Comparison of 2 Multimodal Interventions With and Without Whole Body Vibration Therapy Plus Traction on Pain and Disability in Patients With Nonspecific Chronic Low Back Pain

Gianni F. Maddalozzo, PhD, FACSM,[a] Brian Kuo, MS,[a] Walker A. Maddalozzo,[b]
Conner D. Maddalozzo,[c] and Johnny W. Galver, MS[d]

Abstract

Objective: The purpose of this secondary data analysis was to compare the effect of 2 multimodal exercise-based physical therapy interventions (one with and one without whole-body vibration [WBV] therapy plus traction) on pain and disability in patients with nonspecific chronic low back pain (NSCLBP).
Methods: We conducted a secondary analysis of data from 2 distinct samples. One sample was from the Focus on Therapeutic Outcomes Inc. (FOTO) group (n = 55, age 55.1 ± 19.0 years), and the other was the Illinois Back Institute (IBI) (n = 70, age 47.5 ± 13.4 years). Both groups of patients had NSCLBP for more than 3 months and a pain numeric rating scale (NRS) score of ≥7. Both groups received treatment consisting of flexibility or stretching exercises, core stability training, functional training, and postural exercises and strengthening exercises. However, the IBI group also received WBV plus traction. NSCLBP was measured before and after therapeutic trials using the NRS for pain and Oswestry Disability Index (ODI).
Results: The NRS scores were significantly improved in both groups, decreasing by 2 points in the FOTO group and by 5 points in the IBI group. The ODI scores were significantly improved in both groups; the FOTO group score improved by 9 points and the IBI group improved by 22 points.
Conclusions: The results of this preliminary study suggest that NPS and ODI scores statistically improved for both NSCLBP groups receiving multimodal care. However, the group that included WBV therapy plus traction in combination with multimodal care had greater clinical results. This study had several limitations making it difficult to generalize the results from this study sample to the entire population. (J Chiropr Med 2016;xx:1-9)
Key Indexing Terms: *Low Back Pain; Exercise Therapy*

Introduction

Nonspecific chronic low back pain (NSCLBP)[1] has multifactorial origins and poses a diagnostic and therapeutic challenge for a practicing physician. Americans annually spend more than $50 billion to help alleviate low back pain, and that number continues to grow, resulting in an economic burden on individuals, families, communities, industry, and governments.[2] Each year, more than 149 million workdays are lost at an estimated cost of $560 billion to $635 billion dollars, of which $297 billion to $336 billion are a result of lost productivity and wages.[1,3] NSCLBP is measured by duration and is defined as persistent chronic pain that lasts for more than 3 months and significantly decreases the quality of life of the individual.[4]

Common treatment strategies for NSCLBP include (1) information gathering, office visit consults, laboratory tests, and imaging (radiography, ultrasound, computed tomography, or magnetic resonance imaging); (2) chiropractic treatment; (3) physical therapy (PT) treatments; (4) opioids or nonsteroidal antiinflammatory drugs; (5) intensive

[a] School of Biological and Population Health Sciences, Corvallis, OR.
[b] Oregon Institute of Technology, Wilsonville, OR.
[c] Linn Benton Community College, Albany, OR.
[d] BPM Physical Therapy Center, Salem, OR.
Corresponding author: Gianni F. Maddalozzo, PhD, FACSM, Oregon State University, 226 Langton Hall, Corvallis, OR 97331. Tel.: +1-541-737-6802.
(e-mail: *gianni.maddalozzo@oregonstate.edu*).
Paper submitted June 15, 2015; in revised form July 6, 2016; accepted July 7, 2016.
1556-3707

http://dx.doi.org/10.1016/j.jcm.2016.07.001

multidisciplinary biopsychosocial rehabilitation; and (6) physician visits for nerve blocks, surgeries, or comparable procedures. Unfortunately, a lack of consistency among measures of recovery from NSCLBP makes it extremely difficult to determine whether a treatment strategy has been successful.[2]

Pharmacotherapy as a treatment strategy for NSCLBP results in high cost, minimal pain reduction, side effects, and limited efficacy. According to the Centers for Disease Control and Prevention, pharmaceutical drug prescriptions such as opioid analgesics account for nearly 75% of all pharmaceutical overdose deaths, resulting in more fatalities than heroin and cocaine combined.[5] Americans consume 80% of the global opioid supply and 99% of the global hydrocodone supply, and greater daily use of opioids correlates strongly with lower likelihood of the user returning to work.[6] Returning to work is an important objective personal health outcome, because being out of work is associated with poor health.[7]

It is estimated that nearly 600,000 Americans opt for back surgeries each year, with some resulting in no significant improvement in low back pain or function. In a recent study,[6] the authors reported that after 2 years, only 26% of individuals who had surgery returned to work, compared with 67% of patients who did not have surgery, and 27% had repeat surgery. Additionally, 76% of these patients were still taking opioids 90 days after surgery, with daily doses increasing by 41%, as well as experiencing reported increases in disability, prolonged work loss, and poor return to work rates.[6]

Few, if any, of the most commonly used interventions appear to offer any relief for patients with NSCLBP. In most patients, reductions in the number of NSCLBP-related complaints are nonsignificant while the patient continues to experience pain.[8-10] The current pharmacologic and surgical approach to the treatment of NSCLBP warrants that other noninvasive approaches, without the known adverse pharmacologic and surgical side effects, need to be identified.

One such potential multimodal method that has not been widely studied is whole-body vibration (WBV) therapy in combination with traction, strengthening exercises, core stability training, functional training, flexibility or stretching exercises, and balance and postural control. WBV therapy involves the application of vibratory stimuli throughout the body by standing on a vibrating platform.[11] The vibration is created by a mechanical linear or oscillating motion, which transfers energy through the body, stimulating muscles to contract.[12] WBV has recently been used to reduce back pain and fibromyalgia pain in women.[13,14] Because current theory suggests that pain operates through common mechanisms and that no pain mechanism is an inevitable consequence of a particular disease process,[15] it stands to reason that WBV may be effective in treating NSCLBP.

The purpose of this secondary data analysis was to assess the effect of 2 multimodal interventions to reduce pain in patients with NSCLBP, one combining WBV therapy, traction, and exercise and the other excluding WBV therapy.

Methods

Participants

We conducted a secondary analysis of previously collected data from the Focus on Therapeutic Outcomes, Inc. (FOTO) database (Knoxville, TN)[16-22] and the Illinois Back Institute (IBI) (Chicago, IL). The platform used for outcomes data collection has previously been described.[23-25] Our deidentified analytical sample was selected from 2 data sets of clinics treating patients diagnosed with confirmed chronic low back pain (FOTO, n = 616; IBI, n = 70). Participants' demographic characteristics at baseline are presented in Table 1. From the FOTO data sets, we were able to match FOTO patients (n = 55) to patients from the IBI (n = 70) based on the following inclusion criteria: All patients had to have confirmed NSCLBP, a numeric rating scale (NRS) score of ≥7, and completion of the Oswestry Disability Index (ODI) and the NRS for pain at intake and completion of treatment; all clinics had to have at least 1 physical therapist on staff; and demographic data had to consist of similar body mass index (BMI) and similar number of treatments for both groups. Because this was a preliminary study, we did not consider sex differences or age. The number of treatments each group received during the intervention is presented within Table 1. At baseline, a 1-way analysis of variance was used to determine whether any significant differences existed between the FOTO and IBI participants for NRS and ODI scores, number of PT treatments received, BMI, and time from first onset of pain (years). The Institutional Review Board at Oregon State University approved this study involving secondary analysis of previously collected data. Initial therapy evaluation was categorized as chronic pain lasting >90 days.[26]

Table 1. *Baseline Demographic Characteristics of Participants*

	FOTO (n = 55)		IBI (n = 70)		
Variable	Mean	SD	Mean	SD	*P*
NRS	7.8	0.9	7.5	0.8	>.06
ODI	41.9	16.5	46.8	13.3	>.4
Age (y)	55.1	18.8	50.1	11.3	>.07
Number of treatments	14.1	6.0	13.1	5.9	>.07
BMI	28.3	6.6	27.7	5.3	>.52
Pain onset (y)	1.8	0.4	1.9	0.3	>.060

BMI, body mass index; *FOTO,* Focus on Therapeutic Outcomes; *IBI,* Illinois Back Institute; *NRS,* numeric rating scale; *ODI,* Oswestry Disability Index; *SD,* standard deviation.

Treatment Intervention

The FOTO database allowed the clinician to document, at patient discharge, all interventions that the patient received during the treatment episode. However, clinicians did not document the specific treatment the patient received during each visit. The patients we identified from the FOTO database as NSCLBP (n = 55) received treatment using the McKenzie method, flexibility or stretching exercises, core stability training, functional training, postural exercises, and strengthening exercises.

The McKenzie approach uses exercise to ”centralize” the patient’s pain to the lower back area to treat pain rather than the symptoms. For a detailed account of the full clinical protocol of each of the syndromes and their respective treatment programs, please refer to McKenzie instructional materials.[27] Stretching and flexibility exercises are used to increase range of motion. The aim is to reduce pain, improve movement, and improve functional limitations of movement. Core strengthening exercises are used to restore the coordination and control of the trunk muscles to improve control of the lumbar spine and pelvis.[28,29] These exercises aim to restore the strength and endurance of the trunk muscles to meet the demands of control.[28,29] Posture is addressed through a series of exercises to correct movement dysfunction, which is closely related to postural correction, spinal stability, and restoring neuromuscular control. Functional training exercises are used to restore functional limitations of movement and to train the body for the activities performed in daily living. Muscular strengthening exercises are typically prescribed to improve strength and endurance of major muscle groups to add stabilization and support to the trunk area. Core exercises consist of front and side planks and back bridges. Neuromuscular balance stability exercises followed Vladimir Janda’s protocol to treat muscle imbalance and movement impairment.[30,31] Flexibility exercises are used to improve hamstring, quadriceps, piriformis, and hip joint capsule range of motion.

In addition to these treatments, the IBI group also received WBV therapy plus traction. WBV may use a WBV traction table (0.6-1.2 mm at 20-30 Hz) and vibration platform (0.6-1.2 mm at 40-50 Hz) (IBI, Wheaton, IL; patent pending). The WBV traction table consists of a table with 4 lever arms, 2 at the bottom next to the patient’s feet and 2 at the top next to the patient’s head. The 4 lever arms are designed to create traction on the patient’s spine independently by affecting either one of the 4 posts. The WBV platform is used for functional strengthening exercises movements such as wall squats, squats, and lunges.

Measures

Numeric Rating Scale

The NRS is an 11-point scale for patient self-reporting of pain. It is for adults and children ages 10 years and older.[32] Pain was measured using the NRS[33,34] at baseline and after intervention. The NRS has a numeric range of 0 (no pain) to 10 (worst pain possible).[33] Pain classifications are as follows: 0 = no pain, 1-3 = mild pain, 4-6 = moderate pain, and 7-10 = severe pain.[32] Adequate validity of the NRS has been established with correlation coefficients ≥ 0.80 between the NRS and visual analog and verbal rating scales.[35-37] The NRS has also revealed moderate reliability, with a reported κ coefficient of 0.59.[36,37]

Oswestry Disability Index

The ODI is a self-administered questionnaire measuring “back-specific function” on a 10-item scale with 6 response categories each. Each item scores from 0 to 5, higher scores being worse, which is transformed into a 0-100 scale. The 10 items include pain intensity, personal care, lifting, walking, sitting, standing, sleeping, work, social life, and traveling. Patients with scores between 0 and 20 have minimal disability; between 21 and 40, moderate disability; between 41 and 60, severe disability; between 61 and 80, crippled; and between 81 and 100, bedbound or exaggerating their symptoms. The ODI has been validated for use with patients with low back pain and has high reliability (R = 0.99).[38,39]

Statistics

Power of the study was calculated for a *t* test of a mean decrease in numeric pain rating scale of 3 points. To be conservative, the effect size was reduced by 25% and the standard deviation was increased by 25%. Ninety percent power at 95% confidence is achieved with 44 participants per group. A paired-samples *t* test was conducted to compare changes in percentage of disability scores from the NRS pain scores and ODI questionnaire at baseline and after intervention in the FOTO and IBI groups. For all outcome variables, an α level of 0.025 was considered statistical significance. Statistical analyses were performed with R version 3.0.3 for Windows.

Results

The study included 125 patients: 50 men and 75 women (Fig 1). Patients’ mean age was 51.3 ± 15.2 years for men and 50.5 ± 17.2 years for women. The means and standard deviations are presented in Tables 1-4. At baseline, no significant differences existed between FOTO and IBI for NRS and ODI scores, number of PT treatments received, BMI, and time from first onset of pain (years) (Table 1). When examining the NRS pain score differences before and after treatment (Table 2), we observed a significant difference within each group. Within the FOTO group, we estimate an average drop in pain of 2.44 points after treatment ($P < .001$, 97.5% confidence interval [CI] 1.80, 3.1), whereas the IBI group averaged a decrease in pain of

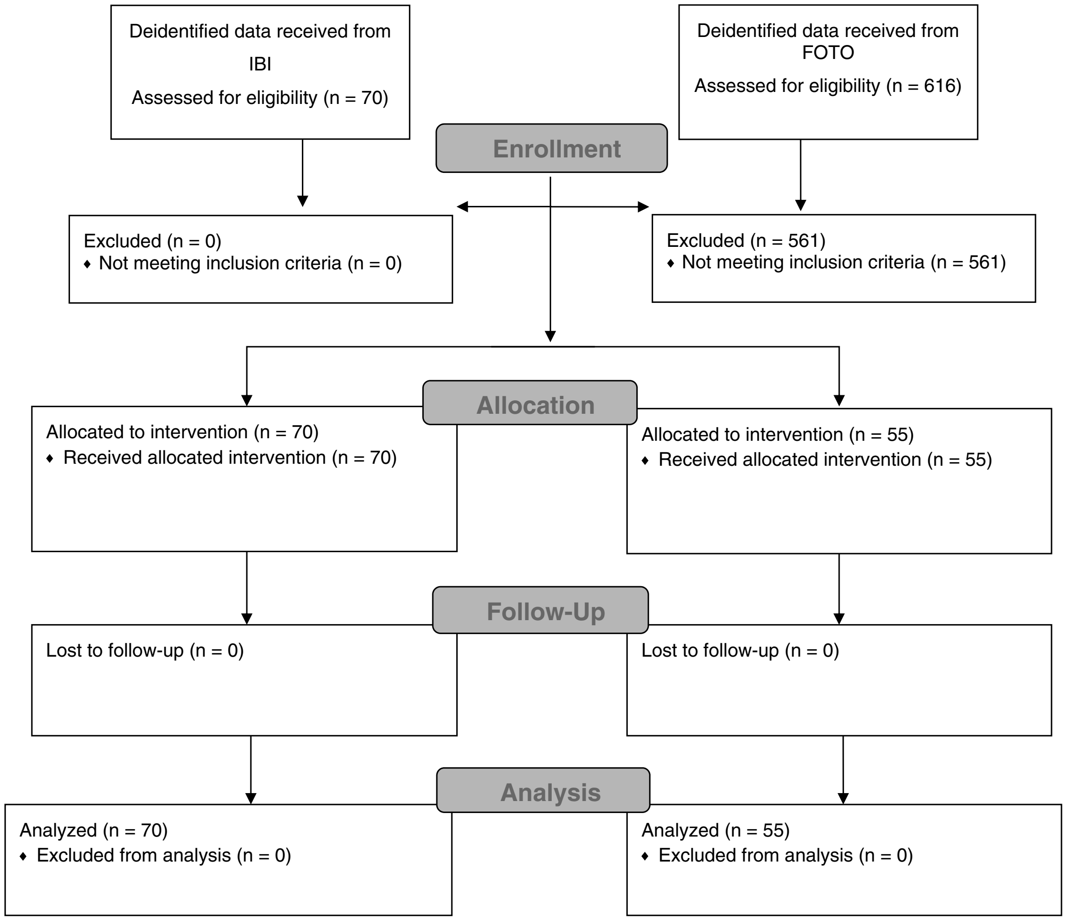

Fig 1. *Flow diagram. FOTO, Focus on Therapeutic Outcomes; IBI, Illinois Back Institute.*

Table 2. *Baseline and Postintervention Means, Standard Deviations, and 97.5% Confidence Intervals for Numeric Rating Scale Scores for the FOTO (n = 55) and IBI (n = 70) Groups*

	FOTO						IBI					
	Baseline		Post				Baseline		Post			
Variable	Mean	SD	Mean	SD	*P*	97.5% CI	Mean	SD	Mean	SD	*P*	97.5% CI
NRS	7.8	0.9	5.4	2.2	<.001 [a]	1.80, 3.07	7.5	0.8	2.2	1.4	<.001 [a b]	4.9, 5.7

CI, Confidence interval; *FOTO,* Focus on Therapeutic Outcomes; *IBI,* Illinois Back Institute; *NRS,* numeric rating scale; *SD,* standard deviation.

[a] Both the IBI and FOTO groups showed significant improvement from baseline.

[b] The IBI group showed statistically greater improvement than the FOTO group.

Table 3. *Means, Standard Deviations, and Confidence Interval Oswestry Disability Index Baseline and Postintervention Scores for Men and Women in FOTO (n = 55) and IBI (n = 70) Groups*

	Baseline		Post		Baseline		Post			
Variable	Mean	SD	Mean	SD	Mean	SD	Mean	SD	*P*	97.5% CI
	FOTO (Men) n = 13				FOTO (Women) n = 42					
ODI % disability	31.7	15.1	20.6	11.5	45.0	15.7	36.2	17.5	.6	13.23%, −8.7%
	IBI (Men) n = 37				IBI (Women) n = 33					
ODI % disability	47.9	14.4	22.1	13.3	45.1	15.7	27.9	13.9	.023	16.3%, 0.11%

CI, Confidence interval; *FOTO,* Focus on Therapeutic Outcomes; *IBI,* Illinois Back Institute; *ODI,* Oswestry Disability Index; *SD,* standard deviation.

Table 4. *Mean, Standard Deviation, and Confidence Interval Oswestry Disability Index Baseline and Postintervention Scores for FOTO (n = 55) and IBI (n = 70) Groups Regardless of Sex*

	FOTO						Illinois Back Institute					
	Baseline		Post			97.5%	Baseline		Post			97.5%
Variable	Mean	SD	Mean	SD	*P*	CI	Mean	SD	Mean	SD	*P*	CI
ODI % disability	41.9	16.5	32.5	17.5	<.001 [a]	5.6%, 13.1%	46.8	13.3	24.8	13.8	<.001 [a b]	17.8%, 26.2%

Although we observed a marginally significant difference between in ODI scores between men in the FOTO and IBI groups, the FOTO group had a population of 14 versus 37 for the IBI group. Because there were no differences observed between genders within the FOTO group and because of the small sample size for men in the FOTO group, we merged sexes for this analysis.

CI, Confidence interval; *FOTO,* Focus on Therapeutic Outcomes; *IBI,* Illinois Back Institute; *ODI,* Oswestry Disability Index; *SD,* standard deviation.

[a] Both the IBI and FOTO groups showed significant improvement from baseline

[b] The IBI group showed statistically greater improvement than the FOTO group.

5.3 points after therapy treatments ($P < .001$, 97.5% CI 4.9, 5.7). Although both the FOTO and IBI groups had a significant decrease in pain reported by the NRS pain score scale, the IBI group's pain decreased significantly more (Table 2).

At the conclusion of the treatment interventions, the groups' differences in percentage of disability (postintervention to preintervention) were obtained from the ODI questionnaire scores; in the FOTO group we found an average decrease of 9.35 points (df = 54, $P < .001$, 97.5% CI 5.6%, 13.1%), whereas the IBI had an average decrease of 22 points (df = 69, $P < .001$, 97.5% CI 17.8%, 26.2%).

The IBI group had a marginally significant difference ($P = .02$) in percentage of disability change between men and women. On average, men had a drop in percentage of disability score that was 8.2 points greater than women within the IBI group (df = 67.7, 97.5% CI 16.3%, 0.11%). There was no difference in scores between sexes within the FOTO group ($P = .56$). For this analysis, we conducted an unequal variance *t* test where the degrees of freedom are approximated by the Satterthwaite method (Table 3).

When considering several regression models (ie, main effects only vs interaction effects with the group variable), it appears that there was a strong association between the groups (FOTO and IBI) and percentage of disability change. On average, the IBI group saw an 11.1-point larger decrease in percentage of disability compared with the FOTO group, after accounting for any effects of age, sex, and BMI (df = 119, $P < .001$, 97.5% CI 4.9%, 17.3%). There was a marginal difference between men and women after accounting for treatment group, age, and BMI, which was mainly due to the IBI group (Table 3). These results suggest that both therapeutic interventions decreased the percentage of ODI disability scores (Table 4).

Discussion

The results of this study indicate that patients' NRS and ODI scores significantly decreased regardless of therapy intervention. However, the IBI group (inclusion of vibration therapy) had better outcomes.

A strength of this study is that participants in both groups had a baseline NRS score of ≥7, a classification of severe pain. The FOTO group's mean NRS was 7.8 and the IBI group's NRS was 7.5, classifying all group participants with severe pain.[33] The majority of exercise intervention studies for NSCLBP that we reviewed reported mean baseline NRS scores ranging between 3.1 and 6.4[40-45] with a pain classification of mild to moderate,[33] or 1-2 classifications below participants in our study. A change of –2 points has been found to be associated with clinically important outcomes such as reduction in pain medication intake or returning to work or both.[46] By having all participants classified with severe pain at baseline (NRS ≥ 7), we believed that if an exercise intervention decreased the patients pain by 2 points (7 to 5 or severe to moderate) it would be more clinically meaningful than a decrease in pain from 4 to 2 (moderate to mild).

Additionally, our participants' baselines ODI scores were 41.9 and 46.8 for the FOTO and IBI groups, respectively, classifying our participants regardless of group as having severe disability,[38,39] whereas the majority of exercise intervention studies for NSCLBP that we reviewed reported mean baseline ODI scores of 19.44-39,[40-45,47-51] classifying these participants as having minimal to moderate disability.[38,39]

The NRS pain and ODI disability scores are among the outcome measures most commonly used by physical therapists.[52] In our study, NRS pain scores were found to decrease significantly in both the FOTO and IBI groups and correspond with the decreases observed from the ODI scores. The IBI group averaged a greater decrease in pain than the FOTO group. In both cases, decrease in pain was clinically significant.[46] A change of 2 points on a 0-10 NRS has been noted as being clinically meaningful in particular if the change results in a score on the lower end of the scale.[46] Hoffman et al[43] reported that pain reductions of ≥50% have been used to classify treatment response in diabetic neuropathy pain trials, with an NRS pain reduction of 2 points considered clinically meaningful. The IBI group's NRS score was reduced by approximately 70%, which is well above the ≥50% reduction recommended by Hoffman et al.[43] For ODI, the IBI group had a greater improvement than the FOTO group. According to Solberg et al,[53] a change score of at least 20 points in the ODI is considered meaningful; however, it is important to note that a minimal clinically important difference score has yet to be established for the ODI. Fairbank et al,[38] who created the ODI, suggested that a final ODI score of ≤20% represented no disability, although no evidence exists to support the notion that an ODI score of ≤20% represents no disability. Others have suggested that improvements of 50% change,[54] 30% change,[55,56] and 10% change[57,58] are required to be clinically meaningful and that changes of <10% may be attributable to error in the measurement.[38] Our analysis revealed that the ODI scores for the FOTO group improved by 22% and for the IBI group by 47%.

Pain classifications have been consistently associated with patient outcomes and medical care utilization,[59] and in the United States pain is the leading cause of physician consultation.[60] For example, in a cross-sectional study of 602 patients with neuropathic pain, 20% of those with moderate pain severity reported reductions in scheduled work time compared with only 12% of those with mild pain.[61] Nearly half of all patients with moderate pain severity in this sample reported visiting their physician at least twice for pain-related issues in the previous week, compared with only 27% of patients with mild pain. Because current theory suggests that pain operates through common mechanisms and that no pain mechanism is an inevitable consequence of a particular disease process,[15] it stands to reason that the number of visits to physicians would be very similar in patients with chronic lower back pain. The IBI group's NRS scores decreased to 2.2, representing an overall classification of mild pain. If the findings of Marchettini et al[61] are correct, all of the IBI group could potentially successfully return to work as productive employees based on a pain classification of mild or better.

We recently found that WBV can significantly reduce pain and improve quality of life and walking speed in people with diabetic neuropathy pain.[62] WBV involves the use of oscillatory muscle stimulation. WBV typically involves either standing or lying on a vibration platform or table. One hypothesis of how WBV works is presented by Rittweger et al,[12] who propose that the vibrations' stimuli are transmitted throughout the body, eliciting muscle stimulation through vibratory tonic reflex when the short and fast changes in muscle length are detected by different proprioceptive organs, thus enhancing the frequency of motor evoked potentials.[12] Kim et al[63] suggest that patients with chronic low back pain do not have the ability to establish lumbar extension strength or static and dynamic balance, all of which require certain levels of strength and balance to establish and maintain a neutral position and to control posture.

Although no specific mechanism for the improvements in the NRS pain and ODI disability scores was identified in this study, Sparto et al[64] have suggested that the coordination between agonist and synergist muscles plays a pivotal role in resisting injury. Agonist–antagonist muscle coactivation that WBV is believed to initiate is an important mechanism of how vertebral joint injury is prevented. WBV exercise has been found to acutely increase muscle activation during exposure,[65,66] resulting in postactivation potentiation,[67] and to improve muscular performance.[66] Zaidell et al[68] has suggested that the tonic vibration reflex is operative during WBV when antagonist musculature is simultaneously being vibrated. Furthermore, Cholewicki et al[69] have reported that antagonistic trunk muscle coactivation is necessary to provide mechanical stability to the lumbar spine around a neutral posture,[69] resulting in an increased response to increased axial load on the spine. Thus, agonist–antagonist muscle coactivation resulting from WBV training could potentially explain the improvements attributed to the IBI group with the implementation of vibration therapy plus traction by improving lumbar extension strength and static and dynamic balance, all of which are needed to maintain a neutral position and to control posture.

Both traction and vibration therapy have been identified as therapies that have produced positive results in decreasing pain in patients with lower back pain. Recently, Wang et al[70] reported that traction applied to patients while lying on a table in combination with 12 Hz of vibration was effective in reducing muscle fatigue of the lumbar erector spinae and upper trapezius muscle groups, resulting in an effective treatment therapy for patients with low back pain. Our findings support the therapeutic benefits of combining traction and vibration reported by Wang et al.[70]

WBV has been reported to reduce pain and fatigue levels; to improve strength, postural control, functional ambulation, mobility, and trunk control[71-78]; and to promote significant improvement in the ODI scores of a group of patients with NSCLBP.[47] Thus, it is possible that WBV may have had a synergistic effect while enhancing the benefits of therapeutic exercise treatments that the IBI group received, resulting in significant improvement in pain scale and ODI scores. Iwamoto et al[14] recently reported that WBV helped in reducing chronic back pain by relaxing the back musculature of postmenopausal osteoporotic women treated with alendronate (commonly prescribed medication for osteoporosis), resulting in a decrease in pain of clinical significance (ie, ≥2 points).

Fear of pain has been identified as an important element of the fear-avoidance model of musculoskeletal pain,[79,80] suggesting that a fear of pain may potentially lead to avoidance behavior that in turn may result in chronic disability and exaggerated pain perception.[79,80] Because WBV treatments are generally considered passive modes of exercise (ie, standing, lying, or sitting on a vibration platform), it is possible that the use of WBV by the IBI treatment may have potentially reduced the fear of pain, thus enabling the participants to increase their physical activity levels on the vibration platform and table, which in turn may have contributed to the significant decreases observed in both the NRS pain and ODI scores.

Limitations

The primary limitation of this study is its inability to identify when and how often each patient received a specific treatment in the FOTO group. The clinician's notes at patient discharge indicate only which interventions the patient received during the treatment episode but not those received per patient visit. Because some types of treatment may produce better outcome results than others, the availability of this knowledge from the FOTO data set would have made our design and interpretation of findings stronger. Additionally, we did not have a true control group (eg, a no-treatment group or a placebo group), and sex and age statistical analyses were not included between groups; this may have influenced the study findings. We are aware that this limits our ability to compare findings between these 2 groups and those reported in other published studies.[81] No posttreatment follow-up assessments were provided, thus not allowing us to determine the long-term effectiveness of either treatment protocol. Regardless, the findings of this primary study provide evidence that WBV therapy in combination with traction and exercise significantly reduces pain and disability scores computed from the ODI questionnaire. Finally, we did not conduct a randomized controlled trial comparing these 2 interventions.

Of course, this study has several limitations that make it difficult to generalize its results to the entire population. Appropriately powered studies are needed to fully elucidate the long-term potential of WBV therapy in combination with traction and exercise to reduce chronic lower back pain. However, the magnitude and broad spectrum of improvements provide a basis to embark expeditiously on such an investigation.

Conclusions

The results of this preliminary study suggest that NPS and ODI scores statistically improved for both groups receiving multimodal care. However, the group that included WBV therapy plus traction in combination with multimodal care had greater clinical results.

Contributorship Information

Concept development (provided idea for the research): G.F.M.

Design (planned the methods to generate the results): G.F.M.

Supervision (provided oversight, responsible for organization and implementation, writing of the manuscript): G.F.M.

Data collection/processing (responsible for experiments, patient management, organization, or reporting data): G.F.M.

Analysis/interpretation (responsible for statistical analysis, evaluation, and presentation of the results): G.F.M., B.K., J.W.G., W.A.M., C.D.M.

Literature search (performed the literature search): G.F.M., B.K., J.W.G., W.A.M., C.D.M.

Writing (responsible for writing a substantive part of the manuscript): G.F.M.

Critical review (revised manuscript for intellectual content, this does not relate to spelling and grammar checking): G.F.M., B.K., J.W.G., W.A.M., C.D.M.

Funding sources and conflicts of interest

Focus on Therapeutic Outcomes Inc. (FOTO; Knoxville, TN) and the Illinois Back Institute (Chicago, IL) provided the data to conduct this secondary analysis. No conflicts of interest were reported for this study.

Practical Applications

- Multimodal care that includes WBV plus traction may help reduce pain and improve function in patients with chronic low back pain.

References

1. Institute of Medicine (US) Committee on Advancing Pain Research, Care, and Education. *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*. Washington, DC: National Academies Press; 2011.
2. National Institutes of Health, National Institute of Neurological Disorders and Stroke. *Low Back Pain Fact Sheet*. NIH Publication No. 15-5161. Bethesda, MD: National Institutes of Health; 2014.
3. Steglitz J, Buscemi J, Ferguson MJ. The future of pain research, education, and treatment: a summary of the IOM report "Relieving pain in America: a blueprint for transforming prevention, care, education, and research". *Transl Behav Med.* 2012;2(1):6-8.
4. Chou R. Low back pain (chronic). *Am Fam Physician.* 2011; 84(4):437-438.
5. Centers for Disease Control and Prevention. *Policy impact: prescription painkiller overdoses*. Available at: http://www.cdc.gov/homeandrecreationalsafety/rxbrief/. Accessed April 15, 2015.
6. Nguyen TH, Randolph DC, Talmage J, Succop P, Travis R. Long-term outcomes of lumbar fusion among workers' compensation subjects: a historical cohort study. *Spine (Phila Pa 1976).* 2011;36(4):320-331.
7. Rueda S, Chambers L, Wilson M, et al. Association of returning to work with better health in working-aged adults: a systematic review. *Am J Public Health.* 2012;102(3):541-556.
8. Bogduk N, Jull G. Manual therapy produces greater relief of neck pain than physiotherapy or general practitioner care. *Physiother.* 2002;48(3):240-241.
9. Bogduk N. Management of chronic low back pain. *Med J Aust.* 2004;180(2):79-83.

10. Koes BW, van Tulder MW, Thomas S. Diagnosis and treatment of low back pain. *BMJ.* 2006;332(7555): 1430-1434.
11. Merriman H, Jackson K. The effects of whole-body vibration training in aging adults: a systematic review. *J Geriatr Phys Ther.* 2009;32(3):134-145.
12. Rittweger J. Vibration as an exercise modality: how it may work, and what its potential might be. *Appl Physiol.* 2010; 108(5):877-04.
13. Alentorn-Geli E, Padilla J, Moras G, Lázaro Haro C, Fernández-Solà J. Six weeks of whole-body vibration exercise improves pain and fatigue in women with fibromyalgia. *J Altern Complement Med.* 2008;14(8):975-981.
14. Iwamoto J, Takeda T, Sato Y, Uzawa M. Effect of whole-body vibration exercise on lumbar bone mineral density, bone turnover, and chronic back pain in post-menopausal osteoporotic women treated with alendronate. *Aging Clin Exp Res.* 2005;17(2):157-163.
15. Woolf CJ, Mannion RJ. Neuropathic pain: aetiology, symptoms, mechanisms, and management. *Lancet.* 1999; 353(9168):1959-1964.
16. Iezzoni LI. Risk adjusting rehabilitation outcomes: an overview of methodologic issues. *Am J Phys Med Rehabil.* 2004;83(4):316-326.
17. Resnik L, Hart DL. Predictors of physical therapy clinic performance in the treatment of patients with low back pain syndromes—author response. *Phys Ther.* 2008;88(9): 1009-1011.
18. Resnik L, Liu D, Hart D, Mor V. Benchmarking physical therapy clinic performance: Statistical methods to enhance internal validity when using observational data. *Phys Ther.* 2008;88(9):1078-1087.
19. Resnik L, Liu D, Mor V, Hart D. Predictors of physical therapy clinic performance in the treatment of patients with low back pain syndromes. *Phys Ther.* 2008;88(9):989-1004.
20. Dobrzykowski EA, Nance T. The Focus on Therapeutic Outcomes (FOTO) Outpatient Orthopedic Rehabilitation Database: results of 1994–1996. *J Rehabil Outcomes Meas.* 1997;1(1):56-60.
21. Swinkels IC, Hart D, Deutscher D, et al. Comparing patient characteristics and treatment processes in patients receiving physical therapy in the United States, Israel and the Netherlands: cross sectional analyses of data from three clinical databases. *BMC Health Serv Res.* 2008;8: 163.
22. Swinkels IC, van den Ende CH, de Bakker D, et al. Clinical databases in physical therapy. *Physiother Theory Pract.* 2007; 23(3):153-167.
23. Freburger JK, Carey TS, Holmes GM. Physician referrals to physical therapists for the treatment of spine disorders. *Spine J* 2005;5(5):530-541.
24. Hart LG, Deyo RA, Cherkin DC. Physician office visits for low back pain. Frequency, clinical evaluation, and treatment patterns from a U.S. national survey. *Spine (Phila Pa 1976).* 1995;20(1):11-19.
25. Iezzoni LI. An introduction to risk adjustment. *Am J Med Qual.* 1996;11(1):S8-11.
26. Zimmerman DR. Improving nursing home quality of care through outcomes data: the MDS quality indicators. *Geriatr Psychiatry.* 2003;18(3):250-257.
27. McKenzie R, May S. *The Lumbar Spine Mechanical Diagnosis & Therapy*. Waikanae, NZ: Spinal Publications; 2003.
28. Nesser TW, Huxel KC, Tincher JL, Okada T. The relationship between core stability and performance in division I football players. *J Strength Cond Res.* 2008; 22(6):1750-1754.
29. Okada T, Huxel KC, Nesser TW. Relationship between core stability, functional movement, and performance. *J Strength Cond Res.* 2011;25(1):252-261.
30. Key J, Clift A, Condie F, Harley C. A model of movement dysfunction provides a classification system guiding diagnosis and therapeutic care in spinal pain and related musculoskeletal syndromes: a paradigm shift—Part 2. *J Bodyw Mov Ther.* 2008;12(2):105-120.
31. Key J, Clift A, Condie F, Harley C. A model of movement dysfunction provides a classification system guiding diagnosis and therapeutic care in spinal pain and related musculoskeletal syndromes: a paradigm shift—Part 1. *J Bodyw Mov Ther.* 2008;12(1):7-21.
32. National Institutes of Health, Warren Grant Magnuson Clinical Center. Pain intensity instruments, July 2003. Available at: http://www.mvltca.net/presentations/mvltca.pdf. Accessed March 12, 2015.
33. Turk DC, Melzack R. *Handbook of Pain Assessment*. 3rd ed. New York, NY: Guilford Press; 2011.
34. Williamson A, Hoggart B. Pain: a review of three commonly used pain rating scales. *J Clin Nurs.* 2005;14(7):798-804.
35. Bijur PE, Silver W, Gallagher EJ. Reliability of the visual analog scale for measurement of acute pain. *Acad Emerg Med.* 2001;8(12):1153-1157.
36. Lara-Muñoz C, De Leon SP, Feinstein AR, Puente A, Wells CK. Comparison of three rating scales for measuring subjective phenomena in clinical research. I. Use of experimentally controlled auditory stimuli. *Arch Med Res.* 2004;35(1):43-48.
37. Ponce de Leon S, Lara-Muñoz C, Feinstein AR, Wells CK. A comparison of three rating scales for measuring subjective phenomena in clinical research. II. Use of experimentally controlled visual stimuli. *Arch Med Res.* 2004;35(2):157-162.
38. Fairbank JC, Couper J, Davies DB, O'Brien JP. The Oswestry low back pain disability questionnaire. *Physiotherapy.* 1980; 66(8):271-273.
39. Nordin M, Skovron ML, Hiebert R, et al. Early predictors of delayed return to work in patients with low back pain. *J Musculoskel Pain.* 1997;5(2):5-27.
40. Baena-Beato PA, Arroyo-Morales M, Delgado-Fernández M, Gatto-Cardia MC, Artero EG. Effects of different frequencies (2-3 days/week) of aquatic therapy program in adults with chronic low back pain. A non-randomized comparison trial. *Pain Med.* 2013;14(1):145-158.
41. Baena-Beato PA, Delgado-Fernández M, Artero EG, Robles-Fuentes A, Gatto-Cardia MC, Arroyo-Morales M. Disability predictors in chronic low back pain after aquatic exercise. *Am J Phys Med Rehabil.* 2014;93(7):615-623.
42. Henry SM, Van Dillen LR, Ouellette-Morton RH, et al. Outcomes are not different for patient-matched versus nonmatched treatment in subjects with chronic recurrent low back pain: a randomized clinical trial. *Spine J.* 2014;14(12):2799-2810.
43. Hoffman DL, Sadosky A, Dukes EM, Alvir J. How do changes in pain severity levels correspond to changes in health status and function in patients with painful diabetic peripheral neuropathy? *Pain.* 2010;149(2):194-201.
44. Kumar T, Kumar S, Nezamuddin M, Sharma VP. Efficacy of core muscle strengthening exercise in chronic low back pain patients. *J Back Musculoskelet Rehabil.* 2015;28(4):699-707.
45. Unsgaard-Tondel M, Fladmark AM, Salvesen O, Vasseljen O. Motor control exercises, sling exercises, and general exercises for patients with chronic low back pain: a randomized controlled trial with 1-year follow-up. *Phys Ther.* 2010; 90(10):1426-1440.
46. Farrar JT. What is clinically meaningful: outcome measures in pain clinical trials. *Pain.* 2000;16(2 Suppl):S106-S112.

47. del Pozo-Cruz B, Hernández Mocholí MA, Adsuar JC, Parraca JA, Muro I, Gusi N. Effects of whole body vibration therapy on main outcome measures for chronic non-specific low back pain: a single-blind randomized controlled trial. *J Rehabil Med.* 2011;43(8):689-694.
48. Majchrzycki M, Kocur P, Kotwicki T. Deep tissue massage and nonsteroidal anti-inflammatory drugs for low back pain: a prospective randomized trial. *ScientificWorldJournal.* 2014; 2014:287597.
49. McDonough SM, Tully MA, Boyd A, et al. Pedometer-driven walking for chronic low back pain: a feasibility randomized controlled trial. *Clin J Pain.* 2013;29(11):972-981.
50. Tekur P, Singphow C, Nagendra HR, Raghuram N. Effect of short-term intensive yoga program on pain, functional disability, and spinal flexibility in chronic low back pain: a randomized control study. *J Altern Complement Med.* 2008; 14(6):637-644.
51. Tsauo JY, Liang HW, Jang Y, Du CL. Physical therapy utilization in subjects with work-related musculoskeletal disorders: Taiwan experience. *J Occup Rehabil.* 2009;19(1): 106-112.
52. Davies C, Nitz AJ, Mattacola CG, et al. Practice patterns when treating patients with low back pain: a survey of physical therapists. *Physiother Theory Pract.* 2014;30(6):399-408.
53. Solberg T, Johnsen LG, Nygaard OP, Grotle M. Can we define success criteria for lumbar disc surgery?: estimates for a substantial amount of improvement in core outcome measures. *Acta Orthop.* 2013;84(2):196-201.
54. Fritz JM, Hebert J, Koppenhaver S, Parent E. Beyond minimally important change defining a successful outcome of physical therapy for patients with low back pain. *Spine (Phila Pa 1976).* 2009;34(25):2803-2809.
55. Gatchel RJ, Mayer TG. Testing minimal clinically important difference: consensus or conundrum? *Spine J.* 2010;10(4): 321-327.
56. Ostelo RWJG, Deyo RA, Stratford P, et al. Interpreting change scores for pain and functional status in low back pain - Towards international consensus regarding minimal important change. *Spine (Phila Pa 1976).* 2008;33(1):90-94.
57. Hagg O, Fritzell P, Nordwall A. The clinical importance of changes in outcome scores after treatment for chronic low back pain. *Eur Spine J.* 2003;12(1):12-20.
58. Ostelo RWJG, de Vet HCW. Clinically important outcomes in low back pain. *Best Pract Res Clin Rheumatol.* 2005;19(4): 593-607.
59. Deyo RA, Mirza SK, Turner JA, Martin BI. Overtreating chronic back pain: time to back off? *J Am Board Fam Med.* 2009;22(1):62-68.
60. Turk DC, Dworkin RH. What should be the core outcomes in chronic pain clinical trials? *Arthritis Res Ther.* 2004;6(4):151-154.
61. Marchettini P, Lacerenza M, Mauri E, Marangoni C. Painful peripheral neuropathies. *Curr Neuropharmacol.* 2006;4(3): 175-181.
62. Maddalozzo G, Guzman RJ, Dvorak RV, Maddalozzo WA, Milroy DA, Koshinski RS. Whole body vibration: an effective treatment for painful diabetic neuropathy. *J Pain Relief.* 2015; 4(2):1-4.
63. Kim DH, Park JK, Jeong MK. Influences of posterior-located center of gravity on lumbar extension strength, balance, and lumbar lordosis in chronic low back pain. *J Back Musculoskelet Rehabil.* 2014;27(2):231-237.
64. Sparto PJ, Parnianpour M, Marras WS, Granata KP, Reinsel TE, Simon S. Neuromuscular trunk performance and spinal loading during a fatiguing isometric trunk extension with varying torque requirements. *J Spinal Disord.* 1997;10(2):145-156.
65. Abercromby AF, Amonette WE, Layne CS, McFarlin BK, Hinman MR, Paloski WH. Variation in neuromuscular responses during acute whole-body vibration exercise. *Med Sci Sports Exerc.* 2007;39(9):1642-1650.
66. Cardinale M, Lim J. Electromyography activity of vastus lateralis muscle during whole-body vibrations of different frequencies. *J Strength Cond Res.* 2003;17(3):621-624.
67. Cochrane DJ, Stannard SR, Firth EC, Rittweger J. Acute whole-body vibration elicits post-activation potentiation. *Appl Physiol.* 2010;108(2):311-319.
68. Zaidell LN, Mileva KN, Sumners DP, Bowtell JL. Experimental evidence of the tonic vibration reflex during whole-body vibration of the loaded and unloaded leg. *PLoS One.* 2013;8(12)e85247.
69. Cholewicki J, Panjabi MM, Khachatryan A. Stabilizing function of trunk flexor-extensor muscles around a neutral spine posture. *Spine (Phila Pa 1976).* 1997;22(19): 2207-2212.
70. Wang LZ, Zhao M, Ma J, et al. Effect of combining traction and vibration on back muscles, heart rate and blood pressure. *Med Eng Phys* 2014;36(11):1443-1448.
71. Ahlborg L, Andersson C, Julin P. Whole-body vibration training compared with resistance training: effect on spasticity, muscle strength and motor performance in adults with cerebral palsy. *J Rehabil Med.* 2006;38(5):302-308.
72. Bogaerts A, Verschueren S, Delecluse C, Claessens AL, Boonen S. Effects of whole body vibration training on postural control in older individuals: a 1 year randomized controlled trial. *Gait Posture.* 2007;26(2):309-316.
73. Ebersbach G, Edler D, Kaufhold O, Wissel J. Whole body vibration versus conventional physiotherapy to improve balance and gait in Parkinson's disease. *Arch Phys Med Rehabil.* 2008;89(3):399-403.
74. Ness LL, Field-Fote EC. Whole-body vibration improves walking function in individuals with spinal cord injury: a pilot study. *Gait Posture.* 2009;30(4):436-440.
75. Rehn B, Lidström J, Skoglund J, Lindström B. Effects on leg muscular performance from whole-body vibration exercise: a systematic review. *Med Sci Sports.* 2007; 17(1):2-11.
76. Roelants M, Delecluse C, Goris M, Verschueren S. Effects of 24 weeks of whole body vibration training on body composition and muscle strength in untrained females. *Sports Med.* 2004;25(1):1-5.
77. van Nes IJ, Latour H, Schils F, Meijer R, van Kuijk A, Geurts AC. Long-term effects of 6-week whole-body vibration on balance recovery and activities of daily living in the postacute phase of stroke: a randomized, controlled trial. *Stroke.* 2006; 37(9):2331-2335.
78. Verschueren SM, Roelants M, Delecluse C, Swinnen S, Vanderschueren D, Boonen S. Effect of 6-month whole body vibration training on hip density, muscle strength, and postural control in postmenopausal women: a randomized controlled pilot study. *J Bone Miner Res.* 2004;19(3): 352-359.
79. Bishop MD, Horn ME, George SZ. Exercise-induced pain intensity predicted by pre-exercise fear of pain and pain sensitivity. *Pain.* 2011;27(5):398-404.
80. Leeuw M, Goossens ME, Linton SJ, Crombez G, Boersma K, Vlaeyen JW. The fear-avoidance model of musculoskeletal pain: current state of scientific evidence. *J Behav Med.* 2007; 30(1):77-94.
81. Kirkham JJ, Dwan KM, Altman DG, et al. The impact of outcome reporting bias in randomised controlled trials on a cohort of systematic reviews. *BMJ.* 2010;340.