

THE ROLE OF PATIENTS' EXPECTATION OF APPROPRIATE INITIAL MANUAL THERAPY TREATMENT IN OUTCOMES FOR PATIENTS WITH LOW BACK PAIN

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ABSTRACT

Objectives: The purpose of this study was to compare the outcomes of patients with low back pain who had a matched, unmatched, or were indifferent with their pretreatment expectation/preference to the manual therapy thrust or nonthrust intervention. A secondary purpose was to explore baseline patient characteristics affiliated with a preference of manual therapy treatment type (thrust or nonthrust manipulation).

Methods: The study is a secondary analysis of a prospective randomized controlled trial that enrolled 149 patients with low back pain, from 16 distinct outpatient physical therapy practices within the United States. Patient's pretreatment expectations were identified before randomization. The intervention included manual therapy (thrust or nonthrust manipulation) with a standardized exercise program, which was carried out for 2 treatment sessions. Six outcomes captured the constructs of (a) disability, (b) pain perception, (c) care intensity, (d) fear avoidance behaviors, and (e) perception of extent of recovery. Descriptive statistics, analysis of variance (and Tukey, a post hoc test), Fisher exact test, and a multivariate logistic regression analysis were used for analysis.

Results: There were no statistical differences in any of the 6 dedicated outcomes measures between the matched, unmatched, and no preference groups. Therapist-determined patient "irritability" was associated with patient preference of nonthrust treatment, and higher body mass index was associated with patient preference of thrust treatment.

Conclusions: This study shows that patients demonstrated no statistical difference in disability or pain outcome measures when matched, unmatched, or indifferent to the intervention. (*J Manipulative Physiol Ther* 2013;36:276-283)

Key Indexing Terms: *Low Back Pain; Patient Preference; Musculoskeletal Manipulations*

For a randomized controlled trial (RCT), a state of "equipoise" or genuine uncertainty in the comparative merits of the treatments being assessed is necessary for a fair; unbiased; and, in some cases, ethical

design.¹ Equipoise is categorized in many ways, including whether there is no evidence within the literature that one intervention is genuinely more effective than another (clinical equipoise), whether there is no evidence that the expert clinical practitioners favor one intervention over another (community or personal equipoise), or whether there is no evidence that patients have expectations/preferences toward one treatment arm or the other.² In reality, most patients likely do have preferences/expectations regarding the treatment choices provided, which could potentially influence the within-group changes and between-group differences.³ Furthermore, it has been hypothesized that when patients are given the opposite intervention to their expectation/preference (unmatched treatment), they have a greater probability of experiencing worse outcomes in comparison with those receiving matched treatment.⁴

The definition of patient preference differs only slightly from patient expectations.⁵ Of the 2, patient expectation is

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more widely studied. Expectation involves the patient's beliefs regarding the potential benefit of the treatment⁶ and the likelihood of an outcome or an expected effect (prognosis).⁷ A patient's expectation has been linked to levels of pain and recovery.^{5,7,8} By definition, patient preference is derived from patient's expectations about the care that they will receive,⁹ and results from deliberation about specific elements, such as anticipated treatments or health outcomes. Although patient preferences for a certain treatment, which are related to, but distinct from, their expectations of the results of that treatment, together both may have an important role in affecting treatment outcome. Recently, in a study by Lurie et al⁹ found that the patients' expectations regarding improvement with nonoperative care was the strongest predictor of their treatment preference.⁹ In essence, the constructs of the 2 definitions are conditionally related and should be considered in combination when examining an effect during a clinical trial.

The determinant that drives a patient to pick an expectation/preference of one intervention over another intervention is less known. The most commonly reported preferences/expectation influence is a patient's past experience with an intervention, a health care provider, or a particular health-related service.¹⁰ Other preferences/expectations involve the ability of the patient to cope with the prescribed intervention, how the intervention may affect lifestyle choices, and verbal and written knowledge of the effectiveness/ineffectiveness of a technique.¹¹ Preferences/expectations may also be associated with the perceived nature of some treatments¹²: in other words, whether the treatment is complex or simple or whether the actionable component of the treatment choice is complementary to the patient's perception of their underlying problem. Recently, Bishop et al¹³ found that patients who received physical therapy for treatment of nonspecific low back pain (LBP) expected active approaches to be more beneficial than passive approaches such as modalities and medications. However, one could argue that a patient who attends a treatment such as physical therapy is looking for an active intervention because this approach is more reflective of what is provided by physical therapists. Those who pursue a massage therapist are likely looking for a passive approach for their care. Yet many of the procedures used in dedicated disciplines are markedly similar in appearance and outcome. What remains unknown is whether patients would have preferences on similar active or passive interventions such as 2 forms of manual therapy or 2 different forms of exercise, if both procedures had similar constructs.

At present, the influence of patient expectations/preferences on outcomes in clinical trials has provided mixed results.^{14,15} Differences in findings may be associated with design variations, how the definitions were used within the study for expectations/preferences, and whether

indifference toward an intervention choice was captured. To our knowledge, no studies have looked at the matched, unmatched, and/or indifferent treatment expectations/preferences on recovery in a manual physical therapy-oriented clinical trial for mechanical LBP. Therefore, the primary objective of this study is to compare the outcomes of patients with LBP who received care that was (a) matched to expectation/preference, (b) unmatched to expectation/preference or included patients who were indifferent to an expectation/preference. A secondary objective was to explore baseline patient characteristics affiliated with a preference of manual therapy treatment type (thrust or nonthrust manipulation) because the interventions are similar in construct and/or both advocated by treatment guidelines.

METHODS

Design

The secondary database analysis is extracted from an RCT (clinicaltrials.gov no. NCT01438203). The RCT compared thrust and nonthrust manipulation in the treatment of LBP; thus, both groups in the study received a manual therapy approach. The study was approved by the Walsh University Human Ethics Review Board. All subjects gave consent to participate in this study.

Participants

The original RCT study from which this secondary analysis was performed has been described elsewhere and is presented to give context for this current study in Figure 1.¹⁶

Participants were 149 patients with LBP, all of which were treated in 1 of 16 distinct outpatient physical therapy practices within the United States by 1 of 17 skilled outpatient physical therapists. Clinicians had undergone extensive manual therapy training and certification in orthopedic manual therapy or were manual therapy fellows within the American Academy of Orthopaedic Manual Physical Therapists.

Study inclusion required an age of 18 years or older with mechanically producible LBP. There were no restrictions on minimum baseline Oswestry Disability Index (ODI) scores or pain scores. Exclusion criteria included the presence of a tumor, metabolic diseases, rheumatoid arthritis, osteoporosis, prolonged history of steroid use, or signs consistent with nerve root compression (any of the following: reproduction of low back or leg pain with straight leg raise <45°, muscle weakness involving a major muscle group of the lower extremity, diminished lower extremity muscle stretch reflex, or diminished or absent sensation to pinprick in any lower extremity dermatome). Participants with a prior surgical history of the lumbar spine and current pregnancy were also excluded.

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