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The impact of structural therapy on functioning and pain in chronic pain patients: A pilot study[1]

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Abstract. *Objective*: The objective of this randomized controlled trial was to assess the efficacy of correcting pelvic obliquity by heel lifts to reduce pain and improve physical and emotional functioning in patients with chronic low back pain.
Methods: Subjects were $\geqslant$ 20 years old with low back pain for at least one year. They were randomly assigned to experimental ($n = 9$) or control ($n = 6$) groups. Degree of pelvic obliquity was determined by postural radiographs. Main outcome measures were level of pain (McGill Pain Questionnaire – Short Form), and physical and emotional functioning (Medical Outcomes Study 36-Item Short Form Health Survey) which were administered at baseline, end of treatment and 3- and 6-month follow-ups. Experimental subjects received heel lifts and custom-molded insoles to correct pelvic obliquity; controls received off-the-shelf insoles. A physical therapist taught exercises to both groups.
Results: Baseline outcomes measures were similar in both groups. With treatment, experimental subjects had significant improvement in general health, physical and social functioning, and vitality, and significantly less pain than controls.
Conclusion: Correction of pelvic obliquity appears to improve pain and functioning in patients with chronic low back pain.

Keywords: Chronic low back pain, pelvic obliquity, leg length discrepancy, pain, function

1. Introduction

Low back pain (LBP) is a condition with far-reaching consequences, both to the individuals affected and to the health care system as a whole. LBP is a major cause of chronic disability, with a prevalence that peaks between the ages of 35 and 60 years [9]. Interestingly, only about 4% of those who develop acute back pain will go on to develop chronic LBP (CLBP), but approximately one-third of those with CLBP will be permanently disabled due to their pain [9]. The extent and severity of this condition has an enormous impact on the health care delivery system, as back pain is the second most common reason patients seek healthcare and patients with LBP consume more health services than people with other disabilities [9].

LBP may be caused by multiple factors, one of which is leg length discrepancy (LLD) [2,3,16,20,31]. Studies show that the prevalence of LLD is greater in those with CLBP than in those without CLBP [16,34]. LBP associated with LLD is typically characterized by 1) gradual onset commonly beginning in late adolescence or early adulthood, 2) a chronic or recurrent course, and 3) onset precipitated by trauma or strain such as lifting [2,20,31].

In addition to LBP, a multiplicity of pain complaints have been attributed to LLD. These complaints involve

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various body regions, including the feet [2,5,6,37], knees [3], hips [5,19], thorax [2,3], and shoulders [2]. An increased risk for degenerative joint changes and intervertebral disc disturbances have also been attributed to LLD [5,17–19,31].

Methods of assessing LLD fall into two categories, those using radiographic measures and those using anatomical landmarks. There are two commonly accepted radiographic methods of determining the degree of LLD, both of which utilize a postural x-ray (a pelvic x-ray taken with the patient standing). One method measures femoral head heights [2,9,15,16]; the other, developed by Tilley and Fann [12–14,40], measures the sacral base instead of femoral head heights to determine the amount of pelvic obliquity (i.e., an unlevel pelvic platform), as the sacrum "acts like an inverted keystone as mediator of the paired lower extremities and pelvis with the single axial vertebral column [33]." It is also reliable, as it is consistent with Beal [2] and Rothenberg [33], whose studies indicate that the reliability of pelvic obliquity measurement is between 1 and 3 millimeters, similar to the reliability of femoral head-height measurement.

The second category for measuring LLD relies solely on tape measurements from palpated anatomical landmarks, and appears much less reliable than the radiographic measurements [1,3,11,42]. Palpatory methods may be used to provide clinical clues to the presence of LLD [3], but they are inaccurate, especially with less than 1 centimeter of discrepancy [1,11].

There are numerous publications, either descriptive studies or case reports, regarding LLD and correction of this abnormality to relieve back pain [20,21,23,33]. Of these, only one study included a validated pain measurement scale [24], and only one [20] included post-treatment follow-up (average of six years) of the patients. No study was found in the literature that compared a group treated with heel lifts to a control group. Another important omission of these studies is that they did not use functional measures to determine outcomes, and functioning may be a more valid method than pain measurements for demonstrating the success of interventions [32].

This study used a randomized controlled method to assess the efficacy of correcting pelvic obliquity to reduce back pain, increase functional ability, and improve emotional and mental health in patients with CLBP. The hypothesis of this study was that treatment aimed at correcting pelvic obliquity would decrease pain and improve functioning more than treatment with therapeutic exercises alone.

2. Methods

2.1. Patients

Fifteen patients with LBP of at least 1 year in duration were recruited from the Physical Medicine and Rehabilitation Services Outpatient Clinic at the Central Arkansas Veterans Healthcare System. All subjects met the following inclusion criteria: able to attend appointments every other week for approximately 3 months; have pelvic obliquity from 3 mm to 25 mm (1/8" to 1") as identified by the x-ray technique described below; and be at least 20 years old. Exclusion criteria included the following: congenital anomalies of the lumbopelvis per radiographs (including spina bifida occulta, lumbarization, sacralization, or spondylolisthesis); bridging osteophytes; history of any vertebral surgery; history of knee replacement surgery; history of ankle or foot surgery with fusion or bone removal; history of severe peripheral neuropathy; history of osteoporosis with vertebral compression fractures; history of fractures of spine/pelvis/lower extremity with malalignment; cognitive deficit that would interfere with compliance/treatment; severe heart or lung disease that would prevent patients from participating in an exercise program; pending litigation or disability claims; history of current drug or alcohol abuse or less than 1 year of sobriety; or pregnancy. Inclusion and exclusion criteria were chosen to make the heterogeneous CLBP population more homogenous. Each patient gave written informed consent in a manner approved by the local Human Research Advisory Committee and VA Research and Development Committee. Patients were randomized into a treatment or control group based upon computer-generated random numbers.

2.2. Measurement instruments

Several measurement instruments were used to measure outcomes. These included postural x-rays to measure LLD, and two questionnaires to measure physical and mental health functional levels and pain levels.

2.2.1. Postural X-rays

Because radiographic measurements are more accurate than a physical exam [42], especially for small differences in leg lengths [1,11], all patients had anterior-posterior (AP) x-rays of the pelvis to include the lumbar spine, femoral heads, and pubic symphysis. Lateral x-rays of the sacral base were also taken. These x-rays

were done with the patient standing (without wearing shoes) and with a plumb line for reference. The amount of pelvic obliquity was determined by the intersulcate line method as described by Fann [12–14]. The degree of obliquity (in millimeters) was used as the patient's goal height for correction. In the experimental group, x-rays were repeated once the goal height was obtained to verify that the pelvis was level. The measurements were made by one investigator. The x-rays were not repeated for the control group because x-ray measurements are stable over time [2,15].

2.2.2. Questionnaires

The following questionnaires were administered to the subjects pre- and post-treatment and at the 3- and 6-month follow-up appointments by a research assistant (RA). The RA was blinded as to the subject's group.

2.2.3. Medical Outcomes Study 36-Item Short Form Health Survey (*SF-36*)

The SF-36 was used to assess physical and mental health functional levels. It surveys general health status and profiles eight subsets for physical and mental health status. The SF-36 includes questions about personal functioning, pain, general health, vitality, social functioning, role functioning, and emotional/mental health. The scale ranges from 0 to 100, with higher numbers indicating better functioning. This scale is valid for measuring physical and mental health constructs in the general population [28,38] and is recommended for measuring outcomes in CLBP subjects [32].

2.2.4. McGill Pain Questionnaire – Short Form (*MPQ-SF*)

The MPQ-SF was used to assess level of pain. It includes 15 descriptors on a 4-point ordinal scale, a visual analogue scale (VAS) for current pain, and a Present Pain Intensity (PPI) Index. Higher numbers indicate more pain. This instrument has good construct validity when compared to the McGill Pain Questionnaire [29].

2.3. Procedures

The following procedures were used to treat the experimental group, provide "sham" treatment to the control group, and to analyze results from this study.

2.3.1. Experimental Group

The experimental group received corrective cork heal-lifts and, if necessary, orthotic devises, as follows.

2.3.2. Corrective Procedures

Pelvic obliquity was corrected per Dr. Irvin's method [25]. Briefly, a cork heel-lift was added to the shoe of the low side. The initial lift was 3 mm (1/8") when the goal height was less than or equal to 12 mm (1/2"), and 6 mm (1/4") if the goal height was greater than 12.5 mm (1/2"). An additional 3 mm (1/8") lift was added every 2 weeks until the target goal height was reached. The heel lift was easily removable so it could be transferred to the shoes the patient would be wearing. The lifts were to be worn by the patient during the majority of their waking hours while they were up and active.

2.3.3. Orthotics

Each patient had both feet examined in the standing position, as a pronated foot may contribute to a LLD [5, 6,37]. If the feet were pronated with fallen arches, the patient was measured for custom-molded orthotics with augmented lateral, medial, and metatarsal arches. Arches were augmented gradually until near-optimum foot position was obtained. The orthotics were to be transferred to shoes worn during the majority of the day when the patient was active.

2.3.4. Control group

To blind each subject to their group assignment (experimental versus control), patients were given off-the-shelf insoles (sham treatment) to wear in their shoes for the majority of the day while they were up and active. Patients were seen every other week for the period of time that would have been necessary for their pelvic obliquity to be gradually corrected if they had been assigned to the experimental group.

2.3.5. Postural exercises

Patients in both groups were taught postural stretches similar to those taught in conventional pain treatment programs, as it would not have been ethical to give the control group no treatment. These stretches were taught and then reviewed by a physical therapist in a group setting after each clinic appointment. Briefly, these exercises included stretching for gastrocnemius, soleus, quadriceps, hamstring, piriformis, iliopsoas/rectus femoris, hip adductors, upper trapezius, scalenes, quadratus lumborum, and anterior thorax. Patients were given a written home exercise program with pictures and instructed to do the exercises once daily.

Table 1
Demographics for experimental and control subjects

Group	Gender	Age	Length of Pain (yrs)	Degree of Pelvic Obliquity (mm)	Low side
Experimental	8 male/ 1 female	52.3 ($\pm$ 9.9)	10.1 ($\pm$ 9.2)	10.7 ($\pm$ 4.1)	5 right/ 4 left
Control	6 male/ 0 female	50.3 ($\pm$ 10.4)	16.8 ($\pm$ 16.6)	8.4 ($\pm$ 5.2)	3 right/ 3 left

2.3.6. Statistical analysis

Two-sample t-tests or χ^2 tests were used to compare the treatment groups with respect to demographic and medical characteristics. For SF-36 and MPQ-SF measures which were obtained at several points in time, methods for nonparametric analyses of longitudinal data described by Brunner et al. [8] were used to analyze the post-intervention data. To adjust the analyses for the effect of baseline measures, changes from baseline were modeled as dependent variables. Group, time and group-by-time interaction terms were included in the models as independent variables. The group-by-time interaction term provides a way to compare the profiles of the time curves between the treatment groups. In the absence of a significant interaction effect, the test of the group effect determines whether the effect "averaged' over time differs among treatments. Finally, the test of the time effect, which was evaluated for each treatment, determines whether simple trends over time exist.

Because six of the fifteen subjects have missing values at the 6-month follow-up period, only measures obtained at the end of treatment and at the 3-month follow-up period were analyzed. Two control subjects, however, did drop-out prior to their 3 month evaluation. To understand how these missing values might affect the proposed analysis, an analysis of the data in which the last observed non-missing value is carried-forward was performed. These results were consistent with the analysis of the unimputed data, and thus are not reported. An α-level of 0.05 was used to determine statistical significance for each test.

3. Results

Fifteen patients were recruited and assigned by a computer-generated randomization schedule to either the experimental or control group - nine were assigned to the experimental group and six to the control group. At baseline, there were no significant differences in mean age, degree of pelvic obliquity, or length of pain between the two groups (Table 1). By the 3-month follow-up, two subjects had dropped out of the control group. By the 6-month follow-up, one experimental subject had died and an additional subject had dropped out of each group.

The experimental and control groups were compared in order to 1) determine whether the intervention improved measures of physical and mental functioning and levels of pain over time as compared to controls (interaction effect), and 2) to determine, in the absence of significant interaction, whether the intervention produced consistent improvements across time (group effect). The results of the nonparametric longitudinal data analyses of the SF-36 and the MPQ-SF responses were as follows.

3.1. Interaction effects

Figures 1 and 2 show the results for the SF-36 and MPQ-SF measures, respectively. The group-by-time interaction terms were not found to be significant for any of the measures, which is not surprising because of the relatively small sample size.

3.2. Group effects

Overall group differences were detected between the intervention and control groups with respect to physical role functioning ($p = 0.012$), bodily pain ($p = 0.045$) and mental health index ($p = 0.025$) of the SF-36. A marginal difference was also detected with respect to physical function ($p = 0.072$). Of the four SF-36 measures that did not demonstrate statistically significant group differences, general health and vitality were consistently improved over time for the intervention group. Similarly, group differences were detected between the intervention and control groups using the sensory and affective scores of the MPQ-SF ($p < 0.01$). There were no significant differences with the PPI and VAS scores.

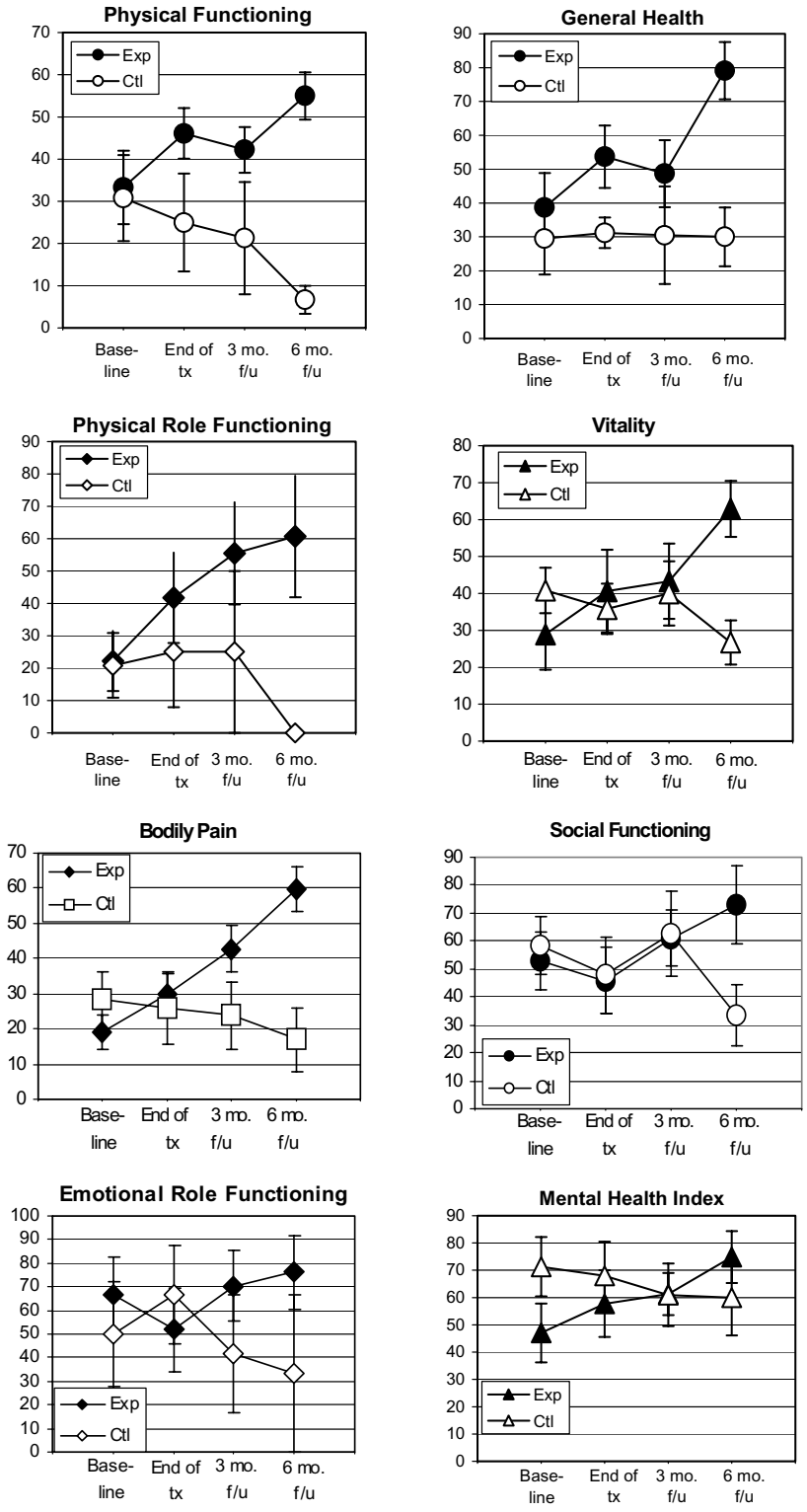

Fig. 1. Mean (and standard error) for the domains of the SF-36 for the experimental and control groups at the different time points.

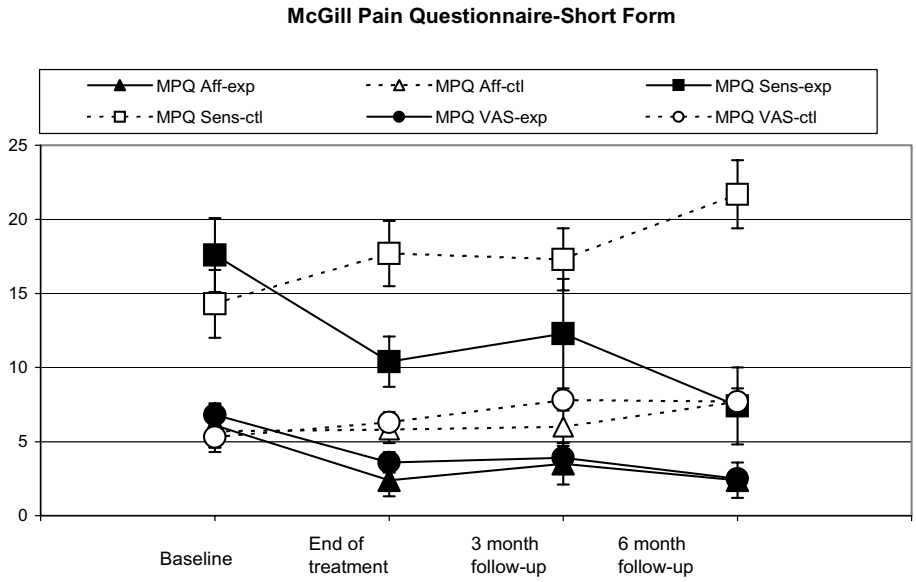

Fig. 2. Mean (and standard error) for the McGill Pain Questionnaire-Short Form for the experimental and control groups at the different time points.

3.3. Time effects

For the control group, none of the measures demonstrated a statistically significant time effect. While these trends were not significant, they were primarily decreasing suggesting that control subjects perceived their conditions to be worsening. A significant time effect was observed in the intervention group with respect to bodily pain of the SF-36 ($p = 0.009$) and the sensory, affective and VAS of the MPQ-SF ($p < 0.05$) where the subjects perceived their pain to be lessening. None of the other SF-36 measures were significant with respect to trends over time, but most did show improvement.

4. Discussion

Data from this study indicate that correction of pelvic obliquity by heel lifts and custom-molded arch supports appears to improve pain, physical and emotional functioning, and mental health indices in patients with CLBP. These findings lend some validity to the desirability of correcting pelvic obliquity in patients with CLBP to improve treatment outcomes. This treatment does have the advantages of being non-invasive, inexpensive, and easily reversible. Like any treatment for patients with chronic pain, improvement may not be seen in all patients. There may be a subset of patients with CLBP that benefit more from postural correction than others.

4.1. Related studies

It is difficult to compare the results from other studies with ours, as we found no other studies in the literature that used randomized methodology to assess the efficacy of correcting pelvic obliquity to improve pain and function. The studies that we did find that assessed correction of pelvic obliquity [20,21,23,24,33] were either descriptive or case reports. The following summarizes key findings from studies similar to ours.

In a study that assessed femoral head-height differences in subjects with and without CLBP, the authors found a higher percentage of those with CLBP had unequal leg lengths [34]. Additionally, for those with LLD, the mean difference in leg lengths was greater in those with CLBP than in those without CLBP. Although this difference was statistically significant, it was not clinically significant. In a study assessing prevalence of pelvic obliquity in subjects with and without CLBP, no significant differences were found in the percentage of subjects with pelvic obliquity or in the degree of pelvic obliquity between the two groups [13].

Numerous studies that investigated the effect of leg length discrepancies on various biomechanical parameters were found in the literature. The studies can be divided into those that simulated LLD and those that evaluated subjects with structural LLD.

4.1.1. Simulated LDD

Assessing standing parameters, Mahar and others found that as little as 1 cm of simulated LLD shifted the mean center of pressure toward the long side and increased postural sway [27]. They concluded that LLD of as little as 1 cm may be biomechanically important. Another study that that simulated LLD to assess the effect on innominate bone rotation found that contralateral innominate was rotated more anteriorly [43]. They also noted increased flexion of the trunk toward the side of the lift (functional scoliotic curve), and that the flexion increased as the size of the lift increased. Similarly, the spine of subjects with simulated LLD showed asymmetric lateral bending during heel-raising gait [26], with the authors concluding that patients with LLD were at greater risk for spinal degenerative joint disease.

Walsh and others simulated LLD in subjects and found compensatory mechanisms in both standing and walking [41]. Pelvic obliquity was the most common compensatory method. More complex mechanisms were used to compensate during walking, and included kinematic changes at the pelvis, knee, and ankle to shorten the long leg in stance and swing phases.

Brand simulated LLD and found no substantial change in the forces at the hip joint in subjects with simulated LLD, and concluded that LLD is unlikely to cause substantial changes in hip forces [7]. However, Gurney and others simulated LLD in older adults who were at least 55 years old (mean age of 72) by having the subjects walk on a treadmill simulating varying degrees of LLD [22]. Electromyography was used to measure muscle activity in the lower limbs. There were increases in oxygen consumption and perceived exertion with as little as 2 cm lift, but there were no statistically significant increases in muscle activity except in the quadriceps.

4.1.2. Structural LDD

Similar to those studies that used simulated LLD, maximum supination force (lateral force) was greater in the longer leg in subjects with structural LLD [35]. This force normalized with the addition of a heel lift. An increased incidence of asymptomatic sacroiliac joint malalignment was also found in college-aged students when LLD was present [36]. Unlike the study by Mahar, Murrell found no increase in postural sway in those with structural LLD as compared to those without, but used an unreliable tape-measure method to determine LLD [30].

Ten Brinke and others evaluated whether or not functional biomechanics of the lumbar spine could explain radicular pain [39]. In patients with documented herniated lumbar disc and radiating pain, pain radiated to the shorter leg in the majority of cases, significantly so in women. They concluded that on the side of the longer leg, lateral bending of the lumbar spine and compression of the disc will occur and, therefore, the disc may protrude on the shorter side.

Bhave and others performed gait studies on patients (mean age of 24) before and after limb-lengthening procedures [4]. They found that correction of LLD normalized stance time asymmetry and improved back pain in patients. With LLD, they found increased stance time on the shorter side, decreased walking velocity, increased cadence, decreased step length on the shorter side, foot in equinus on the shorter side, pelvic drop with leaning on the ipsilateral aspect of the trunk on the shorter side, and flexion of the contralateral knee. The compensatory patterns were to functionally equalize leg length.

4.2. Study limitations

One of the primary limitations of the present study was the small number of patients in each group. However, even with the small number of subjects, the results still showed significant improvement in the functional and pain outcome measures over a 6-month period. In regard to the attrition of the control group, the subjects who dropped out scored worse on the outcome measure that they had completed than those who completed the study; therefore, we expected that this may have artificially improved the control group's outcome measures at the six-month follow-up. Even with this possibility, we still saw significant improvement in the intervention group compared with the control one (see analysis section for analysis of the effect of missing data). Another limitation was the lack of assessment of compliance with the home exercise stretching program. We assumed that because the subjects were randomized, there would be similar compliance between the groups. However, improved functioning and decreased pain in the experimental group may have resulted from better compliance with the exercise program and not from the corrective lifts and orthotics. Finally, this study had a very small percentage of female subjects ($n = 1$). Women may have different outcomes with correction of their pelvic obliquity to treat their CLBP.

5. Conclusion

Our hypothesis was that treatment aimed at correcting pelvic obliquity would decrease pain and improve functioning more than treatment with therapeutic exercises alone. The results of this study do support this; however, because of the study limitations, additional research using larger experimental and control groups that include higher percentages of women, and better monitoring of exercise program compliance, will be needed for these results to be generalizable. But given the lack of randomized controlled studies on this topic, this research is an important first step in validating this non-invasive, low cost, easily reversible intervention for correcting pelvic obliquity and thereby reducing pain and enhancing physical and social functioning for those with CLBP.

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