Published in final edited form as:
Clin J Pain. 2005 ; 21(6): 463–470.

A RANDOMIZED, CONTROLLED TRIAL OF MANUAL THERAPY AND SPECIFIC ADJUVANT EXERCISE FOR CHRONIC LOW BACK PAIN

Michael E. Geisser, Ph.D.[*], **Elizabeth A. Wiggert, P.T.**[*], **Andrew J. Haig, M.D.**[*,+], and **Miles O. Colwell, M.D.**[*]

[*] *The Spine Program, Department of Physical Medicine and Rehabilitation, University of Michigan Health System, Ann Arbor, MI USA*

[+] *Department of Surgery, University of Michigan Health System, Ann Arbor, MI USA*

Abstract

Objective—To examine the effectiveness of manual therapy with specific adjuvant exercise for treating chronic low back pain (CLBP) and disability.

Materials and Methods—A single-blind, randomized, controlled trial was employed. Subjects were prescribed an exercise program that was tailored to treat their musculoskeletal dysfunctions, or given a nonspecific program of general stretching and aerobic conditioning. In addition, subjects received manual therapy or sham manual therapy. Participants were seen for six weekly sessions, and were asked to perform their exercise program twice daily.

Results—Seventy-two out of 100 subjects completed the study. Multivariate tests conducted for measures of pain and disability revealed a significant group by time interaction ($p = .04$, and $p = .05$, respectively), indicating differential change in these measures pre- to post-treatment as a function of the treatment received. When controlling for pretreatment scores, subjects receiving manual therapy with specific adjuvant exercise reported significant reductions in pain. No change in perceived disability was observed, with the exception that subjects receiving sham manual therapy with specific adjuvant exercise reported significantly greater disability at post-treatment.

Discussion—Manual therapy with specific adjuvant exercise appears to be beneficial in treating CLBP. Despite changes in pain, perceived function did not improve. It is possible that impacting CLBP alone does not address psychosocial or other factors that may contribute to disability. Further studies are needed to examine the long-term effects of these interventions, and to address what adjuncts are beneficial in improving function in this population.

Keywords

Low back pain; osteopathic manipulation; exercise; activities of daily living

INTRODUCTION

Chronic low back pain (CLBP) and associated disability is an epidemic in the United States. Annual costs of low back disability in the United States have been estimated to be approximately $50 billion, with the average cost of a single case of work-related back pain exceeding $8000 (1). It has been estimated that 70–80% of the costs for work-related low back

Address all correspondence and requests for reprints to: Michael E. Geisser, Ph.D., University of Michigan Health System, The Spine Program, 325 E. Eisenhower Parkway, Ann Arbor, MI 48108 USA, Phone: 734 615-1750, FAX: 734 615-1770, email:mgeisser@umich.edu.

claims are accounted for by 7–10% of patients who develop CLBP (2,3). Several factors complicate the treatment of CLBP, as most persons with the disorder are reported to have no identifiable pathophysiologic cause for their pain (4,5), and specific interventions for CLBP have little or no demonstrated efficacy (6). Given the available data that psychosocial factors play a significant role in the development and maintenance of CLBP (7,8), physical interventions that fail to address these factors may not be effective for the majority of persons CLBP. The biopsychosocial model of chronic pain has gained widespread acceptance as the appropriate model for understanding chronic pain, and has lead to the development of treatments emphasizing multidisciplinary care (9) and functional restoration (10,11).

Some authors propose that musculoskeletal disorders are frequently overlooked as potential causes of CLBP (12–20), and the pathophysiologic mechanisms underlying musculoskeletal pain have been outlined in the literature (21). It has been reported that the majority of chronic pain patients without spinal pathology have evidence of musculoskeletal dysfunctions, and that remediation of these disturbances leads to reduced pain in many of the patients (22). Musculoskeletal treatment approaches to back pain are quite popular among consumers. Deyo and Tsui-Wu (23) reported that most persons with low back pain sought out care from a primary care physician, although chiropractors and orthopaedists were the next most common sources of care. In addition, consumer satisfaction with chiropractic care is reported to be high and tends to be related to the receipt of information regarding the underlying nature of back pain (24,25).

Given these trends, an interest has emerged in the role of manual medicine and manipulation in the treatment of back pain. Manual medicine refers to hands on therapy that includes gentle joint stretching or mobilization to improve joint mobility in the spine or adjacent structures, with notion that joint restriction contributes to pain (17). Mobilization differs from manipulation in that mobilization produces passive movements within or at the limit of the joint range, while high velocity techniques, often used by chiropractors, thrust the joint beyond its restricted range of movement (26). There are a number of therapeutic mobilization and manipulative techniques in the literature, although available research suggests that no one technique is superior to another (27).

Few empirical studies have examined the efficacy of manual therapy in treating CLBP, and most lack methodological rigor. Mein (28) reported that three studies demonstrated positive results (29–31), while one produced a negative result (26). Koes et al. (32) identified 8 studies examining interventions for subacute and chronic back pain. Of these, 5 reported positive results, 2 reported negative results, and in one study no conclusion was presented. These authors concluded that the efficacy of manual therapy for chronic back pain has not been clearly established. A recent study by Hurwitz et al (33) found that chiropractic care with and without physical modalities, and medical care with and without physical therapy, produced similar and significant improvements in low back pain. However, the sample was largely comprised of persons with acute low back pain.

Clinically, manual therapy is often combined with exercises that are tailored to treat specific musculoskeletal dysfunctions (34). Although the utility of specific exercises for treating CLBP has received little empirical attention, a review of the literature by van Tulder et al. (35) reported that that there is strong evidence that exercise therapy is more effective than usual care by a practitioner and conventional physical therapy. However, they indicate it is unclear whether exercise therapy is more effective than inactive treatment, or what type of exercise is most beneficial.

Recently, Aure et al. (36) examined the impact of manual and exercise therapy in persons with chronic, disabling low back pain. All subjects were prescribed individual home exercises, and

were encouraged to perform aerobic exercise. Subjects receiving manual therapy underwent sessions twice a week for eight weeks, and were also given exercises specifically designed to treat identified musculoskeletal dysfunctions. The authors found significant improvements in both groups on measures of pain and disability, with the manual therapy group displaying significantly greater gains. However, the study design did not allow for examination of the impact of manual therapy alone, or specific exercise alone, or the combined effect of these interventions. In addition, persons with pain lasting more than 6 months were excluded from the study.

Given the importance of psychosocial factors in CLBP, it isn't clear whether physical interventions alone are of benefit in treating the disorder. However, a treatment focus on musculoskeletal dysfunctions is not entirely inconsistent with the biopsychosocial model of chronic pain, as psychosocial factors such as psychological stress have been found to produce increased muscle tension that tends to be specific to painful areas of the body (37,38). In addition, factors such as pain-related fear have been found to be associated with decreased lumbar flexion and muscle firing abnormalities among persons with CLBP, even when controlling for clinical pain intensity (39,40). Given these findings, treating musculoskeletal dysfunctions alone may not be beneficial without directly addressing psychosocial factors that contribute to the experience of pain.

The purpose of present investigation was to examine the efficacy of manual therapy with specific adjuvant exercise for treating CLBP. Subjects were randomized to one of four treatment groups: 1) manual therapy with specific adjuvant exercise; 2) sham manual therapy with specific adjuvant exercise; 3) manual therapy and nonspecific exercise (e.g., exercise not designed to correct specific musculoskeletal dysfunctions); and 4) sham manual therapy and nonspecific exercise. We predicted that only persons with CLBP receiving manual therapy with specific adjuvant exercise would demonstrate improvements in self-reported pain and disability.

METHODS

Participants

One hundred persons with CLBP (defined as pain of 3 or more months duration) were recruited from individuals presenting to the University of Michigan Spine Program for treatment. Subjects were eligible for the study if: 1) they were age 18–65; 2) they had a single or primary complaint of CLBP; and 3) they were judged to have musculoskeletal pain based on evaluation by the physician or physical therapist. Patients were exclude if they displayed: 1) Down's syndrome; 2) osteoporosis of the spine; 3) agenesis of the odontoid process; 4) primary joint disease such as active rheumatoid arthritis; 5) metabolic bone disease; 6) malignant bone disease; 7) fracture; 8) hypermobility of the lumbar/sacral spine; 9) cardiovascular or other medical disorder preventing the person from engaging in strenuous exercise; 10) evidence of radiculopathy, or primary complaint of radiating pain; 11) pregnancy; or 12) severe psychiatric disturbance.

The mean age of persons in the study was 40.7 years (SD = 11.3), with a mean duration of pain of 76.9 months (SD = 97.4). Mean years of education was 14.76 (SD = .26). Fifty-nine were female, and 41 were male. Eighty-five were Caucasian, 8 were African-American, 5 were Asian-American, and 2 were Hispanic. Eight persons were litigating in relation to their pain, and 25 were receiving some form of compensation. Thirty-four subjects were not working due to pain, while the remainder were working full or part-time, were students, or were retired. Eighteen subjects had previous lumbar surgery (laminectomy or discectomy). Subjects were allowed to continue their use of pain medications, but were asked to not change their usage during the course of the study. Twenty-five subjects took no prescription medications for pain,

48 took non-steroidal anti-inflammatory drugs, 35 took narcotic analgesics, 25 were on antidepressants (either for depression, analgesia, sleep disturbance, or a combination of these factors), 12 took antispasm medicines, 8 were on anxiolytics, and 6 took anticonvulsants.

Outcome Measures

Pain—McGill Pain Questionnaire (MPQ) (41). The MPQ measures subjective pain experience in a quantitative form, and consists of twenty groups of single word pain descriptors with the words in each group increasing in rank order intensity. The sum of the rank values for each descriptor based on its position in the word set results in a score termed the Pain Rating Index (PRI). The Total PRI was used in the present study as the measure of self-reported pain intensity, and scores range from 0–78. Previous research found that repeat administration of the MPQ revealed a 70.3% rate of consistency in the PRI score (41).

Visual Analogue Rating (VAS). Self-report of clinical pain intensity was also obtained by having persons rate their average or usual experience of pain during the past week on a VAS. The scale was 10 cm long and anchored by the statements “no pain” on the left and “the most intense pain imaginable” on the right. VAS pain ratings are reported to have good reliability (42,43) and concurrently validity when compared to other methods of pain measurement (44, 45).

Disability—Quebec Back Pain Disability Scale (QBPDS) (46). The QBPDS is a 20-item scale where patients are asked to rate the amount of difficulty they have performing various activities of daily living, such as getting out of bed, walking several miles, and making a bed. Persons are asked to rate their degree of difficulty ranging from 0 “not difficult at all” to 5 “unable to do”. A total score for the scale is derived by summing the responses to each item, and ranges from 0–100. Test-retest reliability is reported to be .93, and internal consistency is .95 (46).

The Interference Subscale of the Multidimensional Pain Inventory (MPI) (47). The Interference subscale of the MPI contains 11 items that assess perception of how much pain interferes with a persons’ life, including family and marital relations, work and social-recreational activity, and satisfaction with level of function in each of these areas. The scores reported are T-scores (mean = 50, SD =10). The reliability estimate for the subscale is .90, and stability is reported to be .86 (47).

Satisfaction With Treatment—A questionnaire was administered at post-treatment to examine satisfaction with treatment, and the degree to which subjects believed they received an actual treatment. The first four questions asked subjects to rate: 1) satisfaction with the feedback provided by the therapist about their condition; 2) satisfaction with the amount of pain relief from therapy; 3) overall satisfaction with therapy; and 4) overall satisfaction with the therapist. Subjects made ratings on a 7-point Likert scale with the anchors “completely dissatisfied” on the left and the anchor “completely satisfied” on the right. The last question asked subjects to rate their agreement with the statement “I believe I received an actual treatment from the therapist”. Anchors used for this latter question were “completely disagree” on the left and “completely agree” on the right. Internal consistency (Cronbach’s alpha) for the scale based on the present sample is .88.

Manual Medicine Screening Evaluation—To determine specific musculoskeletal dysfunctions in order to tailor manual therapy and specific exercise prescription, a manual medicine screening evaluation was performed by the treating therapist during the first visit. The evaluation consisted of having the patient assume different postures while the examiner noted any asymmetries, restrictions of movement, and abnormal tissue texture as outlined by Greenman (17). This was done through visual inspection as well as palpation. The results of

the examination were coded on a standardized worksheet. While standing, subjects were administered the standing forward flexion test to examine the mobility of the SI joint, in addition to the stork test which was utilized to examine hamstring tightness as a cause of SI restriction. Subjects also underwent a seated flexion test, and were examined for medial malleolus symmetry while supine. Anterior superior iliac spine symmetry (ASIS) was also examined with the subject in supine to determine an anterior or posterior rotation of the innominate on sacrum or an upslip or downslip of the entire hemipelvis. Finally, pubic symphysis symmetry was examined with the subject in supine to determine the presence or absence of a dysfunction of the symphysis pubis.

With the subject prone, sacral base symmetry was examined to determine the presence or absence of a sacral dysfunction on the innominate. Also, sacrotuberous ligament tightness was examined, and was noted to be present or absent.

Procedures

After recruitment, subjects were scheduled to meet with the principal investigator to obtain informed consent. They were then administered the self-report measures. All subjects watched a 12-minute videotape that provided educational information on musculoskeletal pain and oriented subjects on how exercise might be beneficial in terms of improving their pain. Persons were then seen by a physical therapist who conducted the standardized manual medicine screening evaluation. Following the first visit, subjects were scheduled for 5 additional, weekly visits. Some subjects rescheduled visits, prolonging the time between the first and last visit. The self-report measures were re-administered following the last visit with the therapist by the principal investigator, who was blind to the treatment condition of the subject. The treating therapist was the same for all subjects, with a few exceptions. The treating therapist was a physical therapist with 12 years postgraduate training in manual medicine. Two therapists who filled in for the primary therapist were also physical therapists with extensive training in manual therapy. The treating therapist was not blind to the treatment group of the subject, but attempted to keep subjects blind to their group assignment.

Participants were randomly assigned to one of four treatment conditions. To obtain equal numbers of subjects in each group, the randomization order was determined prior to the study. One subject was mistakenly placed in the wrong treatment group, accounting for the one group with 26 subjects initially and another with only 24. Blocking or stratification was not employed.

Interventions

Subjects in each group received either manual therapy (MT), or were administered a sham manual therapy procedure (sham MT). Manual therapy interventions primarily involved muscle energy technique (MET) (17). The MET's used depended on the patient's specific musculoskeletal dysfunction or "positional diagnosis". For the sham MT condition, persons were placed in the controlled position that would potentially correct their musculoskeletal dysfunction, but MET's were not performed. The therapist attempted to keep the treatment time consistent between conditions.

Subjects were assigned to one of two exercise conditions. Some subjects received a specific adjuvant exercise program (SE) designed to help improve specific musculoskeletal dysfunctions observed during the standardized manual medicine screening evaluation. Specific exercises were taken from Sahrman (49) and Bookhout (50) and included self-corrections, stretches, and strengthening exercises. Examples of self-corrections included: 1) anterior innominate self-correction; 2) unilateral prone press-up; 3) pubis self-correction; and 4) pelvic clock (50). Commonly used stretches included: 1) supine hip flexor stretching (49); 2) supine hamstring stretch (50); 3) kneeling quadratus lumborum stretch (50); and 4) tensor fascia latae

stretch (50). Examples of strengthening exercises included: 1) lower abdominal progression (49); 2) prone hip extension (50); 3) hip abduction/external rotation side lying (50); and 4) gluteus medius strengthening with hip diagonals (50).

Some subjects received non-specific exercises (NE; VHI Exercise and Rehabilitation Prescription Kit, Tacoma, WA). These exercises were not designed to treat specific musculoskeletal dysfunctions, as they did not target stretching or strengthening dysfunctional muscles, or improving joint mobility in a restricted area. Examples of these exercises included: 1) quadriceps stretch; 2) double or single knee to chest stretch; 3) sitting hamstring stretch; and 4) prone on elbows. In addition, subjects in this group were asked to perform aerobic exercise three times per week. Subjects were trained by the physical therapist to monitor their heart rate and were asked to engage in aerobic exercise for 20 minutes between 70–80% of their maximum heart rate (51). Participants were free to choose how they performed aerobic exercise. Walking at a fast pace was the most common type of aerobic exercise reported by subjects.

Subjects in both groups were asked to do stretches and/or self-corrections twice daily (usually 10 repetitions each time). Patients were asked to hold each stretch for 30 seconds. These exercises were introduced at the first visit, and others were added as the study progressed. Specific strengthening exercises were introduced at the 3rd visit for persons in the SE group (10 repetitions, three times per week), and for NE subjects, aerobic exercise was introduced at this time. Subjects were asked to record their exercise activity on a weekly log to track compliance. In addition, the therapist asked participants to reproduce their exercises periodically during the study and recorded whether participants could accurately reproduce them. The therapist attempted to equate the number of exercises across groups. The average number of exercises given to a subject was 8.0 (SD = 2.1).

RESULTS

Out of the 100 subjects recruited, 72 subjects completed the study. Persons who dropped out of the study were more likely to be receiving compensation ($X^2 = 4.23$, $p = .04$) and reported higher levels of pain on the VAS ($t = -2.34$, $p = .02$) and the MPQ ($t = -5.04$, $p < .001$). In addition, subjects who did not complete the study perceived themselves as being more disabled on the QBPDS ($t = -2.60$, $p = .02$) and the MPI Interference subscale ($t = -2.37$, $p = .02$). Non-completers also had a higher likelihood of being male ($X^2 = 4.19$, $p = .04$). No differences were observed for age, litigation, surgical status, pain duration, or work status.

Chi-square tests and ANOVA were utilized to compare the groups in terms of drop out, age, sex, compensation status, surgical history, education, and pain duration. This data is presented in Table 1. No significant group differences were observed, although there was a trend for subjects in the Sham MT-NE group to be older ($F = 2.3$, $p = .08$). We also examined the association between these variables and the outcome measures, as even small group differences might produce spurious findings if these variables were associated with the outcome measures. No significant associations were found, with the exception that pain duration was significantly associated with change in pain on the VAS ($r = .26$, $p = .03$). Therefore, pain duration was included as a covariate in the multivariate test conducted on the pain measures.

Examination of compliance with exercise revealed that six patients who completed the study were unable to reproduce one or more of their exercises. Inspection of the exercise logs indicated the overall compliance with prescribed exercise was 75.2%. Eight persons who completed the study did not complete any of their exercise logs. ANOVA revealed no significant difference between the groups in exercise compliance.

Data on satisfaction with and perception of receiving a "real" treatment is presented in Table 2. No significant differences were observed in the data, although there was a trend for subjects in the sham MT-SE group to report the least amount of satisfaction with their overall therapy, while persons in the MT-SE reported the greatest satisfaction ($F = 2.3$, $p = .08$).

Scores on the individual pain and disability outcome measures used in the study are presented in Table 3. Two multivariate tests were conducted, one examining the pain measures as dependent variables, and the other compared the disability measures. Treatment group (four levels) was examined as a between-subjects factor, and time (pre- and post-treatment data) and type of measure were examined as within-subjects factors. As we predicted changes in the MT-SE groups, but not necessarily the others, we wished to determine whether the tests revealed a significant treatment group by time interaction. A MANCOVA conducted on the pain measures (controlling for pain duration) revealed a significant main effect of time ($F = 10.7$, $p < .01$), as well as a significant time by treatment group interaction ($F = 2.9$, $p = .04$). Similar results were obtained for the disability measures, as the MANOVA conducted on these data also revealed a significant main effect of time ($F = 27.6$, $p < .001$) and a significant time by treatment group interaction ($F = 2.7$, $p = .05$).

The change in the outcome measures as a function of type of treatment is presented in Table 3. Change scores were calculated by subtracting subjects' pretreatment scores from the post-treatment scores on a particular measure. A negative change score denotes improvement on a particular measure, while a positive score is reflective of decline over the course of treatment. To control for regression to the mean effects in the individual tests, standardized residual change scores (z-scores) controlling for the pretreatment score on a particular measure were calculated, and are also presented in Table 3. These scores were computed by regressing the pretreatment score on the change score and calculating a standardized residual change score for each subject. Standardized scores, or z-scores, have a mean of zero and standard deviation of one. A t-test was performed on each score to determine if the mean standardized residual change score significantly differed from 0.

The standardized residual change scores on the VAS and MPQ for subjects in the MT-SE group were significantly different from zero, indicating that these subjects displayed significant decreases on both pain measures when controlling for the influence of pretreatment scores ($t = -2.33$, $p < .05$; and $t = -2.30$, $p < .05$ respectively). The standardized residual score for the sham MT-NE group on the VAS was not significantly different from zero, nor did the MT-SE, MT-NE, or sham MT-NE group display any significant changes on the disability measures. However, when controlling for pretreatment scores, subjects in the sham MT-SE displayed a significant increase in disability from pre- to post-treatment ($t = 3.56$, $p < .01$).

DISCUSSION

The results of the study indicate that subjects receiving manual therapy with specific exercise displayed significant improvements in pain when controlling for pre-treatment level of pain. No significant changes in disability were observed, with the exception that the sham MT-SE group displayed a significant increase in disability.

In contrast to the Aure et al. (36) study, the results of the present study do not support the notion that manual therapy and specific adjuvant exercise have a significant impact on disability. All subjects in the Aure et al. study performed aerobic exercise, and it is possible that aerobic exercise, and not manual therapy or specific exercise, has a greater impact on disability. In addition, subjects in the Aure et al. study were treated for a longer period of time and more frequently, which may have influenced the outcomes. It would be beneficial in the future to

examine the dose-response relationship between manual therapy, exercise, and treatment outcome.

Some limitations to the study are presented here. First, the study was not double blinded. Evaluation of participants' perception of the therapist and treatment suggested that differences in treatment satisfaction and credibility were not responsible for the outcomes, as no group differences were observed in ratings of treatment satisfaction and perception of receiving a "real" intervention. Second, long-term outcomes were not assessed, and it is not known whether the differences observed at post-treatment can be maintained over time. Third, subjects who dropped out of the study displayed significantly higher levels of pain and disability, were more likely to be receiving compensation, and were more likely to be male. Thus, the results may not be as applicable to chronic pain populations who display high levels of pain and disability and who are receiving compensation. We also did not examine other important treatment outcomes such as pain beliefs, mood, and quality of life.

The rate of attrition in the study was 28%. This is not inconsistent with other treatment outcome studies for chronic back pain, as Koes et al. (32) indicated that 4 of 8 studies they reviewed reported drop-out rates of greater than 20%. One possible reason for the high rates of attrition in this study and others involving exercise may be due to the complexity of the interventions. Past research suggests that there is a high rate of non-compliance with exercise, as Dishman (52) indicates that roughly 50% of persons in a supervised exercise program will dropout in 6 months.

The results suggest that pain reduction associated with CLBP does not necessarily lead to a change in function. This finding is consistent with previous studies reporting little or no relationship between clinical pain intensity and disability among persons with chronic pain (53–55). These findings suggest that the factors that influence pain and disability among persons with CLBP may be different. For example, pain-related fear and depression have been reported to significantly influence disability in this population (56–58). These and other psychosocial factors may need to be addressed in a different fashion during the course of treatment.

On this note, it is interesting that the groups given nonspecific exercise displayed a trend towards reduced disability. These results suggest that the prescription of more effortful activity in this population might be beneficial in reducing disability, as doing so may help persons to confront or reduce pain-related fear. A study by Indahl et al. (59) indicated that persons with acute back injuries who were prescribed light, normal activity had better outcomes compared to persons prescribed rest. Similarly, research on back school and other educational approaches have not been beneficial in reducing injury, and in fact may emphasize the vulnerability of the spine to damage leading to increased health care utilization (60). Specific disability interventions may be beneficial adjuncts to interventions for pain relief in this population.

As deconditioning has been proposed to play a role in chronic pain disability (10,11), it possible that subjects receiving aerobic exercise may have improved their stamina and endurance, which in turn improved their functional status. This could not be assessed directly in the present study, as aerobic fitness was not measured. It would be beneficial in future studies to examine whether changes in aerobic fitness are associated with improvements in function among persons with chronic pain.

The results of the present study do not support the notion that manual therapy alone is beneficial in treating CLBP. The combination of manual therapy and specific adjuvant exercise had the greatest efficacy for treating CBLP. To the extent that the results of this study can be generalized to other forms of mobilization and manipulative therapy commonly available such as chiropractic treatment, it should be noted that manipulation is not usually combined with

exercise in treating CLBP. Further attention should be given to enhancing the effectiveness of manipulation by adding exercise as a part of the intervention.

The findings of the present study do not support the notion that manual therapy and exercise alone are effective in treating CLBP. Multidisciplinary interventions appear the have the greatest efficacy in treating chronic pain (9). However, manual therapy and specific adjuvant exercise may be beneficial components of multidisciplinary treatment, and if used alone, may be beneficial for a subgroup of persons with CLBP. As chronic pain populations are believed to be heterogeneous (61), unimodal interventions for CLBP may benefit persons with relatively low levels of pain and disability, whereas persons high in these dimensions may obtain more benefit from multidisciplinary treatment (62). For example, Turk et al. (63) found that multidisciplinary treatment for persons with temporomandibular disorder had the greatest impact on persons who had a dysfunctional profile type on the MPI.

It should be noted that there are several issues that need to be addressed in the study of manual therapy interventions. First, in clinical settings, manual therapy is individually tailored to the address the musculoskeletal dysfunctions observed in a particular patient, thus making it difficult to "standardize" the intervention in a clinical trial. Second, performing musculoskeletal evaluations, and manual therapy, is a skill. This makes it difficult to replicate studies on manual therapy, as the outcomes to some extent depend on the skill or orientation of the person conducting the treatments. Third, there is little evidence regarding the validity and reliability of musculoskeletal evaluations, and in fact, previous studies have suggested that the inter-rater reliability of various musculoskeletal evaluations is poor (64). One study suggests that reliability of such evaluations can be improved through standardization and training (65). Further research is needed in this area, as the development of uniform and reliable evaluation and treatment methods are crucial to the study of evaluating and treating musculoskeletal pain.

In summary, manual therapy with specific adjuvant exercise appears to be efficacious in the treatment of CLBP, but not associated disability.

Acknowledgements

This research was supported by a grant (R03-HD35893) from the National Center for Medical Rehabilitation Research, National Institute of Child and Human Development, National Institutes of Health.

References

1. Hazard RG, Haugh LD, Reid S, Preble JB, MacDonald L. Early prediction of chronic disability after occupational low back injury. Spine 1996;21:945–51. [PubMed: 8726198]
2. Fast A. Low back disorders: conservative management. Arch Phys Med Rehabil 1977;69:880–91. [PubMed: 2972268]
3. Spengler DM, Bigos SJ, Martin NA, Zeh J, Fisher L, Nachemson A, Wang MH. Back injuries in industry: a retrospective study: I. Overview and cost analysis Spine 1986;11:241–5.
4. White AA, Gordon SC. Synopsis: workshop on idiopathic low back pain. Spine 1982;7:141–9. [PubMed: 6211779]
5. Fordyce WE. Environmental factors in the genesis of low back pain. In: Bonica JJ et al., ed. Advances in pain research and therapy, vol. 3, proceedings of the 2nd World Congress on Pain. New York: Raven Press, 1979: 659–66.
6. Report of the Quebec Task Force on spinal disorders. Scientific approach to the assessment and management of activity-related spinal disorders. A monograph for clinicians. Spine 1987;12(7 suppl):S1–59. [PubMed: 2961086]
7. Flor H, Fydrich T, Turk DC. Efficacy of multidisciplinary pain treatment centers: a meta-analytic review. Pain 1992;49:221–30. [PubMed: 1535122]

8. Gatchel RJ, Polatin PB, Kinney RK. Predicting outcome of chronic back pain using clinical predictors of psychopathology: a prospective analysis. Hlth Psychol 1995;14:415–20.
9. Gatchel RJ, Polatin PB, Mayer TG. The dominant role of psychosocial risk factors in the development of chronic low back pain disability. Spine 1995;20:2702–9. [PubMed: 8747248]
10. Hazard RG, Fenwick JW, Kalish SM, Redmond J, Reeves V, Reid S, Frymoyer JW. Functional restoration with behavioral support: a one year prospective study of patients with chronic low back pain. Spine 1989;14:157–61. [PubMed: 2522243]
11. Mayer TG, Gatchel RJ, Mayer H. A prospective two year study of functional restoration in industrial low back injury: an objective assessment procedure. JAMA 1987;258:1763–7. [PubMed: 2957520]
12. Bonica JJ, Sola AE. Other painful disorders of the low back. In: Bonica JJ, ed. The Management of Pain, Vol. 2, 2nd ed. Philadelphia: Lea and Febiger, 1990: 1484–1514.
13. Rachlin ES. Myofascial Pain and Fibromyalgia: Trigger Point Management. St. Louis: Mosby, 1994.
14. Travell JG, Simons DG. Myofascial Pain and Dysfunction: The Trigger Point Manual, Vol. 1. Baltimore: Williams and Wilkins, 1983.
15. Travell JG, Simons DG. Myofascial Pain and Dysfunction: The Trigger Point Manual, Vol. 2. Baltimore: Williams and Wilkins, 1992.
16. Bourdillon F, Day EA, Bookhout MR. Spinal manipulation, 5th ed. Oxford: Butterworth Heineman, 1992.
17. Greenman PE. Principles of manual medicine, 2nd ed. Baltimore: Williams and Wilkins, 1996.
18. Janda V. Muscle function testing. London: Butterworths, 1983.
19. Lewit K. Manipulative therapy in rehabilitation of the locomotor system, 2nd ed. Oxford: Butterworth Heineman, 1996.
20. Lewit K. Management of muscular pain associated with articular dysfunction. In: Fricton R, Awad E, ed. Advances in pain research and therapy, Vol. 17, myofascial pain and fibromyalgia. New York: Raven Press, 1990: 315–7.
21. Mense S. Nociception from skeletal muscle in relation to clinical pain. Pain 1993;54:241–89. [PubMed: 8233542]
22. Rosomoff HL, Fishbain DA, Goldberg M, Santana R, Rosomoff RS. Physical findings in patients with chronic intractable benign pain of the neck and/or back. Pain 1989;37:279–87. [PubMed: 2526943]
23. Deyo RA, Diehl AK. Patient satisfaction with medical care for low-back pain. Spine 1986;11:28–30. [PubMed: 2939566]
24. Cherkin DC, MacCornack FA. Patient evaluations of low back pain care from family physicians and chiropractors. West J Med 1989;150:351–5. [PubMed: 2525303]
25. Ottenbacher K, Di Fabio RP. Efficacy of spinal manipulation/mobilization therapy: a meta-analysis. Spine 1985;10:833–7. [PubMed: 2935951]
26. Deyo RA. Conservative therapy for low-back pain. JAMA 1983;250:1057–62. [PubMed: 6224032]
27. Mein EA. Low back pain and manual medicine: a look at the literature. Phys Med Rehabil Clinics of North America 1996;7:715–29.
28. Evans DP, Burke MS, Lloyd KN, Roberts EE, Roberts GM. Lumbar spinal manipulation on trial: Part I-clinical assessment. Rheumatol Rehabil 1978;17:46–53. [PubMed: 153574]
29. Ongely MJ, Klein RG, Dorman TA, Eek BC, Hubert LJ. A new approach to the treatment of chronic low back pain. Lancet 1987;2:143–6. [PubMed: 2439856]
30. Waagen GN, Haldeman S, Cook G, Lopez D, DeBoer KF. Short term trial of chiropractic adjustments for the relief of chronic low back pain. Manual Med 1986;2:63–7.
31. Timm KE. A randomized-control study of active and passive treatments for chronic low back pain following L5 laminectomy. J Orthop Sports Phys Ther 1994;20:276–86. [PubMed: 7849747]
32. Koes BW, Assendelft WJJ, van der Heijden GJMG, Bouter LM. Spinal manipulation for low back pain: an updated systematic review of randomized control trials. Spine 1996;21:2860–73. [PubMed: 9112710]
33. Hurwitz EL, Morgenstern H, Harber P, Kominski GF, Belin TR, Yu F, Adams AH. A randomized trial of medical care with and without physical therapy and chiropractic care with and without physical

modalities for patients with low back pain: 6-month follow-up outcomes from the UCLA low back pain study. Spine 2002;27:2193–2204. [PubMed: 12394892]

34. Bookhout MR. Exercise and somatic dysfunction. Phys Med Rehabil Clinics of North America 1996;7:845–62.
35. van Tulder M, Malmivaara A, Esmail R, Koes B. Exercise therapy for low back pain: a systematic review within the framework of the Cochrane Collaboration Back Review Group. Spine 2000;25:2784–96. [PubMed: 11064524]
36. Aure OF, Nilsen JH, Vasseljen O. Manual therapy and exercise therapy in patients with chronic low back pain. Spine 2003;28:523–32.
37. Ohrbach R, McCall WD Jr. The stress-hyperactivity-pain theory of myogenic pain. Pain Forum 1996;5:51–66.
38. Flor H, Birbaumer N, Schugens MM, Lutzenberger W. Symptom-specific psychophysiological responses in chronic pain patients. Psychophysiology 1992;29:452–60. [PubMed: 1410176]
39. Geisser ME, Haig AJ, Wallbom AS, Wiggert EA. Pain-related fear, lumbar flexion, and dynamic EMG among persons with chronic musculoskeletal low back pain. Clin J Pain (in press).
40. Watson PJ, Booker CK, Main CJ. Evidence for the role of psychological factors in abnormal paraspinal activity in patients with chronic low back pain. J Musculoskeletal Pain 1997;5:41–56.
41. Melzack R. The McGill Pain Questionnaire: major properties and scoring methods. Pain 1975;1:277–9. [PubMed: 1235985]
42. Boeckstyns MEH, Backer M. Reliability and validity of the evaluation of pain in patients with total knee replacement. Pain 1989;38:29–33. [PubMed: 2780060]
43. Revill SI, Robinson JO, Rosen M, Hogg MIJ. The reliability of a linear analogue for evaluating pain. Anesthesia 1976;31:1191–8.
44. Downie WW, Leatham PA, Rhind VM, Wright V, Branco JA, Anderson JA. Studies with pain rating scales. Ann Rheum Dis 1978;37:378–81. [PubMed: 686873]
45. Jensen MP, Karoly P, O'Riordan EF, Bland F Jr, Burns RS. The subjective experience of acute pain: an assessment of the utility of 10 indices. Clin J Pain 1989;5:153–9. [PubMed: 2520397]
46. Kopec JA, Esdaile JM, Abrahamowicz M, Abenhaim L, Wood-Dauphinee S, Lamping DL, Williams JI. The Quebec Back Pain Disability Scale: measurement properties. Spine 1995;20:341–52. [PubMed: 7732471]
47. Kerns RD, Turk DC, Rudy TE. The West Haven-Yale Multidimensional Pain Inventory (WHYMPI). Pain 1985;23:345–56. [PubMed: 4088697]
48. Anderson R, Meeker WC, Wirick BE, Mootz RD, Kirk DH, Adams A. A meta-analysis of clinical trials of spinal manipulation . J Manipulation Physiol Ther 1992;15:181–94.
49. Sahrman SA. Diagnosis and treatment of movement impairment syndromes. St. Louis: Mosby, 2002.
50. Bookhout MR. Exercise as an adjunct to manual medicine. Handout and lecture presented in Ann Arbor, MI, February, 1997.
51. American College of Sports Medicine. Guidelines for Exercise Testing and Prescription, 3rd ed. Philadelphia PA: Lea & Febiger, 1986.
52. Dishman RK. Increasing and maintaining exercise and physical activity. Behav Ther 1991;22:345–78.
53. Geisser ME, Roth RS. Knowledge of and agreement with pain diagnosis: relation to pain beliefs, pain severity, disability, and psychological distress. J Occup Rehabil 1998;8:73–88.
54. Millard RW, Wells N, Thebarge RW. A comparison of models describing reports of disability associated with chronic pain. Clin J Pain 1991;7:283–91. [PubMed: 1809441]
55. Vlaeyen JWS, Kole-Snidjers AMJ, Rotteveel AM, Rvesink R, Heuts PHTG. The role of fear of movement/(re)injury in pain disability. J Occup Rehabil 1995;5:235–52.
56. Geisser ME, Haig AJ, Theisen ME. Activity avoidance and function in persons with chronic back pain. J Occup Rehabil 2000;10:215–27.
57. Vlaeyen JWS, Linton SJ. Fear-avoidance and its consequences in chronic musculoskeletal pain: a state of the art. Pain 2000;85:317–32. [PubMed: 10781906]
58. Holzberg AD, Robinson ME, Geisser ME, Gremillion HA. The effects of depression and chronic pain on psychosocial and physical functioning. Clin J Pain 1996;12:118–25. [PubMed: 8776551]

59. Indahl A, Velund L, Reikeraas O. Good prognosis for low back pain when left untampered: a randomized clinical trial. Spine 1995;20:473–7. [PubMed: 7747232]

60. Jones SL, Jones PK, Katz J. Compliance for low-back pain patients in the emergency department: a randomized trial. Spine 1988;13:553–6. [PubMed: 2973132]

61. Rudy TE, Turk DC, Zaki HS, Curtin HD. An empirical taxometric alternative to traditional classification of temporomandibular disorders. Pain 1989;36:311–20. [PubMed: 2710560]

62. Geisser ME, Colwell M. Chronic back pain: conservative approaches. In: Block AR, Kremer EF, Fernandez E, eds. Handbook of pain syndromes: biopsychosocial perspectives. Mahwah NJ: Lawrence Erlbaum, 1998: 169–90.

63. Turk DC, Rudy TE, Kubinski JA, Zaki HS, Greco CM. Dysfunctional patients with temporomandibular disorders: evaluating the efficacy of a tailored treatment protocol. J Consult Clin Psychol 1996;64:139–46. [PubMed: 8907093]

64. McConnell DG, Beal MC, Dinnar U, Goodridge JP, Johnston WL, Karni Z, Upledger JE, Blum G. Low agreement of findings in neuromusculoskeletal examinations by a group of osteopathic physicians using their own procedures. J Amer Osteopathic Assoc 1982;81:322–28.

65. Gerwin RD, Shannon S, Hong CZ, Hubbard D, Gevirtz R. Interrater reliability in myofascial trigger point examination. Pain 1997;69:65–73. [PubMed: 9060014]

Table 1

Demographic and Pain Information by Group for Subjects Completing the Study

Variable	Group			
	MT-SE	**Sham MT-SE**	**MT-NE**	**Sham MT-NE**
# Assigned	26	25	24	25
# Completed	21	18	15	18
Age	39.3 (12.8)	38.7 (9.4)	36.5 (14.4)	46.3 (9.5)
Pain Duration	63.1 (109.6)	82.1 (99.5)	88.2 (105.8)	63.1 (67.8)
Education	14.5 (2.6)	14.6 (2.4)	15.6 (2.8)	14.6 (2.7)
% Female	67%	56%	80%	61%
% Receiving Compensation	10%	17%	20%	33%
% Prior Surgery	14%	17%	13%	22%

Note: Group differences are not statistically significant.

Table 2

Satisfaction With and Perception of Treatment by Group

Variable	Group			
	MT-SE	Sham MT-SE	MT-NE	Sham MT-NE
Feedback on Condition	6.4 (1.4)	6.2 (1.2)	6.2 (1.1)	5.9 (1.5)
Pain Relief	5.1 (1.7)	4.4 (1.9)	5.2 (1.7)	5.3 (1.5)
Overall Therapy	6.3 (1.4)	5.1 (1.9)	6.0 (1.1)	5.9 (1.4)
Overall Therapist	6.6 (1.1)	6.6 (1.0)	6.8 (0.4)	6.6 (1.0)
Received Real Treatment	6.3 (1.2)	5.7 (1.9)	6.0 (1.9)	5.3 (2.2)

Note: Group differences are not statistically significant.

Table 3

Pre- and Posttreatment Scores on the Individual Pain and Disability Measures by Treatment Group.

Variable	Group			
	MT-SE	Sham MT-SE	MT-NE	Sham MT-NE
VAS Pain				
Pretreatment	4.45 (2.3)	3.84 (2.0)	3.91 (2.5)	5.20 (2.2)
Postreatment	2.40 (2.0)	3.46 (2.0)	3.39 (2.5)	4.29 (2.7)
Change	−2.05	−.38	−.52	−.91
Residual Change	−.50*	.21	.16	.24
MPQ				
Pretreatment	22.24 (12.7)	22.00 (7.6)	25.13 (11.6)	23.39 (12.6)
Postreatment	12.86 (10.9)	18.00 (10.3)	22.67 (16.6)	22.11 (11.9)
Change	−9.38	−4.00	−2.47	−1.28
Residual Change	−.51*	.03	.27	.34
QBPDS				
Pretreatment	36.05 (20.8)	34.25 (19.6)	38.47 (16.0)	51.08 (18.6)
Postreatment	31.05 (19.1)	33.28 (19.4)	31.80 (18.0)	42.50 (19.3)
Change	−5.00	−.97	−6.67	−8.58
Residual Change	−.04	.32	−.16	−.13
MPI Interference				
Pretreatment	37.24 (14.1)	36.01 (14.4)	35.07 (14.0)	43.83 (9.8)
Postreatment	32.86 (13.6)	36.06 (14.9)	27.67 (15.1)	38.89 (11.5)
Change	−4.38	.05	−7.40	−4.94
Residual Change	−.06	.51**	−.49	−.03

Notes: Residual change is the change score on each measure controlling for the pretreatment score.

* $p < .05$

** $p < .01$.