A Randomized Clinical Trial Comparing Chiropractic Adjustments to Muscle Relaxants for Subacute Low Back Pain

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Abstract

Background: The adult lifetime incidence for low back pain is 75% to 85% in the United States. Investigating appropriate care has proven difficult, since, in general, acute pain subsides spontaneously and chronic pain is resistant to intervention. Subacute back pain has been rarely studied.

Objective: To compare the relative efficacy of chiropractic adjustments with muscle relaxants and placebo/sham for subacute low back pain.

Design: A randomized, double-blind clinical trial.

Methods: Subjects (N = 192) experiencing low back pain of 2 to 6 weeks' duration were randomly allocated to 3 groups with interventions applied over 2 weeks. Interventions were either chiropractic adjustments with placebo medicine, muscle relaxants with sham adjustments, or placebo medicine with sham adjustments. Visual Analog Scale for Pain, Oswestry Disability Questionnaire, and Modified Zung Depression Scale were assessed at baseline, 2 weeks, and 4 weeks. Schober's flexibility test, acetaminophen usage, and Global Impression of Severity Scale (GIS), a physician's clinical impression used as a secondary outcome, were assessed at baseline and 2 weeks.

Results: Baseline values, except GIS, were similar for all groups. When all subjects completing the protocol were combined (N = 146), the data revealed pain, disability, depression, and GIS decreased significantly ($P < .0001$); lumbar flexibility did not change. Statistical differences across groups were seen for pain, a primary outcome, (chiropractic group improved more than control group) and GIS (chiropractic group improved more than other groups). No significant differences were seen for disability, depression, flexibility, or acetaminophen usage across groups.

Conclusion: Chiropractic was more beneficial than placebo in reducing pain and more beneficial than either placebo or muscle relaxants in reducing GIS. (J Manipulative Physiol Ther 2004;27:388-98)

Key Indexing Terms: *Chiropractic; Central Muscle Relaxants; Low Back Pain; Randomized Controlled Trial*

Introduction

Low back pain (LBP) has an adult lifetime incidence of 75% to 85% in the United States, with a yearly prevalence of 15% to 20%.[1-3] Common classifications, based on pain duration, include acute (2 weeks or less), subacute (2 to 12 weeks), and chronic (more than 12 weeks). Some studies have shown subacute pain to have clinical characteristics similar to acute LBP.[4,5] While acute pain usually subsides spontaneously, chronic pain is generally resistant to intervention[1,2,6-8] and often becomes a recurrent problem.[6]

The Agency for Health Care Policy and Research (AHCPR) noted that nonsteroidal anti-inflammatory compounds and muscle relaxants were effective for the pain component of low back problems.[9] Spinal manipulation was found to be effective for functional recovery and was recommended for uncomplicated acute LBP within the first month of symptoms. Other reviewers found evidence to

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support spinal manipulation for acute LBP, resulting in both short-term benefits[10-14] and long-term benefits of 1 to 3 years.[15-17] Giles and Muller[18] and Hsieh et al[19] concluded that chronic LBP patients benefit from chiropractic adjustments. In a systematic review of conservative interventions for subacute low back pain, Pengel et al[20] concluded there is a major gap in the evidence for interventions that are recommended in current clinical guidelines.

Reviews of LBP studies[10,12,14,15,21] often fail to distinguish between manipulative interventions. Manipulation and spinal manipulative therapy (SMT) are vague terms describing procedures used by chiropractors, physiotherapists, massage therapists, and osteopaths. These maneuvers may decrease ligamentous adhesions and myospasm, increase disk nutrition, or alter the function of the nervous system. The manipulative procedures used in this study, referred to as chiropractic adjustments, involve specific application of force thought to restore mechanical and neurological function to the spine.[22-24]

Routine chiropractic care generally involves adjusting multiple areas of the spine, as indicated through spinal evaluation.[25,26] This is supported by Nyiendo et al[27] in studies of patients suffering chronic, recurrent low back pain. Those patients seeing chiropractors were more likely (61%) to receive full spine adjustment and less likely (39%) to receive adjustment only at the site of pain (lumbopelvic region). Further, in a study of 12 chiropractors who specialized in only performing upper cervical specific adjustments, 28% of new patients presented with low back pain.[28] One explanation for this is that even though the lumbar facets or sacroiliac articulations may generate the primary pain symptom, the primary dysfunction may be found in other areas of the spine, and it has been proposed that central neurological mechanisms may play an important role.[29-31] Arkuszewski[32] supports the involvement of the cervical spine in back pain and the influence of manual treatment of the cervical segments on different signs of dysfunction of the locomotor system. In 100 patients with lumbar pain or sciatica, 60% had concomitant neck pain. Cervical dysfunction was found at the atlanto-occipital segments in 95% of these patients.

Although chiropractic care has fared well in comparison studies,[14,21] no study has directly compared chiropractic adjustments with muscle relaxants. Andersson et al[33] demonstrated subjects with 3 weeks to 6 months of LBP responded equally well to osteopathic spinal manipulation or standard medical care. A muscle relaxant, cyclobenzaprine, was an option of care, but its effect could not be isolated, since a minority of subjects in both treatment groups received the drug.

This study met approval of the Life University institutional review committee. The goal of this trial was to study a specific classification of subacute LBP, comparing chiropractic adjustments with muscle relaxants and placebo, using an intervention phase typical of drug therapy.

Methods

Randomization and Blinding

This study was a randomized clinical trial (RCT) in which subjects and assessors were blinded to the interventions, chiropractic providers were blinded to medical/sham assignment, and an independent consultant provided the statistical analysis. Visit lengths and provider-subject interactions were monitored to preserve patient blinding. Subjects were assigned sequential enrollment numbers that provided group assignment based on a computer-generated randomization chart.

Subject Selection

Advertisements were used to recruit subjects, 21 to 59 years old, with uncomplicated LBP of 2 to 6 weeks duration. Exclusion criteria included previous spinal surgery, spinal fractures, spinal stenosis, and known or suspected disk herniation; previous LBP within 18 months; neuropathy; spondylitis; vascular disease; malignant disease; cervical complaint; pregnancy; and personal injury litigation. Following informed consent procedures, eligibility was established jointly by doctors of chiropractic and medicine through history taking and a physical examination.

Criteria for Chiropractic Adjustment

Chiropractic assessment. A chiropractic examination at the initial visit ascertained the presence and nature of spinal misalignments. The assessment of the spine included palpation of joints and muscles to assess range and resistance of joint motion, as well as level of tenderness and/or presence of inflammation.[34-37]

Radiographic examination. Radiographic procedures were performed on the first visit. Those patients assigned to the chiropractic care group received 6 radiographs: lateral cervical, vertex, 2 nasium cervical views (before and after first chiropractic adjustment), and anterior-to-posterior and lateral lumbopelvic. The films were used for chiropractic radiographic analysis to provide specific spinal adjustments. Radiation exposure was minimized through high-frequency equipment, high-speed film, rare earth screens, lead filters, and shielding.

Sham radiographic examination. Participants in the medical and control groups were positioned so as to receive each of the 6 radiographs, but no exposures were made.

Interventions

Subjects were randomly assigned to 1 of 3 groups: (1) chiropractic adjustments and medical placebo, (2) muscle relaxants and sham adjustments, and (3) medical placebo and sham adjustment. All subjects received acetaminophen as a "rescue medication" to allow assessment of self-

Table 1. *Medical assessment: Global Impression of Severity*

Clinical observation	Description	Maximum value
Limitations in activities of daily living	Patient response was graded 0 to 4 (none, mild, moderate, severe) and multiplied by 2.	8
Tenderness	Scored from 0 to 4 (none, mild, moderate, severe) and was based on patient response to palpation by the medical doctor.	4
Spasm	Scored from 0 to 4 (none, mild, moderate, severe) and was based on palpation by the medical doctor.	4
Schober's test	Lumbar flexion was assessed by measuring changes in the distance between the 2 spinal landmarks (normal: 5 to 8 cm). Result was subtracted from 5 so that a high score indicated an abnormal condition.	5
VAS for pain	Patient marked pain rating on a 10-cm scale; anchors labeled 0- "no pain" and 10- "worst pain."	10
Total		31

VAS, Visual Analog Scale.

medication. Subjects attended 7 chiropractic visits and self-administered medication/placebo capsules over 2 weeks.

Chiropractic adjustments. At each visit, the chiropractic care that was provided was tailored to each subject's needs and included both upper cervical and lumbar, sacral, or pelvic adjustments.[34-37] Manual spinal adjustments were performed on a drop table (equipped with sections that could travel a limited excursion once a preset load was exceeded), with the subject in either a prone or side-lying position using specific, high-velocity, low-amplitude thrusts in the lumbar, pelvic, or sacral spinal region.[36]

Supine leg length inequality (LLI) and adjustment vectors were determined according to the Grostic Procedure.[34,35,38,39] The subject was placed in a side-lying position with the head resting on the mastoid process. Using a handheld instrument (KME Enterprises, Atlanta, Ga) with an electromagnetically driven stylus, a high-velocity, limited excursion thrust was delivered along a lateral-to-medial vector with skin surface contact over the level of the atlas (C1 vertebra) transverse process.

Sham procedures. Sham procedures were designed to mimic chiropractic adjustments with respect to dialogue, visit length, and physical contact. For lower spine sham procedures, the subject was placed prone on a drop table with the lumbar and pelvic sections activated (lifted but not released) or alternatively, in a side-lying (semifetal) position on a bench. The chiropractor's hand was placed over the paravertebral musculature and light pressure was applied. Caution was taken to avoid an actual thrust to the spine. For the cervical sham procedures, the subject was placed in a supine position and the adjusting instrument was positioned over the mastoid. The instrument was disabled so that no thrust was delivered to the spinal articulations.

Drug therapy. The use of muscle relaxants is common in medical practice for treating back pain, and both nonsteroidal anti-inflammatory compounds and muscle relaxants were noted as effective for the pain component of low back problems by the AHCPR.[9] The 3 agents used in this study (cyclobenzaprine HCl, 5 mg; carisoprodol, 350 mg; methocarbamol, 750 mg) and their usage instructions were chosen by the medical doctor based on his own clinical experience and were designed to mimic general medical care with a 2-week duration. The medications affect motor activity through central mechanisms. Cyclobenzaprine HCl reduces tonic somatic motor activity primarily within the central nervous system. Carisoprodol has been shown to produce muscle relaxation in animals by blocking interneuronal activity in the descending reticular formation and the spinal cord. Methocarbamol is thought to depress the central nervous system.[40]

The medical doctor dispensed medication kits that contained 4 bottles. Subjects in the medical group were given 3 muscle relaxants in bottles labeled A, B, and C. Subjects were given written and verbal instructions referring to bottles by letter only. Subjects were instructed to record on a medication log the amount of each drug used and any side effects encountered.

The initial dose was 2 capsules at bedtime from bottle A and 2 capsules, 3 times daily from bottle B. Medication from bottles A and B could be doubled or halved as needed. If subjects experienced excessive side effects such as drowsiness or sleeplessness from a medicine, they were allowed to substitute bottle B for A and bottle C for B, again doubling or halving dosages as necessary. If excessive side effects continued after switching to bottle C, instructions were to stop taking all capsules. Subjects were informed that bottle D contained acetaminophen (500 mg), and the maximum dose was 2 capsules, 3 times daily.

Placebo drug therapy. There was no visual difference between the medication and corresponding placebos. Bottles labeled A, B, and C given to the control and chiropractic groups contained capsules filled with an inactive placebo; bottle D contained acetaminophen tablets. Subjects in the chiropractic and control groups received instructions identical to those of the medical group.

Table 2. *Demographics and baseline characteristics*

	Chiropractic	Medical	Control	Total
Male:female	25:25	32:21	32:21	89:67
Age (y)	42.2 ± 9.7	40.5 ± 10.1	43.1 ± 9.8	41.9 ± 9.9
Pain duration (wk)	3.7 ± 1.3	3.6 ± 1.5	3.8 ± 1.4	3.7 ± 1.4
Pain pattern (constant:intermittent)	37:8	38:14	40:13	115:40
Pain onset (gradual:sudden)	16:34	20:31	20:33	56:98
Previous back pain treatment (yes:no)				
Medication	7:43	11:41	18:35	36:119
Surgery	0:50	0:52	0:53	0:155
Physical therapy	0:50	0:52	2:51	2:153
Exercise	6:44	4:48	7:46	17:138
Number of previous episodes	0.36 ± 0.60	0.46 ± 0.64	0.58 ± 0.67	0.47 ± 0.64
Previous chiropractic care (yes:no)	23:27	16:36	24:29	63:92
VAS	4.52 ± 1.78 (49)	3.95 ± 2.15 (51)	4.24 ± 1.85 (53)	4.24 ± 1.94 (153)
Schober	2.96 ± 1.07 (49)	3.38 ± 1.25 (52)	3.17 ± 1.20 (53)	3.18 ± 1.18 (154)
Oswestry	24.0 ± 11.7 (49)	22.5 ± 12.5 (52)	25.2 ± 12.0 (53)	23.9 ± 12.1 (154)
Zung	17.6 ± 10.4 (48)	15.2 ± 8.73 (52)	17.2 ± 9.70 (53)	16.6 ± 9.60 (153)
GIS*	12.9 ± 3.29 (49)	11.3 ± 3.53 (52)	12.6 ± 3.20 (53)	12.3 ± 3.39 (154)

Mean values, SDs, and sample sizes given as Mean ± SD (N), or, for nominal data, as number of subjects in each category.
VAS, Visual Analog Scale; *GIS,* Global Impression of Severity.
*Significant group differences for GIS ($P < 0.037$); chiropractic group higher than medical group.

Outcome Assessments

After a series of meetings between 1993 and 1997, a World Health Organization informal committee recommended 4 primary outcome measures for clinical trials investigating low back pain.[41] Three valid and reliable measures, a Visual Analog Scale (VAS) for Pain,[42-44] the (original) Oswestry Low Back Pain Disability Questionnaire,[45-47] and the Modified Zung Self-Rating for Depression Scale,[48-51] were administered at the initial visit (baseline) and repeated at 2 weeks and 4 weeks. A fourth measure, Schober's test, was done at baseline and 2 weeks to evaluate lumbar flexibility.[52,53] Two secondary outcome measures were used: acetaminophen usage during the 14-day intervention phase and a final measure, termed Global Impression of Severity (GIS), which was implemented in the study to determine its usefulness in assessing temporal aspects of physical examination findings. GIS scores ranged from 0 to 31 and were derived by combining 5 measures determined by a medical doctor performing a blinded evaluation (Table 1).

Statistical Analysis

The statistical analysis was designed by a doctorate-level biostatistician from an independent university. The initial analysis confirmed the normality of outcome measures at each assessment, lending to parametric methods for significance testing. Subjects were analyzed in the intervention group to which they were randomized (intent-to-treat), but to eliminate erroneous assumptions made for missing data points, data for each outcome measure were restricted to subjects who completed the assessments.

A general linear model analysis of variance (ANOVA) was used for outcome measures looking for a significant time by intervention group interaction ($P < .05$). If groups differentially changed over time, familywise comparisons were made using the Tukey Honestly Significant Difference (HSD) studentized range tests, which control for type 1 error.

Results

Subject Recruitment and Follow-Up

The various recruiting methods used for this study resulted in 2570 inquiries. Most people responded to advertisements or public service announcements from newspapers (1897), radio (98), television (82), magazines (72), or an Internet posting (1). Of the remainder, 89 persons were referrals, and 331 did not recall the advertising source.

Subsequent telephone interviews screened prospective participants based on rigid inclusion criteria. The majority of the subjects (79.2%) failed to qualify for 1 or more reasons. The most common reason for excluding subjects was because their LBP duration was too long (chronic) or the pain pattern was judged recurrent. Other main reasons for exclusion included known or suspected cause of LBP and recent care for the condition. Of the 535 subjects who were eligible based on the telephone interview, about half (246) were sufficiently interested to be scheduled to receive a history and examination by the medical/chiropractic team to determine second-stage eligibility. Of these, 20 failed to show up for their initial appointment and were dropped from the study. Of the subjects that received an examination, 34

Table 3. *Response to question, "Do you think you received actual chiropractic adjustments?"*

Group	No	Yes	Total
Chiropractic	6 (12.5%)	42 (87.5%)	48
Medical	30 (60.0%)	20 (40.0%)	50
Control	39 (79.6%)	10 (20.4%)	49
Total	75 (51.0%)	72 (49.0%)	147

Table 4. *Response to question, "Do you think you received actual medication?"*

Group	No	Yes	Total
Chiropractic	30 (65.2%)	16 (34.8%)	46
Medical	18 (35.3%)	33 (64.7%)	51
Control	20 (40.8%)	29 (59.2%)	49
Total	68 (46.6%)	78 (53.4%)	146

were excluded from the study due to known/suspected cause of pain (18), current medication usage (3), presence of neck pain (2), no time commitment by subject (4), pain duration outside of the 2- to 6-week window (4), recurrent pain (1), no present pain (1), and breast-feeding (1) (contraindication to use of radiographs). The remaining 192 subjects were enrolled in the study and randomly assigned to 1 of 3 groups receiving chiropractic, medical, or no care with appropriate sham/placebo procedures employed to maintain subject blinding to group assignment.

Once enrolled in the study, patient retention was good. Of the 192 subjects who were enrolled in the study, 159 (82.8%) completed the 2-week care phase and 146 (76.0%) returned 2 weeks thereafter for final data collection. There was no group bias for dropouts (chiropractic 13, medical 17, control 13; χ^2 analysis, $P = .75$), and most subjects dropped out due to time constraints. Data from 3 subjects were discarded because 2 had initiated personal injury litigation (an exclusion criterion) and another inadvertently received both forms of active intervention.

Demographics

Randomization resulted in similar groups (Table 2), except for initial GIS scores. The mean ± SD for age and pain duration were 41.9 ± 9.9 years and 3.7 ± 1.4 weeks. Most subjects had constant pain and two thirds had sudden rather than gradual onset of pain. Based on a "yes" or "no" response to the telephone interview question, "Have you ever had any prior episodes of low back pain?," the majority of subjects (60%) reported they were experiencing their first episode of LBP lasting longer than 2 weeks, and in addition, all subjects reported "no" to an interview question regarding whether they had received any treatment for low back pain for the current episode.

Blinding

To help assess the success of blinding as to assignment to treatment group, subjects were asked at the end of the study whether they thought they received true chiropractic adjustments and true medications. Tables 3 and 4 list the results of these 2 questions based on group assignment. Subjects had an equal likelihood of being placed in any of the 3 intervention groups. If subjects understood the experimental design and were successfully blinded to the interventions used, one would expect about one third of the subjects to say they received actual care. This was not the case, and χ^2 analysis revealed significant cross-group differences to both questions (chiropractic adjustments: $P < .001$; medications: $P = .008$). Follow-up pair-wise comparisons revealed that perception of true chiropractic care was significantly higher ($P < .05$) in the chiropractic group than either of the other 2 groups, as might be predicted if the sham maneuver did not closely approximate the true adjustment. However, significantly more subjects in the medical group perceived receiving true chiropractic care than in the control group, a result that is difficult to interpret. When responding to whether they received true medication, response patterns were similar in the medical and control groups, but both of these had significantly higher positive response rates than the chiropractic group.

Table 5. *Cross tabulation of responses to intervention perception*

	True chiropractic?		
True medication?	No	Yes	Total
No	31 (21.4%)	36 (24.8%)	67 (46.2%)
Yes	44 (30.3%)	34 (23.5%)	78 (53.8%)
Total	75 (51.7%)	70 (48.3%)	145 (100.0%)

Table 5 compares response rates to the 2 questions regarding perception of true care. About the same number of subjects fit into each of the 4 potential response combinations (no/no, no/yes, yes/no, yes/yes), even though the study design did not allow subjects to receive both active forms of intervention.

Subject Compliance

The 2-week care phase involved a total of 8 visits over a 2-week period, which was followed by a ninth visit 2 weeks thereafter for a final assessment. The majority of the subject pool that completed the care phase attended all 8 scheduled visits ($N = 154$, mean = 7.68, SD = 0.72). There was no difference in the number of visits across intervention groups.

On completion of the care phase, subjects were asked to return their medication kits along with their completed medication logs. A total of 126 people (82%) returned their medication kits and 121 people (79%) returned their

Table 6. *Data summary*

		Chiropractic			Medical			Control		
	Measure	N	Mean	SD	N	Mean	SD	N	Mean	SD
Initial	VAS	34	4.52	1.82	36	3.89	2.04	40	3.84	1.64
	Oswestry	46	24.78	11.47	47	22.76	12.87	48	24.84	11.68
	Zung	43	18.00	10.72	45	15.29	8.73	47	17.21	9.84
	Schober	48	2.93	1.06	52	3.38	1.25	52	3.13	1.18
	GIS	48	13.02	3.28	52	11.32	3.53	52	12.68	3.16
2 weeks	VAS	34	2.44	2.22	36	2.73	2.15	40	3.18	2.40
	Oswestry	46	17.02	13.75	47	16.99	12.18	48	19.35	13.70
	Zung	43	12.49	9.39	45	12.02	8.06	47	13.83	8.90
	Schober	48	3.20	0.93	52	3.58	1.21	52	3.23	1.11
	GIS	48	7.58	4.00	52	8.57	4.96	52	9.78	4.64
	Analgesic*	43	20.35	23.44	42	18.98	23.98	39	16.51	23.32
	Analgesic†	38	12.39	18.53	40	10.58	14.60	41	9.90	19.63
4 weeks	VAS	34	1.71	1.88	36	2.24	2.23	40	2.21	2.02
	Oswestry	46	11.94	11.93	47	16.04	16.12	48	16.32	12.95
	Zung	47	11.91	10.53	45	11.73	9.01	47	11.81	7.37

VAS, Visual Analog Scale; *GIS,* Global Impression of Severity.
* Tablets used over 2-week period based on bottle counts.
† Tablets used over 2-week period based on drug logs.

medication logs. Turning in kits was moderately associated with turning in logs: 83% of subjects turned in both or neither, kappa = 0.49. Out of concern that medication usage data were biased toward certain types of subjects, a series of *t* tests was performed looking for differences in the 2 groups of subjects who did or did not fill out their medication logs. There was no statistical difference between these groups for baseline values of VAS for Pain, Oswestry Low Back Pain Disability Questionnaire, Modified Zung Self-Rating for Depression Scale, or Schober's test, implying that subjects who provided medication usage data were representative of the entire subject pool.

Medication/placebo usage was appraised from the logs and the bottle counts. Both methods are prone to error; subjects might have forgetten to update their logs when taking medication, and subjects might have taken pills out of the containers without actually ingesting them. Both result in higher bottle counts relative to log counts, and the data indicate bottle counts for all 4 pills combined were, on average, 24.9 pills higher than the log counts. However, there were no usage differences across groups.

In summary, subjects in the 3 intervention groups received the same number of chiropractic procedures (real or sham) and the same number of pills (medication or placebo). The amount of acetaminophen taken (bottle D) is described below in Secondary Outcome Measures.

Primary Outcome Measures

Table 6 lists summary data for all outcome measures.

Visual Analog Scale for Pain. The 4-week VAS was not assessed during a portion of the study due to administrative error.

ANOVA for all subjects combined showed a significant decrease in pain (see Fig 1) over the 4-week trial ($P < .0001$). Mean baseline values for VAS were higher for the chiropractic group (16% and 18% higher than the medical and control groups, respectively) and final values were lower for the chiropractic group (24% and 23%), but none of these differences were statistically significant. However, ANOVA did reveal that the *change* in reported pain during the trial did vary among intervention groups, a result that was significant ($P = .0321$). Post hoc analysis revealed that subjects in the chiropractic group reported greater pain reduction than the control group. Similar findings were seen during the 2-week intervention phase, where there was also a significant difference in change scores across groups ($P = .0301$) and the chiropractic group improved more than the control group ($P < .05$).

Oswestry Disability Index. Figure 2 reveals a significant decline in disability for all groups ($P < .0001$) with the greatest decline occurring in the chiropractic care group, though it was not significantly different ($P = .087$).

Modified Zung. As shown in Figure 3, depression scores improved significantly over the course of the study for all groups ($P < .0001$). However, there were no significant differences among the groups ($P = .319$).

Schober's test. Figure 4 displays a modest, but insignificant, increase in flexibility for combined groups ($P = .055$); there were no differences among the groups ($P = .762$).

Secondary Outcome Measures

Acetaminophen usage. The use of acetaminophen was calculated through remaining pill counts and medication logs. Moderate usage of 1.33 ± 1.67 capsules per day

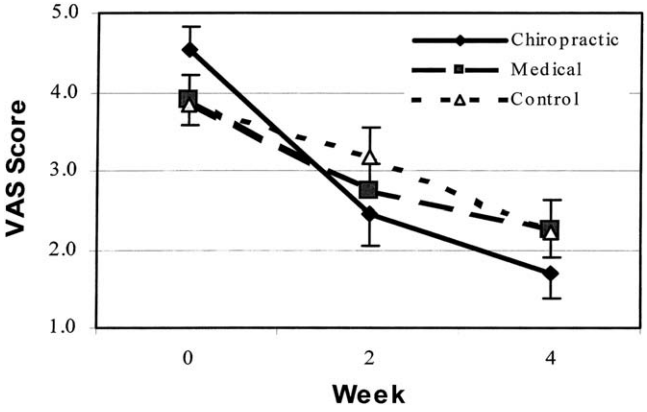

Fig 1. *Mean (±SE) changes in the Visual Analog Scale (VAS) for Pain over the 4-week trial. VAS could range from 0 to 10, with 0 corresponding to "no pain" and 10 corresponding to "worst pain." Subjects showed significant improvement (P < .0001) with the chiropractic group improving significantly more than the control group over both the 2-week intervention interval (P = .0301) and the 4-week trial (P = .0321).*

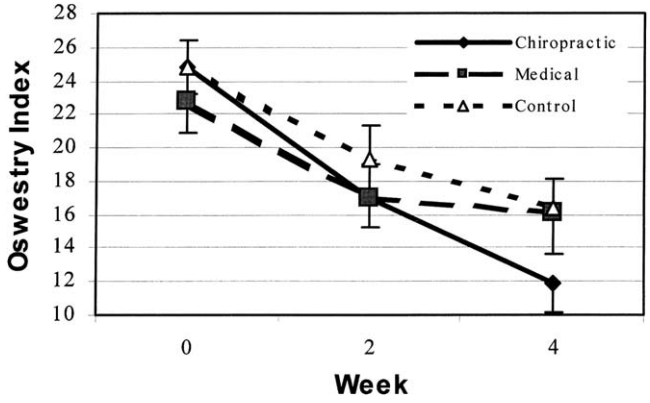

Fig 2. *Mean (±SE) changes in disability over the 4-week trial. Disability assessed at baseline, after the 2-week care period, and at 4-week follow-up using the Oswestry Disability Index. All 3 groups showed a significant downward trend in disability scores indicating improvement (P < .0001). No statistical differences were seen across groups (P = .087), though there was a trend for greater improvement in the chiropractic group.*

measured by bottle counts or 0.78 ± 1.26 per day using logs was demonstrated. There was no statistical difference across groups in the number of tablets taken calculated by bottle counts ($P = .760$) or by logs ($P = .814$).

Global Impression of Severity. Figure 5 shows a significant decline in GIS for all groups ($P < .0001$) and significant differences among groups ($P = .010$). Post hoc analysis revealed the chiropractic group improved significantly more than both other groups ($P < .05$).

Discussion

In all groups, for each outcome measure, there was improvement after 2 weeks of care and further improvement at the 4-week follow-up, so these subacute subjects appear to improve in a manner similar to acute pain sufferers.[4,5] The improvements in the placebo group likely represent natural history.

After the 2-week intervention phase, chiropractic adjustments were shown to be statistically more beneficial than placebo in reducing pain and more beneficial than placebo or muscle relaxants in reducing GIS; however, there were no differences across groups for disability. For the disability measure, post hoc analysis revealed the power of the present study to be 59%. Further, assuming means and variances seen in the present study and a power level of 80%, increasing the sample population to 72 subjects per group could have yielded significant advantages for chiropractic adjustments. No group differences were seen with the Modified Zung, as would be expected since depression is mild during the acute/subacute phase, nor were differences observed for flexibility or analgesic usage.

Previous comparisons of SMT to medical care for LBP have shown mixed results. A study of subjects with 3 to 26 weeks of LBP showed no additional benefit for osteopathic manipulation over standard medical care, which included medicines and physical modality.[33] Similarly, a study of acute LBP showed manipulative physiotherapy was no more beneficial than nonsteroidal anti-inflammatory drugs (NSAIDs).[54] In chronic LBP, no group differences were seen for trunk-strengthening exercises supplemented by either chiropractic manipulation or NSAIDs.[55] Conversely, other chronic spinal pain studies have shown spinal manipulative procedures more beneficial than NSAIDs[18] and spinal manipulation more beneficial than continued care using analgesics and NSAIDs.[15] In light of the differing methodologies across studies, it is difficult to draw any strong conclusions.

In this study, care was restricted to 2 weeks, although in practice, chiropractors typically see patients for longer periods. Other trials comparing chiropractic adjustments to medical care for LBP allowed for 9 visits over 1 month,[56] 10 treatments over 1 year,[16] or, in a childhood asthma study, 20 to 36 visits over 4 months.[57] Though improvement was marked and rapid in the present trial, providing the chiropractors with more latitude in their care plan might have provided additional benefit. As follow-up extended only to 4 weeks, long-term benefits of the interventions are unknown.

Outcomes in randomized drug therapy trials often include assessment of global improvement and 5 specific domains of back pain: local pain, muscle spasm, range of motion, tenderness to palpation, and activities of daily living.[58] The GIS used in this study has not been tested for reliability and validity and is subjective by its very

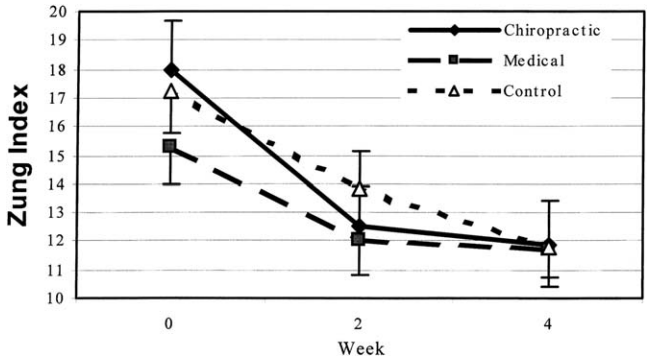

Fig 3. *Mean (±SE) changes in depression over the 4-week trial. The Modified Zung Index was used to assess depression at baseline, after the 2-week care phase, and at the 4-week follow-up. Depression lessened over time (P < .0001), but there were no differences among groups (P = .319).*

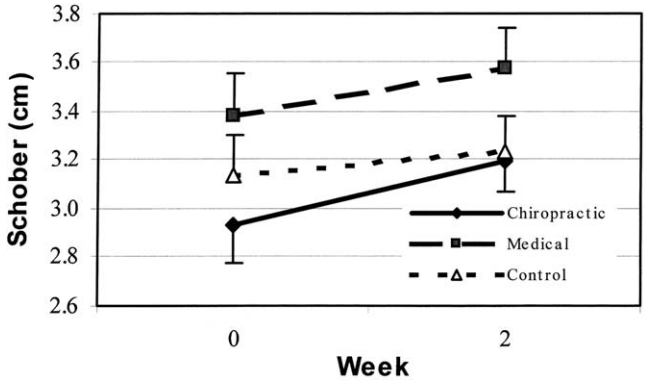

Fig 4. *Mean (±SE) changes in lumbar flexibility over the 2-week care phase. Schober's test was used to assess lumbar flexibility by measuring the change in distance between 2 spinal landmarks during flexion. There was a trend for increased flexibility over the 2 weeks that was not significant (P = .055). No differences among groups were seen (P = .762).*

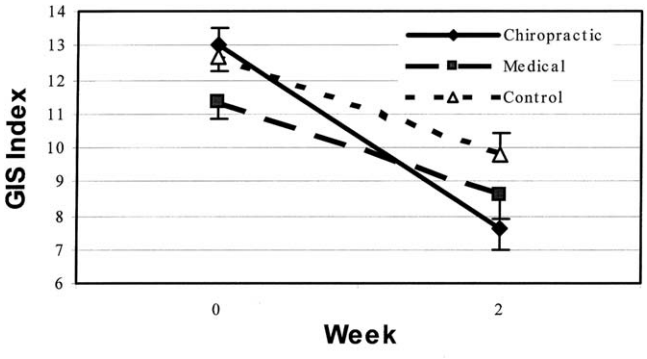

Fig 5. *Mean (±SE) changes in the Global Impression of Severity (GIS) over the 2-week care phase. GIS combined scores from 5 physical examination findings (see Table 1); higher numbers indicate greater severity. Baseline scores varied significantly (P = .037), with chiropractic subjects having higher scores than medical subjects. Subjects improved significantly over the 2-week interval (P < .0001). Significant group differences were evident (P = .010) with the chiropractic group improving more than the other 2 groups (P < .05).*

nature. It is, therefore, limited in its usefulness and significance. The measure did provide a broadly based assessment, was normally distributed, demonstrated a useful range, and was responsive to 2 weeks of intervention/time. In a clinical perspective, the severity of a patient presenting for care is often subjectively rated. In this study, the GIS represented a blinded evaluation of severity by the medical doctor using his own scoring method. There was overlap in outcome assessments, since GIS was formed from 5 measures, 2 of which were analyzed individually. However, analysis of GIS data without the VAS or Schober's components did not change the results. The GIS showed that subjects given chiropractic adjustments and placebo medicine improved more than subjects who received placebo medicine or muscle relaxants did (in combination with sham adjustments). However, it should be noted that the chiropractic group mean was worse at baseline, giving a slightly more favorable advantage toward improvement based solely on natural history.

In this study population, only modest changes in flexibility were seen and no difference among groups emerged using Schober's test. The reliability and validity of Schober's test for testing lumbar flexibility have been debated. Researchers have found Schober's test works as well as the computerized CA-6000 Spinal Motion Analyzer (Orthopedic Systems Inc, Union City, Calif) in assessing lumbar flexion and that a modified Schober test is superior to double inclinometer methods for flexion, while another study suggests use of a modified Schober could introduce systematic errors and its use is questionable.[59-61]

Although lifetime usage figures are not available, approximately 7% to 10% of the overall population uses chiropractic in a given year.[62,63] The study population was not naïve to chiropractic interventions. Since 40% also reported previous LBP (exclusion criteria: occurrence >18 months prior), it is not surprising to find a 41% lifetime history of chiropractic care (exclusion: occurrence >18 months prior). Even so, the post hoc analysis found no significant association of previous chiropractic care with blinding, dropout rate, or changes in VAS for pain.

Although blinding procedures directed toward the providers and assessors were successful, whether subjects remained blinded is debatable. A high percentage of subjects in the chiropractic and medical groups responded correctly to questions regarding the intervention received. This is not unusual in clinical trials, since many interventions deliver a powerful and readily apparent effect. However, it is difficult

to interpret why statistically more control subjects than chiropractic subjects in this study thought they were receiving true medications. It would seem that the blinding procedures used here were no less successful than those used in other rigorous randomized clinical trials.[56,57,64]

Blinded, randomized clinical trials are considered the gold standard of experimental design.[9,15,21,65] Yet, blinding remains elusive in studies where the intervention may be invasive (eg, surgery, acupuncture) or involve physical contact between the subject and the care provider (eg, chiropractic, osteopathy, massage). An appropriate chiropractic sham procedure requires a maneuver that makes subjects think they are getting a spinal adjustment without actually causing osseous rearrangement. Joint cavitation commonly occurs during activities that approach endpoint range of motion, and this may cause changes in the spine. Joint cavitation was noted twice in the present study during lumbar sham procedures. Even well-designed sham procedures could cause inadvertent correction. Further, there is the possibility that palpation of spastic paraspinal muscles and other contiguous tissues may cause spinal changes. Thus, previous rigorous sham-controlled studies in chiropractic that demonstrated global benefits to all intervention groups while failing to show differential benefits[57] may have been inadvertently providing benefit to the control group.

Study Limitations

In a factorial design, a fourth group could have been randomized to receive both active interventions. Furthermore, this study did not provide for a 1-year follow-up. Possibly, long-term follow-up could help to identify different recovery patterns in these groups. Stratification on the study population for the wide ranges in pain and disability scores (large SD) in a separate analysis may provide characteristics of responders versus nonresponders for both types of interventions.

Health care providers often rate the severity of presenting complaints of patients using subjective means. The GIS used for a blinded assessment by the medical physician needs to be tested for reliability and validity; therefore, the significance of the results for GIS should be interpreted cautiously.

Increasing the sample size according to power analysis, lengthening the care phase to 6 weeks to provide care more in line with practice standards, and providing a 1-year follow-up would improve future studies.

Conclusion

This study identified a sample population of subacute low back pain sufferers for which chiropractic care provided an equally effective management to the conservative medical care of muscle relaxants. However, as subjects responded well to time (and placebo), these design changes may not provide the strong clinical evidence needed to recommend a particular intervention for management of subacute back pain.

Statistically, the chiropractic group responded significantly better than the control group with respect to a decrease in pain scores.

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References

1. Allan DB, Waddell G. An historical perspective on low back pain and disability. Acta Orthop Scand 1989;60:1-23.
2. Andersson GBJ. Epidemiology of low back pain. Acta Orthop Scand 1998;69(Suppl 281):28-31.
3. Waddell G. Low back pain: a twentieth century health care enigma. Spine 1996;21:2820-5.
4. Linton SJ, Hallden K. Can we screen for problematic back pain? A screening questionnaire for predicting outcome in acute and subacute back pain. Clin J Pain 1998;14:209-15.
5. Sinclair SJ, Hogg-Johnson S, Mondloch MV, Shields SA. The effectiveness of an early active intervention program for workers with soft-tissue injuries: the early claimant cohort study. Spine 1997;22:2919-31.
6. Carey TS, Garrett J, Jackman A, McLaughlin C, Fryer J, Smucker DR. The outcomes and costs of care for acute low back pain among patients seen by primary care practitioners, chiropractors, and orthopaedic surgeons. N Engl J Med 1995; 333:913.
7. Deyo RA, Phillips WR. Low back pain. A primary care challenge. Spine 1996;21:2826-32.
8. Von Korff M, Saunders K. The course of back pain in primary care. Spine 1996;21:2833-9.
9. Bigos SJ, Bowyer OR, Braen GR, Brown KC, Deyo RA, Haldeman S, et al. Acute low back pain problems in adults. Clinical practice guideline no. 14. Rockville (MD): Agency for Health Care Policy and Research; 1994 (AHCPR publication 95-0642).
10. Abenhaim L, Bergeron AM. Twenty years of randomized clinical trials of manipulative therapy for back pain: a review. Clin Invest Med 1992;15:527-35.
11. Haldeman S. Spinal manipulative therapy in sports medicine. Clin Sports Med 1986;5:277-93.
12. Moritz U. Evaluation of manipulation and other manual therapy. Criteria for measuring the effect of treatment. Scand J Rehabil Med 1979;11:173-9.

13. Raftis KL, Warfield CA. Spinal manipulation for back pain. Hosp Pract (Off Ed) 1989;24:89-90, 95-6, 102.
14. Shekelle PG, Adams AH, Chassin MR, Hurwitz EL, Brook RH. Spinal manipulation for low back pain. Ann Intern Med 1992;117:590-8.
15. Koes BW, Bouter LM, van Mameren H, Essers AH, Verstegen GM, Hofhuizen DM, et al. The effectiveness of manual therapy, physiotherapy, and treatment by the general practitioner for nonspecific back and neck complaints. Spine 1992; 17:28-35.
16. Meade TW, Dyer S, Browne W, Townsend J, Frank AO. Low back pain of mechanical origin: randomized comparison of chiropractic and hospital outpatient treatment. BMJ 1990; 300:1431-7.
17. Meade TW, Dyer S, Browne W, Frank AO. Randomized comparison of chiropractic and hospital outpatient management for low back pain: results from extended follow-up. BMJ 1995; 311:349-51.
18. Giles LG, Muller R. Chronic spinal pain syndromes: a clinical pilot trial comparing acupuncture, a nonsteroidal anti-inflammatory drug, and spinal manipulation. J Manipulative Physiol Ther 1999;22:376-81.
19. Hsieh CY, Phillips RB, Adams AH, Pope MH. Functional outcomes of low back pain: comparison of four treatment groups in a randomized controlled trial. J Manipulative Physiol Ther 1992;15:4-9.
20. Pengel HM, Maher CG, Refshauge KM. Systematic review of conservative interventions for subacute low back pain. Clin Rehabil 2002;16:811-20.
21. Anderson R, Meeker WC, Wirick BE, Mootz RD, Kirk DH, Adams A. A meta-analysis of clinical trials of spinal manipulation. J Manipulative Physiol Ther 1992;15:181-94.
22. Gatterman MI. What's in a word? In: Gatterman MI, editor. Foundations of chiropractic: subluxation. St. Louis: Mosby-Year Book; 1995. p. 5-17.
23. Janse J. History of the development of chiropractic concepts: chiropractic terminology. In: Goldstein M, editor. The research status of spinal manipulative therapy. US Department of Health, Education, and Welfare. Bethesda (MD): Public Health Service; 1975. p. 25-42 (National Institutes of Health NINCDS Monograph 15).
24. Leach RA. Manipulation terminology. In: Leach RA, editor. The chiropractic theories: principles and clinical applications. 3rd ed. Baltimore: Williams and Wilkins; 1994. p. 15-22.
25. Meeker WC, Haldeman S. Chiropractic: a profession at the crossroads of mainstream and alternative medicine. Ann Intern Med 2002;136:216-27.
26. Christensen MG, Kerkoff D, Kallasch MW. Job analysis of chiropractic. A project report, survey analysis and summary of the practice of chiropractic within the United States. Greeley (CO): National Board of Chiropractic Examiners; 2000. p. 115-7.
27. Nyiendo J, Haas M, Goodwin P. Patient characteristics, practice activities, and one-month outcomes for chronic, recurrent low-back pain treated by chiropractors and family medicine physicians: a practice-based feasibility study. J Manipulative Physiol Ther 2000;23:239-45.
28. Hoiriis KT, Owens EF. Changes in general health status during upper cervical chiropractic care: a practice-based research project update. Chiropr Res J 1999;6:65-70.
29. Henderson C. Three neurophysiologic theories on the chiropractic subluxation. In: Gatterman MI, editor. Foundations of chiropractic: subluxation. St. Louis: Mosby; 1995. p. 225-33.
30. Lantz C. The vertebral subluxation complex. In: Gatterman M, editor. Foundations of chiropractic: subluxation. St. Louis: Mosby; 1995. p. 149-74.
31. Miller KE, Douglas VD, Richards AB, Chandler MJ, Foreman RD. Propriospinal neurons in the C1-C2 spinal segments project to the L5-S1 segments of the rat spinal cord. Brain Res Bull 1998;47:43-7.
32. Arkuszewski Z. Involvement of the cervical spine in back pain. Man Med 1986;2:126-8.
33. Andersson GBJ, Lucente T, Davis AM, Kappler RE, Lipton JA, Leurgans S. A comparison of osteopathic spinal manipulation with standard care for patients with low back pain. N Engl J Med 1999;341:1426-31.
34. Grostic JD. Upper cervical care and functional leg length inequality. Proceedings of the Sixth Annual Conference on Research and Education. 1991 June 21-23; Monterey, California. San Jose (CA): Consortium for Chiropractic Research; 1991. p. 70-3.
35. Grostic JD, DeBoer KF. Roentgenographic measurement of atlas laterality and rotation: a retrospective pre and post manipulation study. J Manipulative Physiol Ther 1982;5: 63-9.
36. Reinert OC, editor. Chiropractic procedure and practice. Florissant (MO): Marian Press; 1976. p. 78-95.
37. Downe JW, editor. Technique manual of Life College, School of Chiropractic. Marietta (GA): Life University; 1993. p. 14-34.
38. Hinson R, Brown S. Supine leg length differential estimation: an inter- and intra-examiner reliability study. Chiropr Res J 1998;5:17-22.
39. Hinson R, Pfleger B. Pre- and post-adjustment supine leg-length estimation. J Chiropr Educ 2000;14:37-8.
40. Walsh P. Physicians' desk reference. 55th ed. Montvale (NJ): Medical Economics; 2001. p. 1929, 2716, 3252.
41. Jayson MIV. Outcome measures for back pain: introduction, justification, and epidemiology. In: Erhlich GE, Khaltaev NG, editors. Low back pain initiative. Geneva: World Health Organization; 1999. p. 8-12.
42. Ferraz MB, Quaresma MR, Aquino LR, Atra E, Tugwell P, Goldsmith CH. Reliability of pain scales in the assessment of literate and illiterate patients with rheumatoid arthritis. J Rheumatol 1990;17:1022-4.
43. McCormack HM, Horne DJ, Sheather S. Clinical applications of visual analogue scales: a critical review. Psychol Med 1988; 18:1007-19.
44. Scott J, Huskisson EC. Vertical or horizontal visual analogue scales. Ann Rheum Dis 1979;38:560.
45. Baker DJ, Pynsent PB, Fairbank JCT. The Oswestry Disability Index revisited: its reliability, repeatability and validity, and a comparison with the St Thomas Disability Index. In: Roland MO, Jenner JR, editors. Back pain: new approaches to rehabilitation and education. Manchester, England: Manchester University Press; 1989. p. 174-86.
46. Fairbank JCT, Couper J, Davies JB, O'Brien JP. The Oswestry Low Back Pain Disability Questionnaire. Physiotherapy 1980; 66:271-3.
47. Stratford PW, Binkley J, Solomon P, Gill C, Finch E. Assessing change over time in patients with low back pain. Phys Ther 1994;74:528-33.
48. Hedlund JL, Vieweg BW. The Zung Self-rating Depression Scale: a comprehensive review. J Oper Psychiatry 1979;10: 51-64.
49. Lambert MJ, Hatch DR, Kingston MD, Edwards BC. Zung, Beck, and Hamilton rating scales as measures of a treatment outcome: a meta-analytic comparison. J Consult Clin Psychol 1986;54:54-9.
50. Main CG, Wood PLR, Hollis S, Spanswick CC, Waddell G. The distress and risk assessment method: a simple patient classification to identify distress and evaluate the risk of poor outcome. Spine 1992;17:42-52.

51. Tanaka-Matsumi J, Kameoka VA. Reliabilities and concurrent validities of popular self-report measures of depression, anxiety, and social desirability. J Consult Clin Psychol 1986;54: 328-33.
52. Dequeker J, Panayi G, Pinus T, Grahame R. Medical management of rheumatic musculoskeletal and connective tissue disease. New York: Marcel Dekker; 1997. p. 41.
53. Evans RC. Schober's test. In: Evans RC, editor. Illustrated essentials in orthopedic assessment. St. Louis: Mosby; 1994. p. 326-7.
54. Waterworth RF, Hunter IA. An open study of diflunisal, conservative and manipulative therapy in the management of low back pain. N Z Med J 1985;98:372-5.
55. Bronfort G, Goldsmith GH, Nelson CF, Boline PD, Anderson AV. Trunk exercise combined with spinal manipulative or NSAID therapy for chronic low back pain: a randomized, observer blinded clinical trial. J Manipulative Physiol Ther 1996;19:570-82.
56. Cherkin DC, Deyo RA, Battie M, Street J, Barlow W. A comparison of physical therapy, chiropractic manipulation, and provision of an educational booklet for the treatment of patients with low back pain. N Engl J Med 1998;339: 1021-9.
57. Balon J, Aker PD, Crowther ER, Danielson C, Cox PG, O'Shaughnessy D, et al. A comparison of active and simulated chiropractic manipulation as adjunctive treatment for childhood asthma. N Engl J Med 1998;339:1013-20.
58. Browning R, Jackson JL, O'Malley PG. Cyclobenzaprine and back pain: a meta-analysis. Arch Intern Med 2001;161: 1613-20.
59. Dopf CA, Mandel SS, Geiger DF, Mayer PJ. Analysis of spine motion variability using a computerized goniometer compared to physical examination. A prospective clinical study. Spine 1995;19:586-9.
60. Miller SA, Mayer T, Cox R, Gatchel RJ. Reliability problems associated with the modified Schober technique for true lumbar flexion measurement. Spine 1992;17:345-8.
61. Williams R, Binkley J, Bloch R, Goldsmith CH, Minuk T. Reliability of the modified Schober and double inclinometer methods for measuring lumbar flexion and extension. Phys Ther 1993;73:33-44.
62. Eisenberg DM, Davis RB, Ettner SL, Appel S, Wilkey S, Van Rompay M, et al. Trends in alternative medicine use in the United States, 1990-1997. Results of a follow-up national survey. JAMA 1998;280:1569-75.
63. Eisenberg DM, Kessler RC, Foster C, Norlock FE, Calkins DR, Delbanco TL. Unconventional medicine in the United States–prevalence, costs, and patterns of use. N Engl J Med 1993;328: 246-52.
64. Morin CM, Colecchi C, Brink D, Astruc M, Mercer J, Remsberg S. How "blind" are double-blind placebo-controlled trials of benzodiazepine hypnotics? Sleep 1995;18:240-5.
65. van Tulder MW, Koes BW, Bouter LM. Conservative treatment of acute and chronic nonspecific low back pain: a systematic review of randomized controlled trials of the most common interventions. Spine 1997;22:2121-56.