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The Effectiveness and Harms of Spinal Manipulative Therapy for the Treatment of Acute Neck and Lower Back Pain

A Systematic Review of the Evidence

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Disclosure

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VA Evidence-based Synthesis (ESP) Program Overview

- Sponsored by VA Office of R&D and Quality Enhancement Research Initiative (QUERI).
- Established to provide timely and accurate syntheses/reviews of healthcare topics identified by VA clinicians, managers and policy-makers, as they work to improve the health and healthcare of Veterans.
- Builds on staff and expertise already in place at the Evidence-based Practice Centers (EPC) designated by AHRQ. Four of these EPCs are also ESP Centers:
  - Durham VA Medical Center; VA Greater Los Angeles Health Care System; Portland VA Medical Center; and Minneapolis VA Medical Center.

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- Provides evidence syntheses on important clinical practice topics relevant to Veterans, and these reports help:
    - develop clinical policies informed by evidence,
    - the implementation of effective services to improve patient outcomes and to support VA clinical practice guidelines and performance measures, and
    - guide the direction for future research to address gaps in clinical knowledge.
- Broad topic nomination process – e.g. VACO, VISNs, field – facilitated by ESP Coordinating Center (Portland) through online process:

http://www.hsrd.research.va.gov/publications/esp/TopicNomination.cfm

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- Steering Committee representing research and operations (PCS, OQP, ONS, and VISN) provides oversight and guides program direction.
- Technical Expert Panel (TEP)
    - Recruited for each topic to provide content expertise.
    - Guides topic development; refines the key questions.
    - Reviews data/draft report.
- External Peer Reviewers & Policy Partners
    - Reviews and comments on draft report
- Final reports posted on VA HSR&D website and disseminated widely through the VA.

http://www.hsrd.research.va.gov/publications/esp/reports.cfm

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Current Report

The Effectiveness and Harms of Spinal Manipulative Therapy for the Treatment of Acute Neck and Lower Back Pain: A Systematic Review (December, 2015)

Full-length report available on ESP website:

http://www.hsrd.research.va.gov/publications/esp/reports.cfm

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Introduction

- Background information
  - Back pain and neck pain are among the most common symptoms prompting patients to seek care.
  - While data specific to Veterans are not available, in the general population lifetime prevalence estimates of low back pain are as high as 80% in the US population.
- Spinal manipulative therapy (SMT) is a treatment option available in VA
  - Treatment is provided mostly but not entirely by Doctors of Chiropractic.
  - The VA has had a significant increase in requests for chiropractic care since these services became covered by the VHA.
  - Findings from an evidence synthesis about the effectiveness of spinal manipulative therapy (SMT) or chiropractic care will help the VA identify approaches for treating acute neck and lower back pain and ensure the VA is providing Veterans with optimal healthcare services.

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Key Questions

- Key Question 1: What are the benefits and harms of spinal manipulation/chiropractic services for acute lower back pain (less than 6 weeks duration) compared to usual care or other forms of acute pain management?
- Key Question 1A: What is the relationship between the use of spinal manipulation/chiropractic services for lower back pain and the use of opiate medication?
- Key Question 2: What are the benefits and harms of spinal manipulation/chiropractic services for acute neck pain (less than 6 weeks duration) compared to usual care or other forms of acute pain management?
- Key Question 2A: What is the relationship between the use of spinal manipulation/chiropractic services for acute neck pain and the use of opiate medication?

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Methods

- Data Sources and Searches:
  - Spinal manipulation is a topic that has been the subject of numerous prior systematic reviews, including 3 reviews by members of the ESP review team.
  - We began with reference mining existing systematic reviews, and then performing an update search to identify new studies published since the end date of the searches of the most recent reviews.

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Methods

- Study Selection:
  - **Participants:**
    - Adults with acute (defined as 6 weeks or less) neck or lower back pain
    - Patients with sciatica were included
    - Studies of patients with chronic back pain were excluded
    - If studies included patients with longer durations of pain, we included them if they presented stratified results or if the majority of patients had pain for less than 6 weeks duration
    - Studies of children were excluded
  - **Intervention:**
    - Spinal manipulation by any provider type
    - Studies where spinal manipulation was given alone or as part of a “package” of therapies were included

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Methods

- Study Selection:
  - **Comparator (study design):**
    - Other forms of management for acute pain, such as analgesics, exercises, physical therapy, etcetera. Sham-controlled studies were included.
  - **Outcome:**
    - Pain management, functional status, quality of life, opiate use, disability claims, return to work, health care utilization.
  - **Timing:**
    - Studies had to report at least one outcome within 6 weeks to be eligible.
  - **Setting:**
    - Ambulatory/outpatient settings. Studies in hospital settings were excluded.
  - **Study design:**
    - Only randomized controlled trials (RCTs) were eligible for assessing benefits. Both RCTs plus observational studies were used for assessing harms.

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Methods

- Data Abstraction and Quality Assessment:
  - Data were extracted by 2 reviewers, and discrepancies were reconciled after discussion.
  - We assessed the quality of studies using the Cochrane Back Group Risk (CBG) of Bias Tool (ROB).
    - This tool has 11 items in the following domains: randomization; concealment; baseline differences; blinding – patient; blinding – care provider; blinding – outcome; co-interventions; compliance; dropouts; timing; and intent to treat.
- Data Synthesis and Analysis:
  - We constructed evidence tables showing the study characteristics and results for all included studies. Random effects meta-analyses were conducted using the Hartung-Knapp Method.
  - We converted pooled effect sizes back into clinically relevant outcomes by multiplying the effect size by the average standard deviation for outcomes in the included studies.

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Results

Results of Literature Search:

- We identified a total of 1,173 titles for screening
- Of these we had 52 included articles:
    - 39 articles relevant to lower back pain (25 were included):
        - 5 articles relevant to neck pain
        - 8 articles relevant to adverse events
    - Of the 14 not included in the analyses:
        - 3 publications were focused on the subpopulation of patients with sciatica
        - 2 publications were only relevant to clinical prediction discussions
        - 2 publications did not have the necessary outcome data
        - One publication had a unique patient population judged by our TEP as clinically dissimilar to the other studies.

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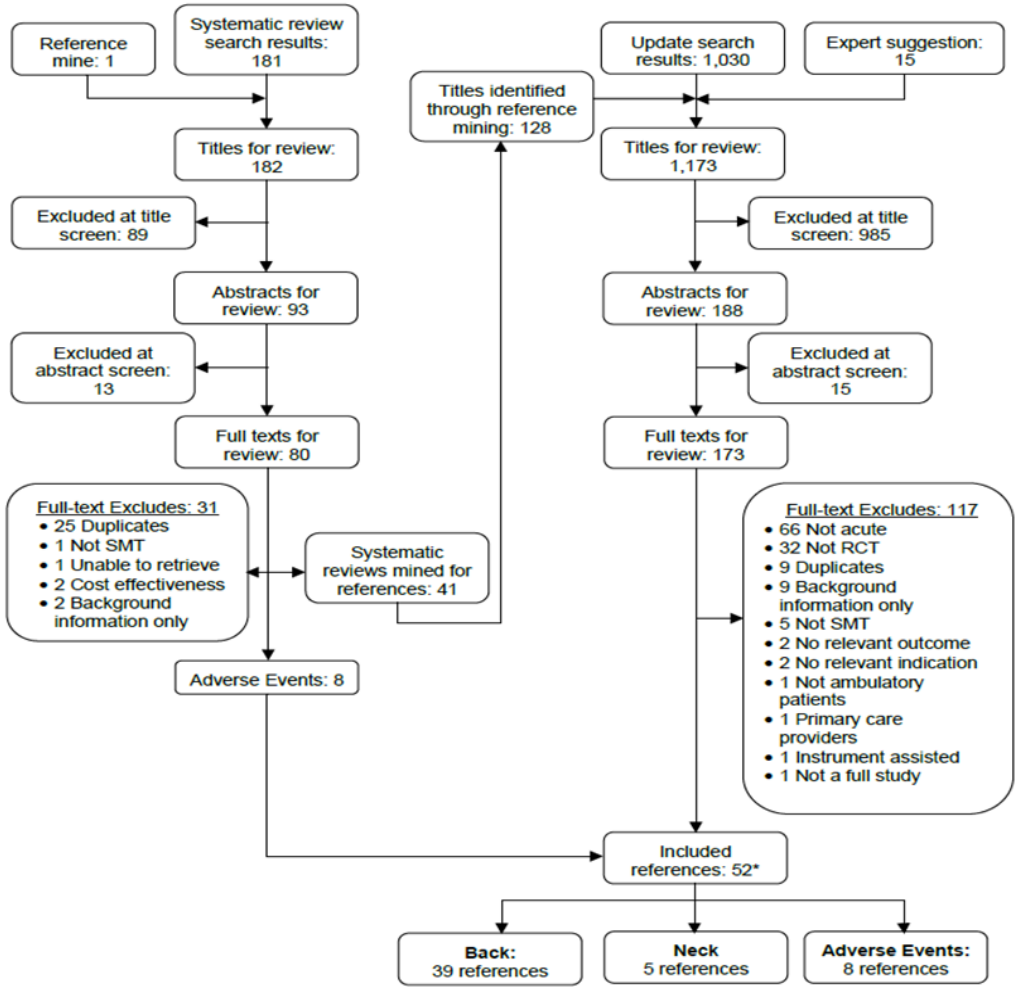
Flow Chart



* Manuscript reference list includes additional references cited for background and methods plus websites relevant to key questions.

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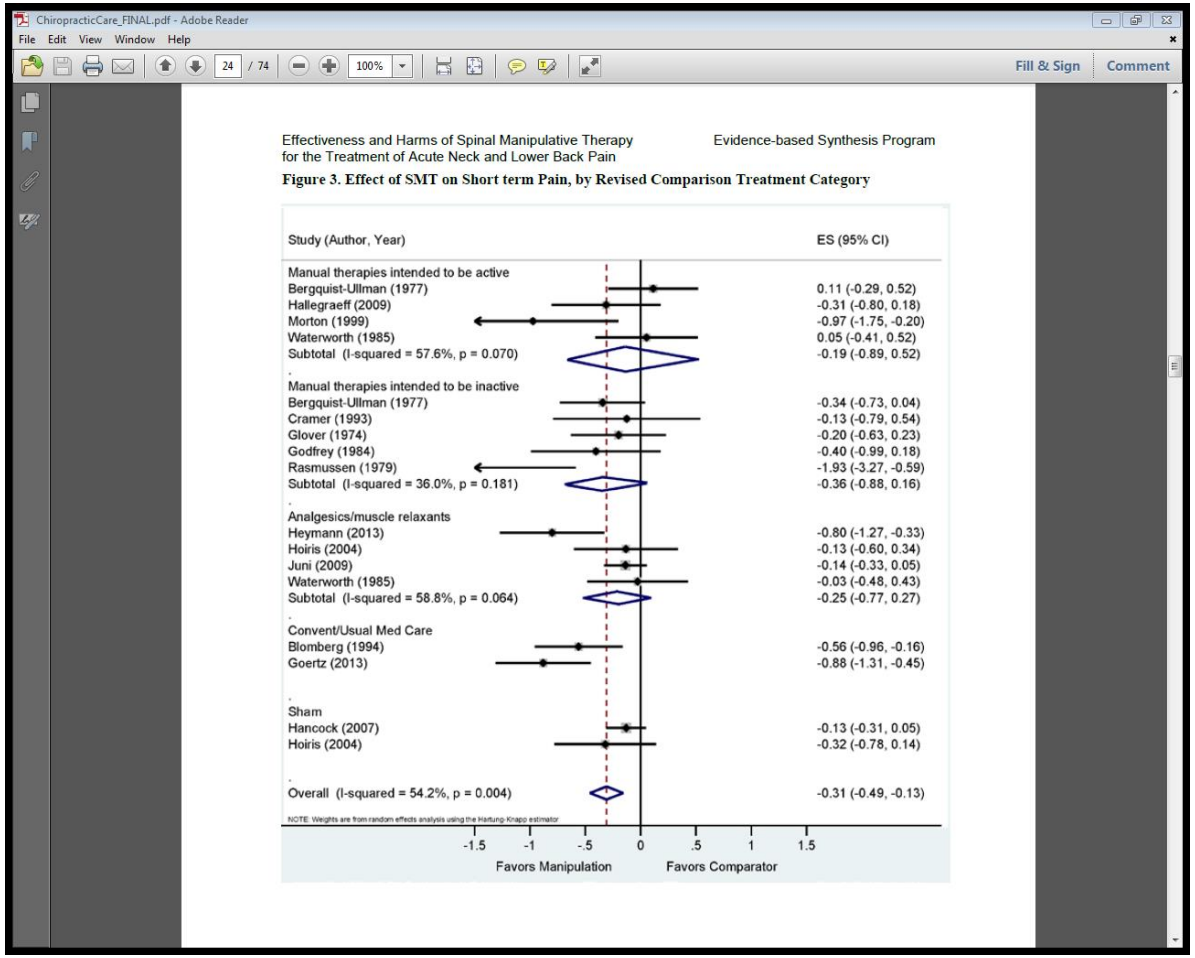
Effect of SMT on Immediate-term pain



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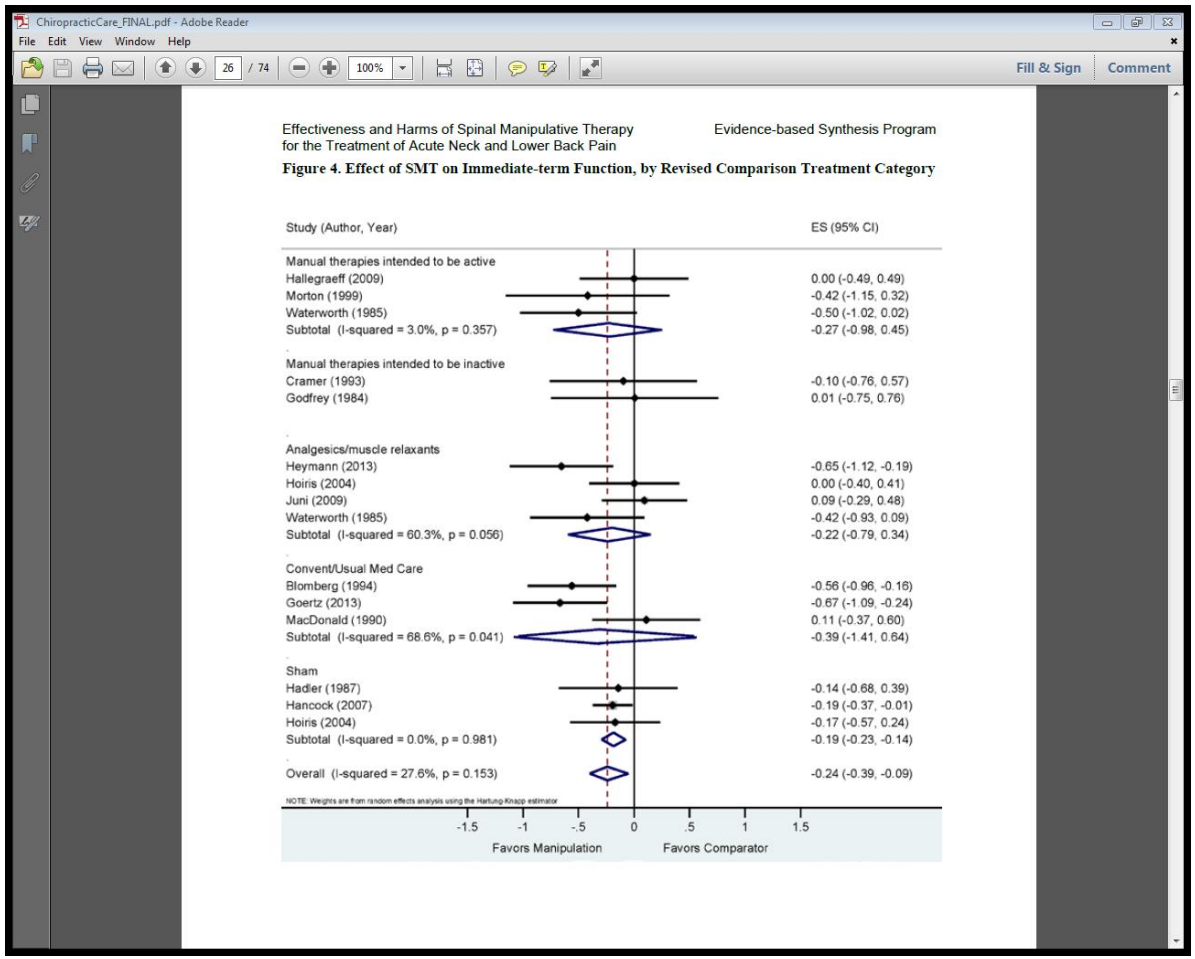
Effect of SMT on Immediate-term Function



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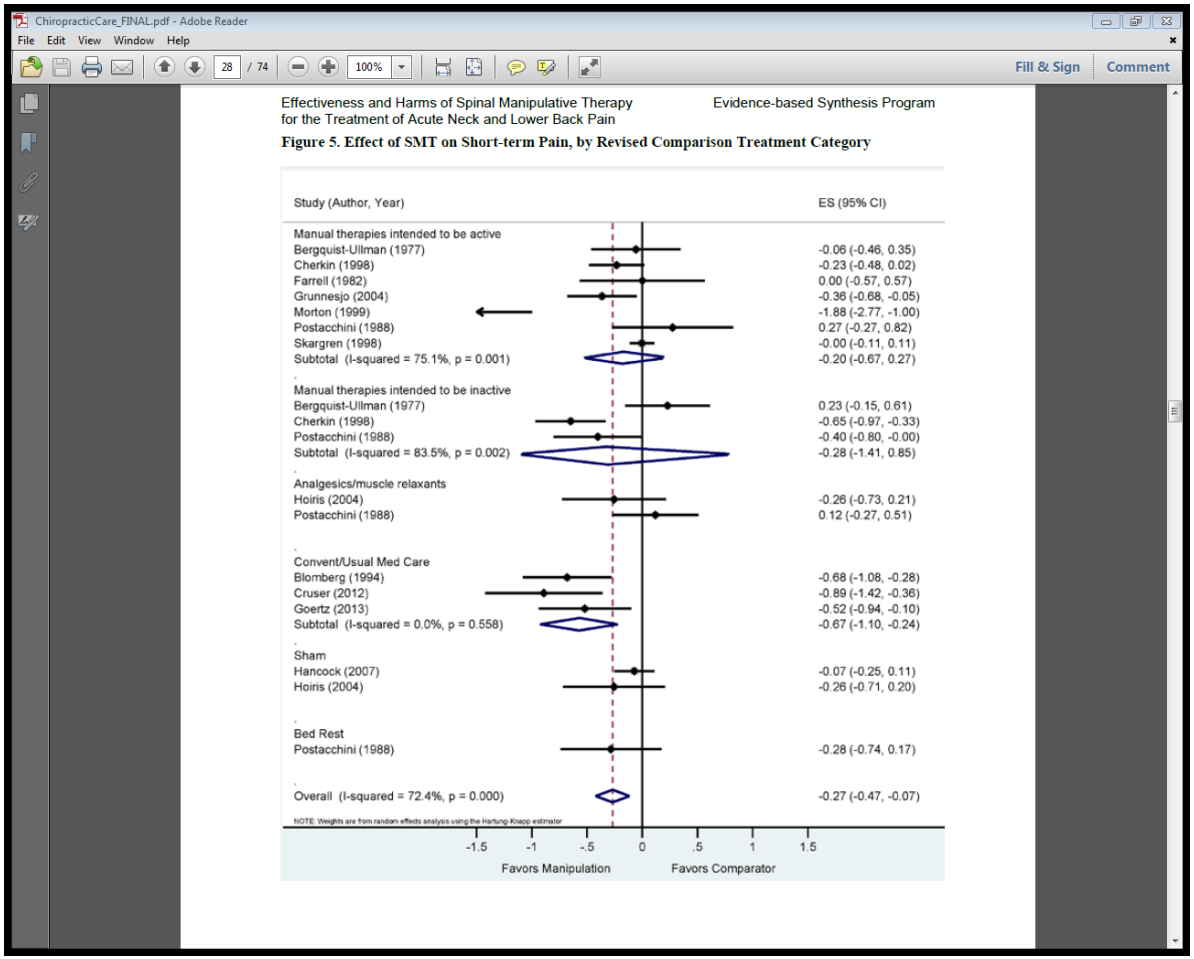
Effect of SMT on Short-term Pain



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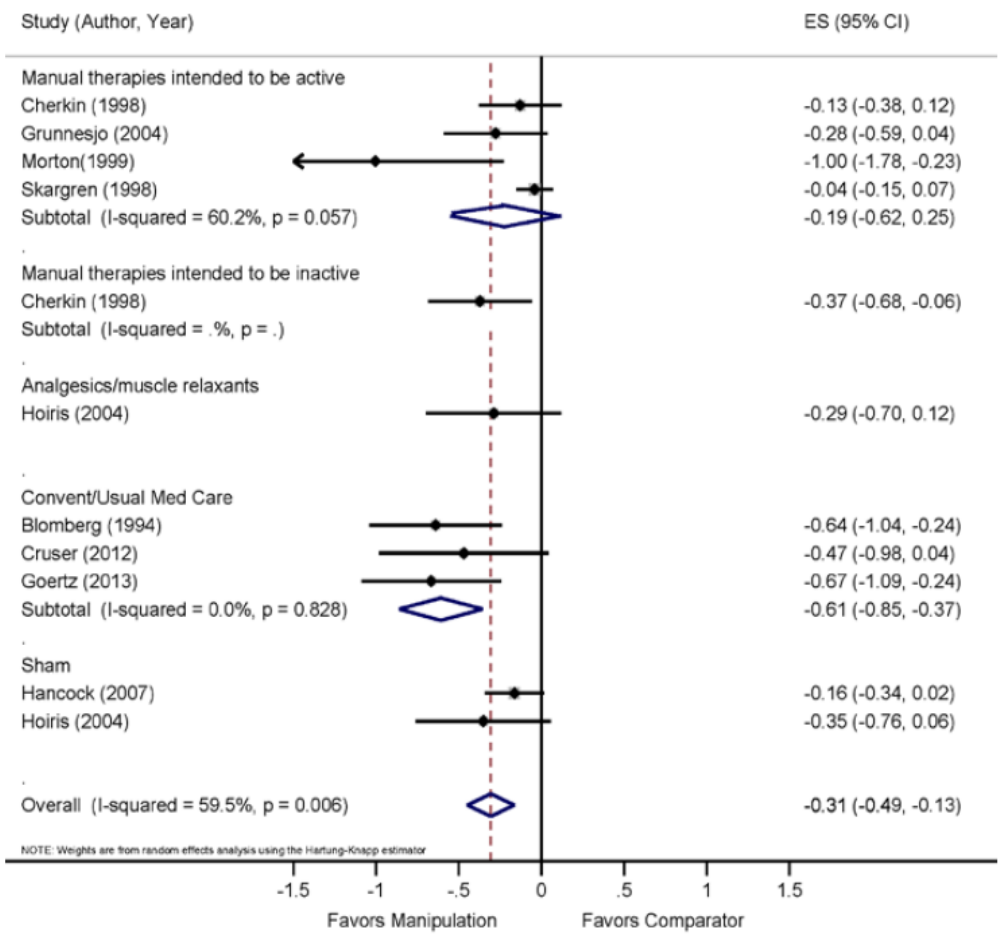
Effect of SMT on Short-term Function



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Interpreting Effect Sizes

- Effect sizes of 0.2 - 0.3 are roughly equivalent to an 8 - 10 mm difference in a 100 mm VAS pain scale or a 1.5 – 2.0 change in the Roland Morris Disability Questionnaire.

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- Exploratory analyses for sources of heterogeneity showed that SMT with thrust had larger effect sizes than non-thrust SMT and studies of higher quality had larger effect size then did studies of low quality, however these differences were not statistically significant.

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Neck Pain

- Only 5 studies were identified of SMT compared to a non-SMT treatment group for patients with acute neck pain. Although each study reported favorable results on at least one outcome, in total only 198 patients have been studied.

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Studies of a Clinical Prediction Rule

- There were four studies that tested a clinical prediction rule to identify patients with acute low back pain more likely to benefit from SMT.
- The first three studies reported very large effects in function for patients positive on the clinical prediction rule. However, the most recent study found statistically significant, but clinically trivial benefits. Therefore, the usefulness of the clinical prediction rule remains uncertain.

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Adverse Events Reported in RCTs of SMT for Acute Low Back Pain

Article	Side Effect
Juni 2009[40]	"Two serious adverse events occurred in the experimental group (4%) and 2 in the control group (4%). In the experimental group there was one patient with an acute loss of motor and sensory function due to a herniated disk after randomization, but before any SMT treatment was initiated. In the control group, there was one patient with symptomatic cholelithiasis and one patient with a femoroacetabular impingement syndrome."
Morton 1999[42]	"No adverse effects were documented for either group."
Heymann 2013[38]	"Safety analysis did not show any unexpected untoward events in either group."
Goertz 2013[35]	"There were no serious adverse events." [2 mild AEs were reported in SMT group; both were pain that resolved in 24-48 hours]
Waterworth 1985[46]	"Adverse experiences with therapy were not specifically itemized, but their seizures and drug relationship were recorded. Group 3 [SMT] patients experienced less adverse reactions to treatments on the second assessment then group 1."
Blomberg 1994[21]	Has a table of side effects by group. "The treatment hurts" was statistically significantly more likely in the group treated with SMT than continued medical care.

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Results from Prospective Studies of Adverse Events of SMT

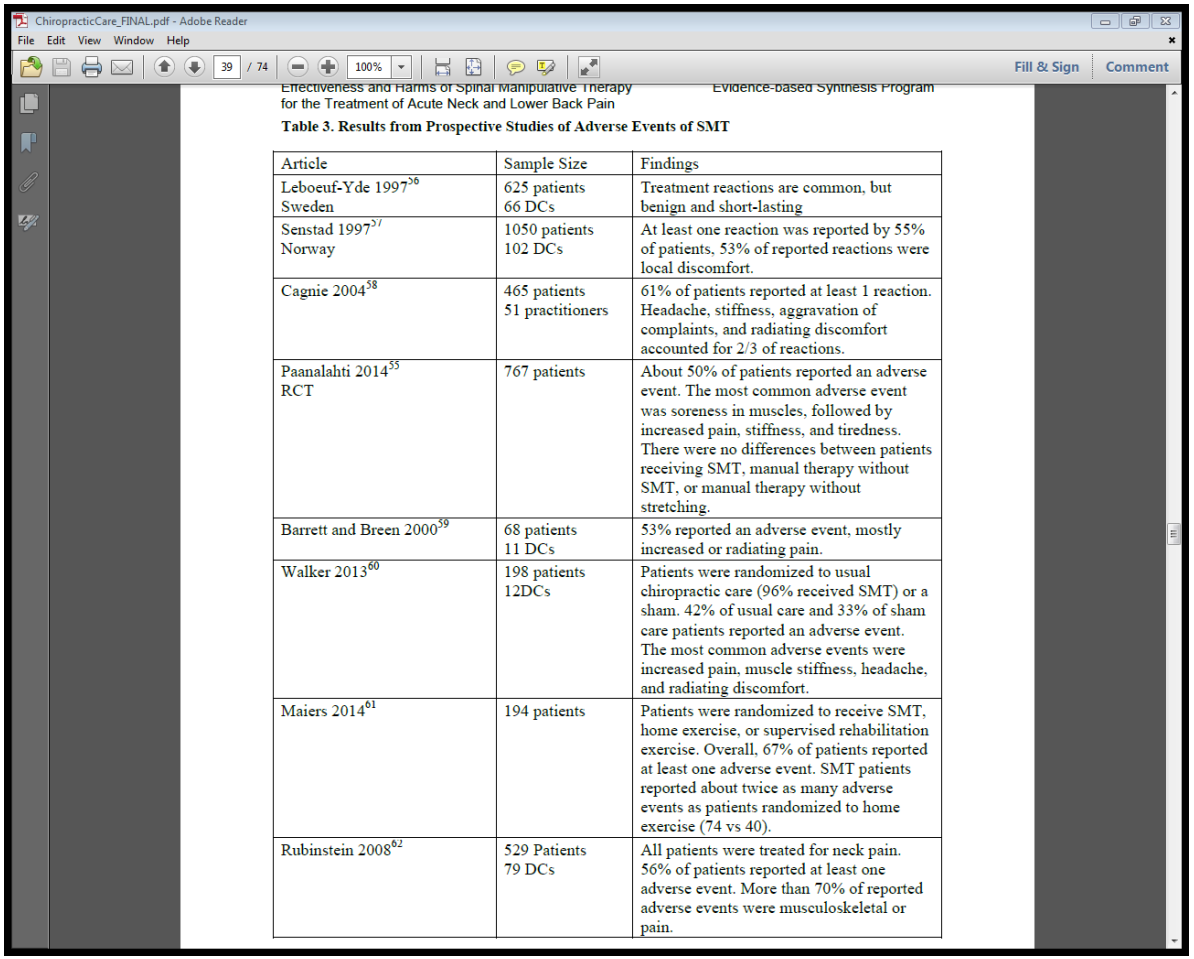

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Table 3. Results from Prospective Studies of Adverse Events of SMT

Article	Sample Size	Findings
Leboeuf-Yde 1997[56] Sweden	625 patients 66 DCs	Treatment reactions are common, but benign and short-lasting
Senstad 1997[57] Norway	1050 patients 102 DCs	At least one reaction was reported by 55% of patients, 53% of reported reactions were local discomfort.
Cagnie 2004[58]	465 patients 51 practitioners	61% of patients reported at least 1 reaction. Headache, stiffness, aggravation of complaints, and radiating discomfort accounted for 2/3 of reactions.
Paanalahti 2014[55] RCT	767 patients	About 50% of patients reported an adverse event. The most common adverse event was soreness in muscles, followed by increased pain, stiffness, and tiredness. There were no differences between patients receiving SMT, manual therapy without SMT, or manual therapy without stretching.
Barrett and Breen 2000[59]	68 patients 11 DCs	53% reported an adverse event, mostly increased or radiating pain.
Walker 2013[60]	198 patients 12DCs	Patients were randomized to usual chiropractic care (96% received SMT) or a sham. 42% of usual care and 33% of sham care patients reported an adverse event. The most common adverse events were increased pain, muscle stiffness, headache, and radiating discomfort.
Maiers 2014[61]	194 patients	Patients were randomized to receive SMT, home exercise, or supervised rehabilitation exercise. Overall, 67% of patients reported at least one adverse event. SMT patients reported about twice as many adverse events as patients randomized to home exercise (74 vs 40).
Rubinstein 2008[62]	529 Patients 79 DCs	All patients were treated for neck pain. 56% of patients reported at least one adverse event. More than 70% of reported adverse events were musculoskeletal or pain.

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Summary of Results for Key Questions and Strength of Evidence

- Key Question 1: What are the benefits and harms of spinal manipulation/chiropractic services for acute lower back pain (less than 6 weeks duration) compared to usual care or other forms of acute pain management?
  - Twenty-two studies of SMT treatments for acute low back pain found overall statistically significant evidence of a clinical benefit that was, on average, modest.
  - We explored 6 potential sources of heterogeneity, and although type of manipulation, comparison group, patient selection, and study quality may explain some of the heterogeneity, most of the differences in outcome between studies remain unexplained.
- Key Question 1A: What is the relationship between the use of spinal manipulation/chiropractic services for lower back pain and the use of opiate medication?
  - Among the 25 studies included in our pooled analysis only one specifically reported on the use of opiate medications.
  - With only a single study reporting this outcome and that one not reporting the actual use by treatment group, we classified the quality of evidence as insufficient for this outcome.

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Summary of Results for Key Questions and Strength of Evidence

- Key Question 2: What are the benefits and harms of spinal manipulation/chiropractic services for acute neck pain (less than 6 weeks duration) compared to usual care or other forms of acute pain management?
  - Only 5 studies were identified of SMT compared to a non-SMT treatment group for patients with acute neck pain. Although each study reported favorable results on at least one outcome, in total only 198 patients have been studied in total.
- Key Question 2A: What is the relationship between the use of spinal manipulation/chiropractic services for acute neck pain and the use of opiate medication?
  - None of the included studies reported on the use of analgesic medications or opiate medication as an outcome.

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Discussion

- Limitations:
  - We did not find evidence of publication bias, although no evidence of bias is not the same as evidence of no publication bias.
- Study Quality:
  - Study quality was highly variable and in our pooled analysis is split about equally between studies considered “high” and studies considered “low” quality.
  - Our analysis found no evidence to support a hypothesis that our results are due to low-quality studies with inflated effect sizes.
- Heterogeneity:
  - Heterogeneity in the results is the primary limitation of this analysis.
  - Our investigation of multiple potential sources of heterogeneity yielded no results that were statistically significant, although visually there were suggestions that the comparison group and the type of SMT may be important.

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Discussion

- Applicability of Findings to the VA Population:
  - We identified no studies specific to VA population.
  - Acute back pain in primary care is probably quite similar within VA to outside VA, and these results have to be considered at least moderately applicable to VA populations.
- Research Gaps/Future Research:
  - There continues to be a great deal of unexplained heterogeneity in results of SMT for acute low back pain, so a research gap is better understanding what contributes to patient selection and intervention to improve the consistency of the result.
  - Replication of the clinical prediction rule RCT or new RCTs with more detailed data collection on the patient clinical characteristics and details of the SMT intervention.
  - For neck pain, there are simply too few studies to draw firm conclusions.
  - Additional RCTs are warranted.

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Questions?

If you have further questions,
feel free to contact:

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The full report and cyberseminar presentation is available on the ESP website:

http://www.hsrd.research.va.gov/publications/esp/