Does Maintained Spinal Manipulation Therapy for Chronic Nonspecific Low Back Pain Result in Better Long-Term Outcome? Randomized Trial

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Mohammed K. Senna, MD, and Shereen A. Machaly, MD
These physicians are MD certified, well-trained, have been in practice for more than 10 years with good experience in managing LBP, and they are staff members of Rheumatology & Rehabilitation Department, Mansoura University [Egypt].

Nonspecific chronic LBP is not attributable to a recognizable, known specific pathology (such as infection, tumor, osteoporosis, fracture, structural deformity, inflammatory disorder, radicular syndrome, or cauda equina syndrome). It represents about 85% of LBP patients seen in primary care. "About 10% [of these patients] will go on to develop chronic, disabling LBP," using the majority of health care and socioeconomic costs.

This prospective single blinded placebo controlled study was conducted to assess the effectiveness of spinal manipulation therapy (SMT) for the management of chronic nonspecific low back pain (LBP) and to determine the effectiveness of maintenance SMT in long-term reduction of pain and disability levels associated with chronic low back conditions. The efficacy of maintenance SMT in chronic nonspecific LBP has not been studied.

1) Sixty patients with chronic, nonspecific LBP lasting at least 6 months, were randomized to receive either:
A)) 12 treatments of sham SMT over a 1-month period
B)) 12 treatments consisting of SMT over a 1-month period
C)) 12 SMT treatments over a 1-month period plus maintenance SMT every 2 weeks for the following 9 months.

2) Follow-up evaluations occurred at 1-, 4-, 7-, and 10-months, assessing:
A)) Pain (Visual Analog Scale [VAS]
The "VAS is a valid tool to indicate the current intensity of pain."

B)) Disability [Oswestry Disability Questionnaire]
The Oswestry disability questionnaire has been shown to be a valid indicator of disability in patients with LBP.

C)) Generic health [SF-36]
The 36-Item Short Form Health Survey (SF-36) measures eight dimensions: general health perception, physical function, physical role, bodily pain, social functioning, mental health, emotional role, and vitality. "The SF-36 is a valid and reliable instrument widely used to measure generic health status, particularly for monitoring clinical outcomes after medical interventions."

3) These authors hypothesized that if spinal manipulation therapy (SMT) is maintained for longer periods that it will be more beneficial in maintaining the desirable outcomes obtained after short-term treatment.

4) The spinal manipulation was defined as a "high velocity thrust to a joint beyond its restricted range of movement."

RESULTS [rounded]

	Sham SMT 12 visits in 1 mo.	**Real SMT 12 visits in 1 mo.**	**Real SMT 12 visits in 1 mo. + Maintenance SMT 2X/mo. for 9 mo.**
Pain at Baseline	41/100	42/100	43/100
Pain at 1 mo.	33/100	29/100	29/100
Pain at 4 mos.	35/100	35/100	26/100
Pain at 7 mos.	37/100	36/100	25/100
Pain at 10 mos.	38/100	39/100	23/100
Disability at Baseline	38%	39%	40%
Disability at 1 mo.	33%	24%	25%
Disability at 4 mo.	33%	30%	23%
Disability at 7 mo.	35%	32%	22%
Disability at 10 mo.	37%	35%	20%
Generic Health at Baseline	27	27	28
Generic Health at 1 mo.	27	32	32
Generic Health at 4 mo.	26	29	32
Generic Health at 7 mo.	26	28	33
Generic Health at 10 mo.	26	28	34

5) Results:

A)) Patients receiving real manipulation "experienced significantly lower pain and disability scores" than patients receiving sham manipulation at the end of 1-month.

B)) Only the group that was given spinal manipulations (SM) during the follow-up period (maintenance) showed more improvement in pain and disability scores at the 10-month evaluation.

C)) "In the non-maintained SMT group, the mean pain and disability scores returned back near to their pretreatment level."

6) "SMT is effective for the treatment of chronic nonspecific LBP. To obtain long-term benefit, this study suggests maintenance SMT after the initial intensive manipulative therapy."

7) Many reviews evaluated the role of spinal manipulation (SM) in the treatment of LBP, and concluded that SM is an efficacious treatment for nonspecific LBP.

8) "One possible way to reduce the long-term effects of LBP is maintenance care (or preventive care)."

9) "This study confirms previous reports showing that SMT is an effective modality in chronic nonspecific LBP."

10) The disability and pain scores in this study "are significantly reduced in the short-term evaluation—but not in long-term—when compared with the sham manipulation."

11) "The disability score difference (>14 points) observed after 10 months in the current study between the maintained SMT group and nonmaintained SMT group is statistically significant and clinically important."

12) "The postulated modes of action of SMT include disruption of articular or periarticular adhesions, improvement of trunk mobility, relaxation of hypertonic muscle by sudden stretching, release of entrapped synovial folds or plica, attenuation of alpha-motor neuron activity, enhancement of proprioceptive behavior, and release of β endorphins, thus increase pain threshold. These mechanisms are expected to sustain during maintenance SMT."

13) "SMT is effective for the treatment of chronic nonspecific LBP."

14) "To obtain long-term benefit, this study suggests maintenance SMT after the initial intensive manipulative."

15) "The most common adverse effects reported in this study were local discomfort and tiredness but no serious complications were noted. Most adverse effects were transient and began within 24 hours after treatment and were of mild to moderate severity."

KEY POINTS FROM AUTHORS:

1) "This study demonstrated that SMT is an effective modality in chronic nonspecific LBP for short-term effects."

2) "We suggest that maintained SMT is beneficial to patients of chronic nonspecific LBP particularly those who gain improvement after initial intensive manipulation to maintain the improved post-treatment pain and disability levels."

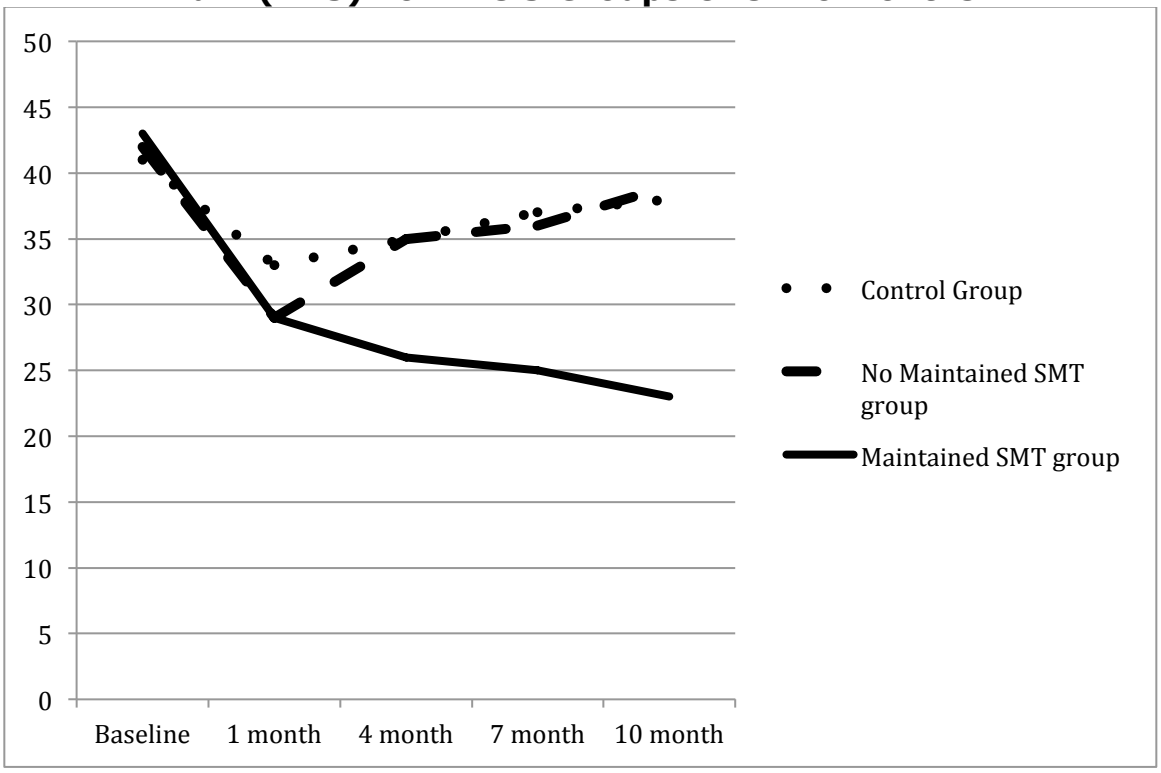
COMMENTS FROM DAN MURPHY:

This is our third Article Review supporting the necessity of patients being under life-long spinal maintenance adjusting. The other two studies are:

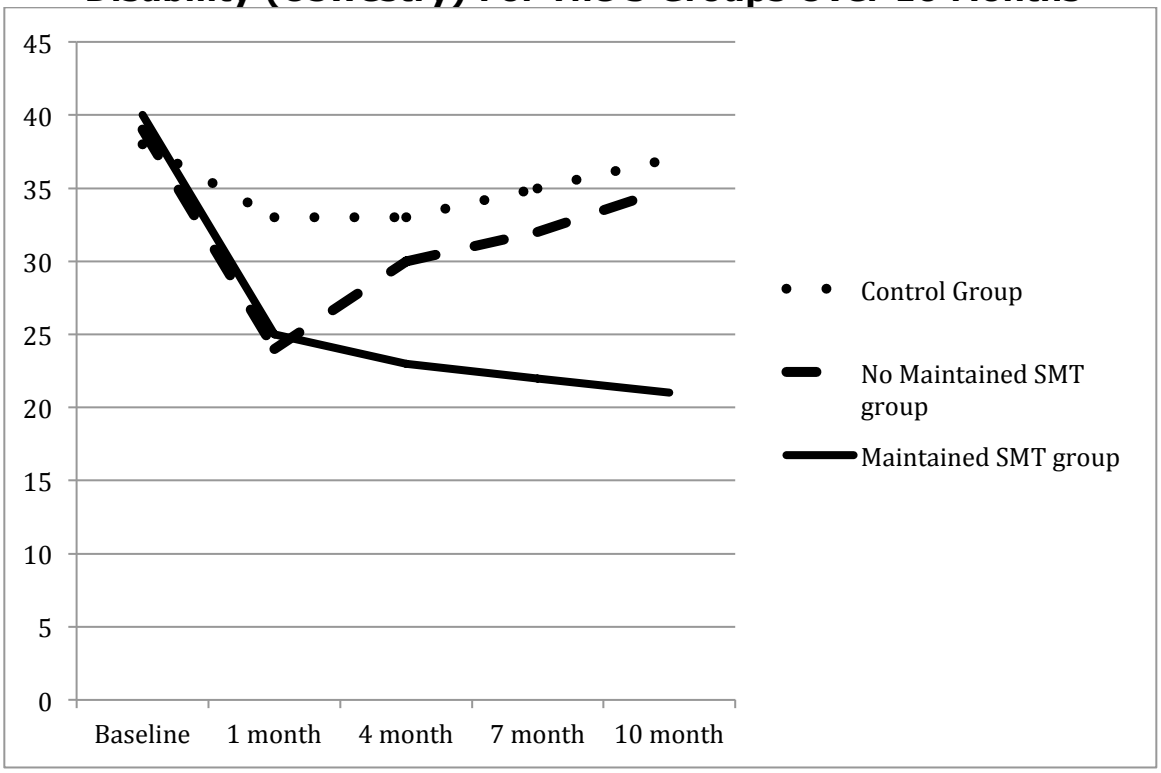
Article Review #16-12
Health Maintenance Care in Work-Related Low Back Pain and Its Association With Disability Recurrence
Journal of Occupational and Environmental Medicine
March 14, 2011

Article Review #23-13
A theoretical basis for maintenance spinal manipulative therapy for the chiropractic profession
Journal of Chiropractic Humanities
December 2011

Pain (VAS) For The 3 Groups Over 10 Months



Disability (Oswestry) For The 3 Groups Over 10 Months



A theoretical basis for maintenance spinal manipulative therapy for the chiropractic profession

Journal of Chiropractic Humanities
December 2011; Vol. 1; No. 1; pp.74-85

David N. Taylor DC, DABCN

KEY POINTS FROM THIS ARTICLE:

1) The purpose of this article is to discuss a theoretical basis for wellness chiropractic manipulative care.

2) A search of PubMed and of the Manual, Alternative, and Natural Therapy Index System was performed with a combination of key words: chiropractic, maintenance and wellness care, maintenance manipulative care, preventive spinal manipulation, hypomobility, immobility, adhesions, joint degeneration, and neuronal degeneration, 1970-2011.

3) The search revealed surveys of doctors and patients, an initial clinical pilot study, randomized control trials, and laboratory studies that provided correlative information to provide a framework for development of a hypothesis for the basis of maintenance spinal manipulative therapy.

4) "Maintenance care optimizes the levels of function and provides a process of achieving the best possible health. It is proposed that this may be accomplished by including chiropractic manipulative therapy in addition to exercise therapy, diet and nutritional counseling, and lifestyle coaching."

5) "It is hypothesized that because spinal manipulative therapy brings a joint to the end of the paraphysiological joint space to encourage normal range of motion, routine manipulation of asymptomatic patients may retard the progression of joint degeneration, neuronal changes, changes in muscular strength, and recruitment patterns, which may result in improved function, decreased episodes of injuries, and improved sense of well-being."

6) "This article considers the scientific basis of the commonly practiced procedure of chiropractic maintenance care and whether a hypothesis of a physiological basis can be generated to explain findings and practice."
Dr. Taylor cites studies to support these concepts:

A)) Acute chiropractic care for the management of acute conditions.

B)) "Care for chronic/recurrent conditions is defined as medically necessary care for conditions that are not expected to completely resolve, but in which one can provide documented improvement."

[Chronic/recurrent care is **medically necessary**, even though the condition is not expected to completely resolve]
[Use **measurement outcomes** to document improvements]

C)) "Wellness or maintenance care may not be defined as being 'medically necessary' for a current condition."
"However, this type of care optimizes the levels of function and provides a process of achieving the best possible function and health. This care includes chiropractic manipulative therapy in addition to exercise therapy, diet and nutritional counseling, and lifestyle coaching."
[Use measurement outcomes to show **functional improvement** which may qualify such care as being **medically necessary**]

7) The purpose of chiropractic maintenance care is to optimize spinal function and decrease the frequency of future episodes of back pain.

8) Other definitions for chiropractic maintenance care include:

A)) "Appropriate treatment directed toward maintaining optimal body function. This is treatment of the symptomatic patient who has reached pre-clinical status or maximum medical improvement, where condition is resolved or stable."

B)) "A regimen designed to provide for the patient's continued wellbeing or for maintaining the optimum state of health while minimizing recurrences of the clinical status."

9) The medical profession uses "wellness" as providing diagnostic tests for "early detection of disease processes."

10) For this article, "maintenance care and wellness care are used synonymously to represent the process of spinal manipulative therapy for an asymptomatic patient or a patient that has reached maximum therapeutic improvement."

11) Some insurance companies have defined maintenance care as "care provided for a stable condition without any functional improvement of the patient net health outcome over a 4-week period and further determine it as not being medically necessary."

12) In published surveys, 90+% of chiropractors opined that the purpose of maintenance care was to minimize recurrences or exacerbations; 80+% of chiropractors responded that it would optimize the patients' health.

13) 97% of American and 85% of the Australian chiropractors use manipulative therapy as a component of the maintenance care.

14) "95% of chiropractors recommended maintenance care to minimize recurrences or exacerbations of conditions and 90% recommended the care to optimize the health of the patient."

15) In a study 96% of elderly patients who received maintenance care believed that it was "either considerably or extremely valuable."

16) "It has been reported that 79% of patients in chiropractic offices are recommended maintenance care and nearly half of those patients elect to receive these services."

17) In animal studies, fixation of facet joints for 4-8 weeks causes degenerative changes and osteophyte formation of the articular surfaces. "These findings may provide an explanation to the anecdotal findings reported in clinical practice in which patients report increased well-being and decreased incidence of spinal complaints with once per month preventive wellness manipulation."

18) Sadly, facet articular surface degeneration began at less than 1 week. The "common clinical treatment frequency at every 4 weeks correlates with the findings of the threshold of 4 weeks for irreversible degenerative osteophyte formation." "This finding correlates with the common practice pattern of progressive decreasing of the frequency of manipulation as the patients progress in recovery from an acute incident. It also indicates that even when patients present for once per month asymptomatic preventive manipulation, the process of degeneration of the articular surfaces may have already begun."

19) Facet joint fixation also resulted in synovial fold fibrotic adhesions that "progressed to mild adhesions in 4 weeks, moderate adhesions in 8 weeks, and severe adhesions after 12 weeks." In humans, "it can be hypothesized that there is a period where the adhesions are forming without clinical symptoms. This would also support the common once per month maintenance spinal manipulation."

20) It has also been demonstrated that lumbar spinal manipulation gaps the facet joints which may break up adhesions. This "would lend additional support for the once per month clinically recommended spinal manipulative therapy."

21) Four weeks of joint immobilization has been found to cause a time dependent loss of neurons that becomes progressively worse thereafter. An increase in neurons occurs after release of the fixation.

22) Such immobilization also causes time dependent muscle weakness, atrophy and fatty deposition of the multifidi muscles. The time-dependent factor progressed from normal muscles to mild, moderate, and severe muscular atrophy.

23) "There may also be a possibility of reversal of the neuronal degeneration and muscular weakness through manipulation and remobilization of the joint."

24) These progressive adverse physiological consequences of joint immobility, create a "line of reasoning arises that generates a theoretical framework for a physiological hypothesis of the basis of maintenance manipulative therapy."

25) Evidence "clearly demonstrates that the clinical consensus of dosage of maintenance manipulative therapy has been found to be most beneficial at an average of once every 2 to 4 weeks. We also see here that it closely correlates with the studies that show onset of facet joint degeneration, neural degeneration, neuroplastic changes, and muscular atrophy and weakness at an average of 2 to 4 weeks."

26) "Taking into account the neurological and biomechanical consequences of manipulative therapy, it is plausible to hypothesize that monthly manipulative therapy retards the progression of adhesion formation, joint degeneration, neuronal changes, and changes in muscular strength and recruitment patterns. This could result in improved function, decreased episodes of injuries, and improved sense of well-being."

27) A 2004 chiropractic study of chronic low back pain showed that the group of patients who received 9 months of maintenance manipulation at the frequency of once per every 3 weeks maintained their initial clinical improvement while the control group returned to their previous levels of disability. The authors "concluded that there were positive effects of preventive maintenance chiropractic spinal manipulation in maintaining functional capacities and reducing the number and intensity of pain episodes after the acute phase of treatment of low back pain patients."

28) Swedish surveys of chiropractors find consensus on providing maintenance care to prevent disability relapses.

29) "There is a common thread of the time dependency noted in all the laboratory and clinical studies. The periods of onset of the anatomical and physiological changes ranged from 2 to 4 weeks. The clinical studies also provided MMT every 4 weeks and noted positive changes in the pain and disability measures. This time interval also correlates with the common recommendations found in the surveys of chiropractic physicians."

Health Maintenance Care in Work-Related Low Back Pain and Its Association With Disability Recurrence

Journal of Occupational and Environmental Medicine
March 14, 2011; Vol. 197 [epub]

Manuel Cifuentes, MD, PhD, Joanna Willetts, MS, Radoslaw Wasiak, PhD, MA, MSc

BACKGROUND FROM DAN MURPHY:
This study used Hazard Ratios. Hazard ratios compare two treatments. A Hazard Ratio of 2.0 means the rate is twice the rate of the other group.

FROM ABSTRACT:
Objectives: To compare occurrence of repeated disability episodes across types of health care providers who treat claimants with new episodes of work-related low back pain (LBP).

Method: A total of 894 cases followed 1-year using workers' compensation claims data. Provider types were defined for the initial episode of disability and subsequent episode of health maintenance care.

Results: Controlling for demographics and severity, the hazard ratio [HR] of disability recurrence for patients of physical therapists (HR = 2.0) or physicians (HR = 1.6) was higher than that of chiropractor (referent, HR = 1.0), which was similar to that of the patients non-treated after return to work (HR = 1.2).

Conclusions: In work-related nonspecific LBP, the use of health maintenance care provided by physical therapist or physician services was associated with a higher disability recurrence than in chiropractic services or no treatment.

KEY POINTS FROM THIS STUDY:

1) Low back pain (LBP) is "one of the costliest work-related injuries in the United States in terms of disability and treatment costs." "An additional, important component of the human and economic costs is the recurrence of LBP."

2) There has been little success in preventing recurrent LBP.

3) "Health maintenance care is a clinical intervention approach thought to prevent recurrent episodes of LBP. It conceptually refers to the utilization of health care services with the aim of improving health status and preventing recurrences of a previous health condition." Health maintenance care is defined as "treatment. . . after optimum recorded benefit was reached."

4) "Health maintenance care can include providing advice, information, counseling, and specific physical procedures. Health maintenance care is

predominantly and explicitly recommended by chiropractors" who advocate health maintenance procedures to prevent recurrences.

5) Chiropractors focus more on return to work while physicians focus more on pain control.

6) "An association between specific type(s) of treatment or providers and significant recurrence of a condition (measured as recurrent work disability) could imply an important advancement in the treatment of work-related back injuries."

IN THIS STUDY

7) This study consisted of 894 cases, median age of 41 years, 32% women.

8) Temporary total disability was defined as the worker completely unable to work on a temporary basis due to health related impairment.

9) The health maintenance care was defined as the period after the initial disability episode had ended and the person had returned to work for at least 14 days.

10) Recurrent disability was defined as resumption of temporary total disability after a period of health maintenance care.

11) Recurrent disability was defined as the resumption of at least 15 consecutive days of temporary total disability payments following the health maintenance care period.

12) Chiropractic patients had "less expensive medical services and shorter initial periods of disability than cases treated by other providers."

13) Taking opiate pain drugs during the period of health maintenance care was significantly associated with recurrent disability (more than doubled the risk).

14) "Provider type during the health maintenance care period was significantly associated with recurrent disability with the only or mostly physical therapy group having the highest proportion of recurrent disability (16.9%) and the only or mostly chiropractor (6.5%) and the no (5.5%) health maintenance care groups having the lowest proportion of recurrent disability."

15) Chiropractic patients who did suffer a recurrence did so 29 days later than the physical therapy or physician patients who suffered a recurrence.

16) "Compared with the only or mostly chiropractor (referent), the groups of only or mostly physical therapy and only or mostly physician had significantly higher HRs (2.0 and 2.7 respectively)." USING ALTERNATIVE ANALYSIS

17) "Compared with receiving treatment only or mostly by chiropractors during the health maintenance care period, receiving treatment by physical therapists, physicians, or a combination of both tended to result in significantly higher HRs of recurrent disability."

18) "After controlling for demographics and severity indicators, the likelihood of recurrent disability due to LBP for recipients of services during the health maintenance care period by all other provider groups was consistently worse when compared with recipients of health maintenance care by chiropractors."

19) "Care from chiropractors during the disability episode ("curative"), during the health maintenance care period (main exposure variable, "preventive"), and the combination of both (curative and preventive) was associated with lower disability recurrence HRs."

20) "This clear trend deserves some attention considering that chiropractors are the only group of providers who explicitly state that they have an effective treatment approach to maintain health."

21) "Our results, which seem to suggest a benefit of chiropractic treatment to reduce disability recurrence, imply that if the benefit is truly coming from the chiropractic treatment, there is a mechanism through which care provided by chiropractors improves the outcome." **[Very Important]**

22) These authors speculate that "the main advantage of chiropractors could be based on the dual nature of their practice." **[regular care + maintenance care]**

23) "After controlling for severity and demographics, no health maintenance care is generally as good as chiropractor care." **[Key Point]**

24) As a "hypothesis, chiropractors might be preventing some of their patients from receiving procedures of unproven cost utility value or dubious efficacy."

25) Chiropractors argue that they provide treatment to the "whole patient." This approach may provide "more opportunities for a provider–patient relationship that improves communication, and likely emphasizes the importance of return to work over symptom control, and focuses on psychosocial issues that have been demonstrated to be important in the evolution of LBP disability."

26) Chiropractic patients had "fewer surgeries, used fewer opioids, and had lower costs for medical care than the other provider groups."

27) "After controlling for demographic factors and multiple severity indicators, patients suffering nonspecific work-related LBP who received health services mostly or only from a chiropractor had a lower risk of recurrent disability than the risk of any other provider type."

28) "Our findings seem to support the use of chiropractor services, as chiropractor services generally cost less than services from other providers."

COMMENTS FROM DAN MURPHY:

This is a great study. It shows that in the treatment of Workers Compensation low back injury that:

1) Chiropractically managed patients are significantly less likely to have a recurrence of low back pain.
2) Chiropractically managed patients that do have a recurrence of low back pain do so an average of 29 days later than those treated by a physical therapist or medical doctor.
3) Chiropractically managed patients have shorter periods of disability, meaning they returned to work earlier.
4) Chiropractic patients had "fewer surgeries, used fewer opioids, and had lower costs for medical care than the other provider groups."
5) Chiropractors treat the "whole patient," providing "more opportunities for a provider–patient relationship that improves communication, and likely emphasizes the importance of return to work over symptom control, and focuses on psychosocial issues that have been demonstrated to be important in the evolution of LBP disability."
6) The reduced recurrence of low back disability is the consequence of "chiropractic treatment."
7) No health maintenance care is generally as good as chiropractor care.
8) "Chiropractors are the only group of providers who explicitly state that they have an effective treatment approach to maintain health."
9) Chiropractic appears to be an "important advancement" in the treatment of work-related back injuries.
10) This study certainly supports the concept and value of chiropractic maintenance care.

Provider Type	Increased Risk Compared to Chiropractic Analysis #1	Increased Risk Compared to Chiropractic Analysis #2	% of Patients with Recurrent Disability During Entire Period(curative + prevention)	% of Patients with Recurrent Disability During Maintenance (prevention)
Chiropractor	None	None	5.7%	6.5%
No Treatment	20%	?	5.5%	5.5%
Medical Doctor	60%	170%	16.7%	?
Physical Therapist	100%	100%	?	16.9%