviating from existing treatment models that view pain as a chronic health problem that can be managed but is unlikely to remit. In a 12-week program, PSRT aims to address underlying stressors and psychological contributors to persistent pain (eg, stressful conflicts and aversive affective states), as well as conditioned pain responses and fear-avoidant behaviors. A pilot randomized control trial (RCT; NCT 04039139) showed that PSRT for CBP was feasible and beneficial, with greater effects than MBSR (an active comparator) and usual care (UC) extending to 6-month follow-up.[11]

Using data from the original RCT, the present exploratory study aims to examine additional treatment effects and mechanisms. Ashar et al,[9] who studied a similar pain re-appraisal and exposure-based psychological approach to treating chronic primary pain (pain reprocessing therapy), examined the percentage of CBP patients who reported 30% pain reduction, 50% pain reduction, and being pain-free or nearly pain-free at post-treatment and 1-year follow-up—in addition to examining continuous pain outcomes. They found that a consistent percentage of participants who received pain reprocessing therapy achieved 30% and 50% reductions in symptoms and pain-free levels. Conversely, the proportion of participants achieving 30% and 50% reductions in symptoms and pain-free levels in the placebo and usual care groups differed based on the examined benchmark. For example, 78%, 70%, and 66% of the participants who received pain reprocessing therapy reported 30% reductions, 50% reductions, and being pain-free or nearly pain-free at post-treatment, respectively. Although 49% of the participants who received a placebo reported 30% pain reduction at post-treatment, only 29% reported 50% reduction, and only 20% reported being pain-free or nearly pain-free. Participants in the usual care group reported even less reduction in symptoms than in the placebo group; however, the pattern of post-treatment response rates was similar in that 38% reported 30% pain reduction, 16% reported 50% pain reduction, and only 10% reported being pain-free or nearly pain-free.

Given that PSRT has a similar goal of recovery from CBP, the primary aim of this study was to explore whether symptom reduction (ie, reduction in back pain-related disability) followed a similar pattern in our sample at 30%, 50%, and 75% reduction rates and to compare rates across the three study conditions (PSRT, MBSR, and UC). The second aim and main objective of this study was to examine reductions in pain-related anxiety as a potential mechanism of PSRT. PSRT was founded on the notion that nonspecific back pain is a symptomatic manifestation of a psychophysiological process driven by stress, negative emotions, and other psychological processes. Therefore, PSRT presumably eliminates pain by addressing these drivers of pain. One such driver—and thus, a primary treatment target of PSRT—is pain-related anxiety. Pain anxiety can result in hypervigilance to bodily sensations such that a person is more aware of painful sensations, perceives pain to be more severe, and actively avoids potentially painful stimuli. This process paradoxically results in increased pain, distress, and disability.[13] By addressing pain anxiety using neuroscience education and experiential exercises, PSRT aims to reverse this process. We therefore hypothesized that the beneficial effects of PSRT on back pain disability would be explained by greater reductions in pain-related anxiety following treatment. Identifying mediators associated with positive outcomes is essential for optimizing treatments for CBP.

# Materials and Methods

## Participants

Participants were adults aged 18 to 67 with CBP lacking a clear organic etiology (eg, malignancy or infection). CBP was defined as back pain occurring at least 3 days a week for the 3 months before enrollment. Individuals were excluded from the study if they (1) were >67 years because of an increased risk of underlying organic etiology of pain; (2) had diagnosed organic disease as cause of pain, such as malignancy, neurologic disorder (eg, amyotrophic lateral sclerosis), and cauda equina syndrome; (3) had vertebral disk disease with neurological impairment; (4) had a diagnosis of significant psychiatric comorbidities such as schizophrenia, dementia, and bipolar disorder; and/or (5) were not willing to participate for the full duration of the study. Participants with depression were not excluded. Pain in patients with disk

disease was not an exclusion unless there were neurological impairments. Participants were recruited via social media (Facebook and Twitter posts), flyers, and physician referrals for a prospective, three-armed pilot RCT to establish the efficacy of PSRT compared to MBSR and UC. A total of 35 participants (40% male, 60% female) completed the study and were included in analyses (PSRT: 11, MBSR: 12, UC: 12). The trial's methodology, including a Consort diagram, has been described in detail in a prior publication (PMID: 34589642).[11] Participant demographic characteristics and pain history can be found in Table 1.

## Procedure

The purpose of this study was to conduct secondary data analyses from a prior randomized trial. The original study was approved by the Beth Israel Deaconess Medical Center Institutional Review Board, complies with the Declaration of Helsinki, and all participants provided written informed consent. Participants were randomized in a 1:1:1 ratio to the PSRT, MBSR, and UC arms in blocks with random sizes of 3 or 6. Participants in the intervention group (PSRT) and the active comparator group (MBSR) were blinded to the existence of the other group. Participants' adherence was tracked throughout the original randomized controlled trial. For the PSRT arm, the median number of sessions attended was 13 of 17 (76%). For the MBSR arm, the median number of sessions attended was 7 of 9 (78%). Participants completed baseline questionnaires prior to randomization and enrollment and completed the same questionnaires at 4-, 8-, 13-, and 26-weeks after enrollment.

### Psychophysiologic Symptom Relief Therapy (PSRT, Intervention)

Participants randomized to the PSRT arm attended 2-hr virtual group classes twice a week for 4 weeks (total 16 hr, 8 sessions), followed by the same 8-week protocol used in the MBSR arm (total 22 hr, 9 sessions); thus, the intervention

**Table 1** Demographics and Pain History (N = 35)

| Variable | PSRT n = 11 | MBSR n = 12 | UC n = 12 |
|---|---|---|---|
| Age, years (mean, SD) | 38.4 (12.8) | 39.3 (14.4) | 43.1 (13.0) |
| **Sex (n, %)** | | | |
| Male | 5 (45%) | 6 (50%) | 3 (25%) |
| Female | 6 (55%) | 6 (50%) | 9 (75%) |
| **Race (n, %)** | | | |
| African American | 1 (9%) | 3 (25%) | 1 (8%) |
| Asian | 2 (18%) | 0 (0%) | 0 (0%) |
| White | 5 (45%) | 6 (50%) | 10 (83%) |
| Other | 3 (27%) | 3 (25%) | 1 (8%) |
| **Education[a] (n, %)** | | | |
| Some college or vocational school | 4 (36%) | 4 (33%) | 3 (27%) |
| College graduate | 3 (27%) | 6 (50%) | 4 (36%) |
| Master's degree or higher | 4 (36%) | 2 (17%) | 4 (36%) |
| **Previous diagnosis related to pain (n, %)** | | | |
| Radiculopathy | 4 (36%) | 4 (33%) | 4 (33%) |
| Musculoskeletal disease | 2 (18%) | 3 (25%) | 2 (17%) |
| Piriformis Syndrome | 0 (0%) | 1 (8%) | 0 (0%) |
| Osteoarthritis | 3 (27%) | 1 (8%) | 0 (0%) |
| **Previous pain interventions (n, %)** | | | |
| Spinal injections | 3 (27%) | 8 (67%) | 5 (42%) |
| Surgical intervention | 1 (9%) | 2 (17%) | 3 (25%) |
| Physical Therapy | 8 (73%) | 9 (75%) | 10 (83%) |
| Chiropractor | 4 (36%) | 6 (50%) | 5 (42%) |
| Other therapy | 4 (36%) | 7 (58%) | 5 (42%) |

**Notes**: [a]1 patient in UC group missing education information. Missing values excluded from calculations of counts and percentages.

totaled 38 hr over 17 sessions. The first 4 weeks of PSRT treatment included education, desensitization, and emotional awareness exercises. Education focused on providing patients with information about the role of stress and psychological processes in precipitating and perpetuating physical symptoms. Using desensitization exercises, participants were encouraged to approach, rather than avoid, physical activities first through visualization (eg, visualizing an action that typically induces symptoms) and then through physical exposures of feared symptom-inducing activities (eg, walking upstairs). Emotional awareness (eg, expressive writing) exercises were introduced during the educational component of PSRT and were utilized throughout the treatment. The 8-week MBSR portion of PSRT was conducted in the context of participants having already learned the origins of their pain and experiencing substantial improvements in their functional activity and pain level. The PSRT protocol is included in a prior publication (see Supplementary Materials in PMID: 34589642).[11]

### Mindfulness-Based Stress Reduction (MBSR, Active Comparator)

Participants randomized to the MBSR arm attended 2-hr virtual group classes once a week for 8 weeks, with one full-day class lasting 6 hr (total 22 hr, 9 sessions). In this study, MBSR program was conducted according to the established MBSR protocol.[14] The MBSR protocol focuses on providing patients with mindfulness skills such as practicing awareness of breath, body scan, and sitting meditation.

### Usual Care (UC, Control)

Participants randomized to UC were encouraged to continue their ongoing independent and physician-guided treatment without interference from study staff.

## Measures

### Back Pain Disability

The 24-item Roland-Morris Back Pain and Disability Questionnaire (RDQ)[15] was used to assess the impact of back pain on functional activities. This validated questionnaire was scored 0 through 24, with higher scores indicating higher back pain-induced disability. RDQ has good psychometric properties, has been validated in patients with back pain, and is widely used.[15]

### Pain Anxiety

Pain-related anxiety was measured using the Pain Anxiety Symptom Scale (PASS-20),[16] a 20-item scale, with response options ranging from 0 to 5. Higher responses indicate higher pain anxiety. Individual items were summed to create a total PASS-20 score ranging from 0 to 100. The PASS-20 shows strong internal consistency and reliability and has been validated in chronic pain populations.[16]

## Statistical Analysis

Change scores were calculated for all study variables from baseline to 4-, 8-, 13-, and 26-weeks post-enrollment. Outcomes were analyzed dichotomously (eg, ≥75% reduction from baseline vs <75% reduction from baseline) using Stata 17.0 (College Station, TX). The proportion of patients with ≥30%, ≥50%, and ≥75% reduction in back pain disability and pain anxiety from baseline was compared across groups, specifically between PSRT vs MBSR and PSRT vs UC groups, using Fisher's exact tests at each follow-up timepoint. A two-sided p-value <0.05 was considered to be statistically significant for all analyses in both aims.

Simple mediation analyses examined the indirect relationship between treatment group (PSRT vs MBSR; PSRT vs UC) and change in back pain disability through change in pain-related anxiety. Specifically, changes in pain-related anxiety (PASS-20) from baseline to 13-weeks and from baseline to 26-weeks were tested as mediators. Change in back pain disability (RDQ; continuous outcome) from baseline to 26-weeks was used as the dependent variable in the mediation analyses. Mediation analyses were conducted using the PROCESS macro in SPSS version 28. To test the mediation model, 95% confidence intervals of 5000 bootstrap samples were obtained.[17]

# Results

## Treatment Response Rates

We assessed treatment response rates at ≥30%, ≥50%, and ≥75% reduction in symptoms across the three study conditions. As shown in Table 2, in general, participants in the PSRT group were significantly more likely to achieve ≥30%, ≥50%, and ≥75% reductions in pain-related anxiety and back pain disability compared to participants in the UC group across all four study timepoints. When comparing PSRT to an active comparator, MBSR, the between-group differences were less consistent for ≥30% and ≥50% reductions in symptoms. For example, PSRT led to significantly more patients reporting ≥30% and ≥50% reductions in symptoms earlier on (ie, 4-week timepoint) compared to MBSR, but the two treatment groups did not significantly differ at later follow-up points (ie, 13- and 26-weeks). However, compared to MBSR, PSRT led to significantly more participants achieving ≥75% reductions in pain-related anxiety across all timepoints except for 13-weeks, and significantly more participants achieving ≥75% reductions in back pain disability at all four study timepoints, including 13-week and 26-week follow-up (see Table 2).

## Mediation Results

We examined whether the beneficial effects of PSRT on change in back pain disability (RDQ) from baseline to 26 weeks, compared to MBSR and UC, would be mediated by greater reductions in pain-related anxiety (PASS-20) from baseline to 13 weeks and baseline to 26 weeks. See Figure 1 and Table 3 for the mediation model and statistics.

**Table 2** The Number and Percentage of Participants Who Experienced a 30%, 50%, and 75% Reduction in Symptoms in Each Study Group, and Results of Fisher's Exact Test Results Comparing Reductions Between Groups

| | **n (%) Achieving 30% Reduction** | | | | | |
|---|---|---|---|---|---|---|
| | **PSRT n = 11** | **MBSR n = 12** | **UC n = 12** | **PSRT vs MBSR vs UC *p*** | **PSRT vs MBSR *p*** | **PSRT vs UC *p*** |
| **PASS-20** | | | | | | |
| Baseline > 4 weeks | 9 (82%) | 4 (33%) | 2 (17%) | *0.004* | *0.036* | *0.003* |
| Baseline > 8 weeks | 10 (91%) | 8 (67%) | 4 (33%) | *0.017* | 0.317 | *0.009* |
| Baseline > 13 weeks | 10 (91%) | 8 (67%) | 5 (42%) | *0.042* | 0.317 | *0.027* |
| Baseline > 26 weeks | 10 (91%) | 9 (75%) | 4 (33%) | *0.014* | 0.590 | *0.009* |
| **RDQ** | | | | | | |
| Baseline > 4 weeks | 10 (91%) | 5 (42%) | 3 (25%) | *0.004* | *0.027* | *0.003* |
| Baseline > 8 weeks | 11 (100%) | 7 (58%) | 5 (42%) | *0.007* | *0.037* | *0.005* |
| Baseline > 13 weeks | 10 (91%) | 7 (58%) | 3 (25%) | *0.007* | 0.155 | *0.003* |
| Baseline > 26 weeks | 9 (82%) | 7 (58%) | 5 (42%) | 0.165 | 0.371 | 0.089 |
| | **n (%) Achieving 50% Reduction** | | | | | |
| | **PSRT n = 11** | **MBSR n = 12** | **UC n = 12** | **PSRT vs MBSR vs UC *p*** | **PSRT vs MBSR *p*** | **PSRT vs UC *p*** |
| **PASS-20** | | | | | | |
| Baseline > 4 weeks | 8 (73%) | 1 (8%) | 2 (17%) | *0.002* | *0.003* | *0.012* |
| Baseline > 8 weeks | 10 (91%) | 4 (33%) | 3 (25%) | *0.003* | *0.009* | *0.003* |
| Baseline > 13 weeks | 10 (91%) | 5 (42%) | 3 (25%) | *<0.001* | *0.027* | *0.003* |
| Baseline > 26 weeks | 9 (82%) | 5 (42%) | 2 (17%) | *0.009* | 0.089 | *0.003* |
| **RDQ** | | | | | | |
| Baseline > 4 weeks | 9 (82%) | 1 (8%) | 2 (17%) | *<0.001* | *0.001* | *0.003* |
| Baseline > 8 weeks | 9 (82%) | 5 (42%) | 3 (25%) | *0.024* | 0.089 | *0.012* |
| Baseline > 13 weeks | 9 (82%) | 7 (58%) | 3 (25%) | *0.022* | 0.371 | *0.012* |
| Baseline > 26 weeks | 8 (73%) | 5 (42%) | 4 (33%) | 0.175 | 0.214 | 0.100 |

(*Continued*)

**Table 2** (Continued).

| | n (%) Achieving 75% Reduction | | | | | |
|---|---|---|---|---|---|---|
| | **PSRT n = 12** | **MBSR n = 12** | **UC n = 12** | **PSRT vs MBSR vs UC *p*** | **PSRT vs MBSR *p*** | **PSRT vs UC *p*** |
| **PASS-20** | | | | | | |
| Baseline > 4 weeks | 5 (45%) | 0 (0%) | 0 (0%) | *0.001* | *0.014* | *0.014* |
| Baseline > 8 weeks | 9 (82%) | 3 (25%) | 0 (0%) | *<0.001* | *0.012* | *<0.001* |
| Baseline > 13 weeks | 8 (72%) | 5 (42%) | 1 (8%) | *0.006* | 0.214 | *0.003* |
| Baseline > 26 weeks | 8 (72%) | 3 (25%) | 1 (8%) | *0.006* | *0.039* | *0.003* |
| **RDQ** | | | | | | |
| Baseline > 4 weeks | 8 (73%) | 1 (8%) | 0 (0%) | *<0.001* | *0.003* | *<0.001* |
| Baseline > 8 weeks | 9 (82%) | 3 (25%) | 0 (0%) | *<0.001* | *0.012* | *<0.001* |
| Baseline > 13 weeks | 9 (82%) | 4 (33%) | 1 (8%) | *0.002* | *0.036* | *0.001* |
| Baseline > 26 weeks | 8 (73%) | 2 (17%) | 3 (25%) | *0.013* | *0.012* | *0.039* |

**Note**: *p*-values less than 0.05 are italicized.

## PSRT vs MBSR

Change in pain anxiety from baseline to 26 weeks ($M_2$) significantly mediated the relationship between treatment group (X) and change in back pain disability from baseline to 26 weeks (Y), B = −2.82, SE = 1.37, 95% CI [−5.74, −0.32]. Mediation analyses examining change in pain anxiety from baseline to 13 weeks ($M_1$) as a mediator did not reach statistical significance.

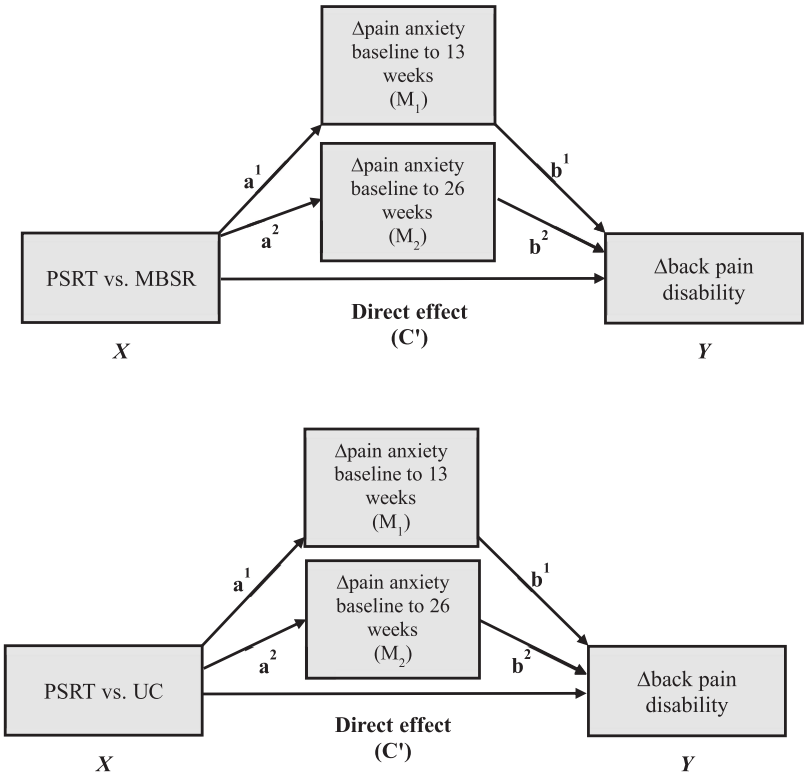


**Figure 1** Direct and indirect effects of treatment group (**X**) on change in back pain disability from baseline to 26 weeks post-enrollment (Y) through change in pain-related anxiety from baseline to 13 weeks ($M_1$), and baseline to 26 weeks ($M_2$).

**Table 3** Direct and Indirect Effects of Treatment Group on Change in Back Pain Disability (RDQ) from Baseline to 26 Weeks Post-Enrollment Through Change in Pain-Related Anxiety (PASS-20) from Baseline to 13 Weeks ($M_1$), and Baseline to 26 Weeks ($M_2$)

| IV | Total Effect | Path a | Path b | Indirect Effect (Path ab) | Direct Effect (path C') |
|---|---|---|---|---|---|
| 1-PSRT vs MBSR | −1.77 | −16.85 | 0.12 | −1.99 | 0.23 |
| ($M_1$ = Δpain anxiety baseline to 13 weeks) | (−5.84, 2.31) | (−35.67, 1.98) | (0.03, 0.20) | (−6.10, 0.12) | (−3.56, 4.01) |
| 2-PSRT vs MBSR | −1.77 | −16.89 | 0.17 | −2.82 | 1.06 |
| ($M_2$ = Δpain anxiety baseline to 26 weeks) | (−5.84, 2.31) | (−32.91, −0.87) | (0.08, 0.26) | (−5.74, −0.32) | (−2.44, 4.56) |
| 1-PSRT vs UC | 6.02 | 28.18 | 0.12 | 3.47 | 2.54 |
| ($M_1$ = Δpain anxiety baseline to 13 weeks) | (2.15, 9.88) | (12.66, 43.70) | (0.02, 0.22) | (0.19, 7.58) | (−1.92, 7.01) |
| 2-PSRT vs UC | 6.02 | 33.39 | 0.12 | 4.13 | 1.88 |
| ($M_2$ = Δpain anxiety baseline to 26 weeks) | (2.15, 9.88) | (17.98, 48.79) | (0.02, 0.23) | (0.43, 7.66) | (−2.96, 6.72) |

**Notes**: 1 designates paths $a^1$,$b^1$; 2 designates paths $a^2$,$b^2$.

### PSRT vs UC

Change in pain anxiety from baseline to 13 weeks ($M_1$) significantly mediated the relationship between treatment group (X) and change in back pain disability from baseline to 26 weeks (Y), B = 3.47, SE = 1.92, 95% CI[0.19, 7.58]. Change in pain anxiety from baseline to 26 weeks ($M_2$) also significantly mediated the relationship between treatment group (X) and change in back pain disability from baseline to 26 weeks (Y), B = 4.13, SE = 1.88, 95% CI [0.43, 7.66].

## Discussion

The current study sought to investigate patterns of treatment response rates (ie, improvements in health symptoms) following PSRT, a novel Sarno-based treatment for chronic back pain, compared to MBSR and UC. We also examined a potential mechanism of PSRT, reduction in pain-related anxiety, as a mediator between treatment group and reduction in back pain disability.

Compared to MBSR and UC, PSRT generally helped more participants achieve large-magnitude reductions in pain-related anxiety and back pain disability. Compared to UC, PSRT consistently led to more participants achieving ≥30%, ≥50%, and ≥75% reductions in symptoms across all study follow-up timepoints. When comparing PSRT to MBSR, the number of participants who achieved ≥30% and ≥50% reductions in symptoms did not consistently significantly differ between these two treatment groups at later timepoints (eg, 13- and 26-weeks); however, PSRT consistently led to more participants achieving ≥75% reductions in symptoms at 4- and 8-weeks, and importantly, at 13- and 26-week follow-up. This pattern is consistent with findings by Ashar et al[9] demonstrating that pain reprocessing therapy—a similar Sarno-based approach—helped 66–78% of patients achieve 30% and 50% symptom reductions and pain remission at post-intervention, whereas a placebo resulted in 49% of patients reporting 30% pain reduction, but only 29% reporting 50% reduction and 20% reporting pain remission. These collective findings indicate the potential of Sarno-based approaches, such as PSRT and pain reprocessing therapy, to produce larger-magnitude reductions in symptoms compared to other mind-body approaches and placebos. Notably, the use of a higher threshold (eg, 75% reduction in disability, pain remission) when comparing psychological pain treatments may be useful and meaningful. Although comparator groups may result in similar proportions of patients achieving 30% symptom reduction, between-group differences may be more apparent when using a larger benchmark.

There are several treatment elements specific to PSRT that may explain its potentially large and enduring impact on pain-related anxiety and back pain-related disability. Mindfulness-based interventions for chronic pain, such as MBSR, aim to reduce pain by helping patients achieve acceptance and nonreactivity to difficult thoughts, emotions, and physical sensations, and decrease pain-related stress,[18–20] regardless of the etiology of the pain symptoms. PSRT, in contrast, employs a different approach to chronic pain treatment by highlighting, early on, the potential of the brain to not only modulate pain but to also generate pain experiences. Further, the PSRT model highlights to patients that nonorganic pain is maintained by fear, avoidance of activities, and beliefs that pain indicates physical injury. Thus, through PSRT, patients receive the message that pain (without clear organic pathology) is generated by the brain, and in turn that significant pain reduction (or even elimination) is possible and achievable.

From this framework, patients then actively practice additional elements of PSRT including desensitization, exposure to feared activities, emotional awareness and expression, and mindfulness.

Results of the mediation analyses indicated that when comparing PSRT and UC, reductions in pain-related anxiety from baseline to 13-weeks and baseline to 26-weeks mediated the relationship between treatment group and reduction in back pain disability from baseline to 26-weeks. When comparing PSRT and MBSR, reduction in pain anxiety from baseline to 26-weeks mediated the relationship between treatment group and reduction in back pain disability from baseline to 26-weeks. Challenging pain-related avoidance and fear-driven beliefs and behaviors is a central component of PSRT. By providing participants with a psychologically driven model of CBP and emphasizing the potential to reduce or eliminate pain, participants quickly engage with the idea that emotional, cognitive, and behavioral modifications can impact their pain and that their pain is not a sign of a dangerous physiological problem.

Exposure to feared stimuli is widely viewed as an important component of many effective psychological treatments,[21] and fear of movement, or *kinesiophobia*, and the associated fear of pain, are important factors in the development and maintenance of CBP. Thus, in PSRT, participants were encouraged to test their fears about avoided activities early on in treatment through visualization exercises (eg, activity visualization) and behavioral exposures to difficult emotions and feared activities in order to learn that their fears about pain do not come true. This "testing out" may in turn have decreased participants' pain-related anxiety, probability overestimation of negative outcomes, and catastrophizing about feared activities, and in turn increased their engagement in previously feared activities and decreased back pain-related disability.

## Strengths, Limitations, and Future Directions

This study has several strengths, including the utilization of a novel pain intervention, tracking of symptoms across four timepoints, and the inclusion of both a usual care control and a rigorous, active control condition (MBSR). Notably, however, this was a post-hoc exploratory analysis of data from a single-center, pilot randomized controlled trial. As such, a power analysis was not conducted a priori for this study, and some analyses may have been underpowered, particularly the mediation analysis. The generalizability of our findings is limited due to the small sample size and particular demographics of our sample. Future studies are needed to replicate our findings in larger and more diverse samples, including other pain and medical populations. Additional limitations specific to the original RCT are described in a prior publication (PMID: 34589642).[11]

Our findings suggest that pain-related anxiety may be a critical target for intervention in CBP patients and can be improved through PSRT. However, future research should examine additional treatment mechanisms. By identifying additional mediators and elements of PSRT that contribute most robustly to its benefits, we can refine this intervention to optimize outcomes and patient satisfaction while reducing burden on patients, providers, and insurance payers. Identifying which patients benefit most from this approach is also of interest.

# Conclusions

Secondary findings from a randomized controlled trial indicate that a novel mind-body intervention (PSRT) may help more patients achieve substantial improvements in functioning compared to an established treatment (MBSR) and usual care. The present study identified change in pain-related anxiety as a mechanism by which this intervention may lead to enhanced pain-related outcomes. Further randomized controlled trials are needed to replicate these findings in larger and more diverse samples, and to identify additional treatment mechanisms and types of patients who benefit most from this promising approach. Notably, the use of a large benchmark (eg, 75% symptom reduction) when comparing psychological pain treatments may be essential in detecting between-group differences and help move the field toward more precise and effective treatment for those with chronic back pain.

# Abbreviations

CBP, Chronic back pain; PSRT, Psychophysiologic symptom relief therapy; MBSR, Mindfulness-based stress reduction; UC, Usual care; RDQ, Roland-Morris Back Pain and Disability Questionnaire; PASS-20, Pain Anxiety Symptom Scale.

## Data Sharing Statement

Individual deidentified participant data are available upon reasonable request from Michael W. Donnino (email: mdonnino@bidmc.harvard.edu) with regulatory approval. Requested deidentified data (ie, participant responses to self-report measures) and/or questionnaires will be made available as Excel files and PDFs, respectively, via GitHub or other agreed-upon mechanism. We will keep individualized data for a minimum of 2 years.

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Shivani Mehta is currently affiliated with the New York Institute of Technology College of Osteopathic Medicine, though was affiliated with Beth Israel Deaconess Medical Center/Harvard Medical School throughout this study.

This study was registered with ClinicalTrials.gov before recruitment (NCT04039139).

## Disclosure

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