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Chiropractic and Usual Medical Care for US Service Members with LBP: Comparative Effectiveness Trial

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ABSTRACT

INTRODUCTION: *The clinical trial aims to determine whether the addition of chiropractic care to usual medical care results in better pain relief and pain-related function when compared with usual medical care alone.*

METHODS: *A 3-site pragmatic comparative effectiveness clinical trial using adaptive allocation was conducted from September 28, 2012, to February 13, 2016, at 2 large military medical centers in major metropolitan areas and 1 smaller hospital at a military training site. Eligible participants were active-duty US service members aged 18 to 50 years with low back pain from a musculoskeletal source.*

RESULTS: *Of the 806 screened patients who were recruited through either clinician referrals or self-referrals, 750 were enrolled (250 at each site). The mean (SD) participant age was 30.9 (8.7) years, 175 participants (23.3%) were female, and 243 participants (32.4%) were nonwhite. Statistically significant site \times time \times group interactions were found in all models. Adjusted mean differences in scores at week 6 were statistically significant in favor of usual medical care plus chiropractic care compared with usual medical care alone overall for low back pain intensity (mean difference, -1.1 ; 95% CI, -1.4 to -0.7), disability (mean difference, -2.2 ; 95% CI, -3.1 to -1.2), and satisfaction (mean difference, 2.5 ; 95% CI, 2.1 to 2.8) as well as at each site. Adjusted odd ratios at week 6 were also statistically significant in favor of usual medical care plus chiropractic care overall for perceived improvement (odds ratio = 0.18 ; 95% CI, 0.13 - 0.25) and self-reported pain medication use (odds ratio = 0.73 ; 95% CI, 0.54 - 0.97). No serious related adverse events were reported.*

CONCLUSION: *Chiropractic care, when added to usual medical care, resulted in moderate short-term improvements in low back pain intensity and disability in active-duty military personnel. This trial provides additional support for the inclusion of chiropractic care as a component of multidisciplinary health care for low back pain, as currently recommended in existing guidelines. However, study limitations illustrate that further research is needed to understand longer-term outcomes as well as how patient heterogeneity and intervention variations affect patient responses to chiropractic care.*

ANALYSIS

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Background Information

Musculoskeletal disorders, led by low back pain (LBP), trail only depression as the leading cause of disability worldwide (1). Given the high costs of treatment (\$34 billion in direct costs in the USA in 2010 [2]!), lost productivity (3) and the growing opioid crisis in the United States and elsewhere (4, 5), an urgent need for cost-effective, low-risk, non-pharmacological treatment for LBP exists. Chiropractic care has the potential to fill this void. Only an estimated 8-14% of the population regularly uses chiropractic care (6, 7), indicating there is considerable untapped potential for the profession.

Despite early evidence showing promise (8), chiropractic treatment in a military population is a topic that is under-represented in the literature. Military populations tend to be younger and more racially and ethnically diverse than those in existing clinical trials (9), thus warranting separate investigation. Therefore, the goal of this study was to investigate whether adding chiropractic care to usual medical care (UMC) improves outcomes for military personnel suffering from low back pain.

Pertinent Results:

Study Participants:

806 patients were screened for inclusion. 750 patients (250 at each of the 3 sites) were enrolled in the study, with 375 receiving usual medical care plus chiropractic treatment (intervention group) and 375 receiving only usual medical care (control group).

Primary Outcomes:

Results were consistently in favour of usual medical care (UMC) + chiropractic over UMC alone for LBP (mean difference, -1.1 ; 95%CI, -1.4 to -0.7) and disability (mean difference, -2.2 ; 95%CI, -3.1 to -1.2) at 6-week follow-up.

Relative risks (RRs) were, overall, statistically significantly in favour of greater benefit for the intervention group over controls at weeks 6 (LBP intensity: RR = 1.43; 95% CI, 1.23 to 1.68; disability: RR = 1.35; 95% CI, 1.16 to 1.56) and 12 (LBP intensity: RR = 1.43; 95% CI, 1.23 to 1.68; disability: RR = 1.26; 95% CI, 1.11 to 1.43).

Secondary Outcomes:

The worst LBP experienced by participants was significantly lower in the intervention group (UMC + chiropractic) vs. controls at both 6 and 12 weeks (week 6: mean difference, -1.2 ; 95%CI, -1.6 to -0.8 ; week 12: mean difference, -1.1 ; 95%CI, -1.6 to -0.7).

Patients in the intervention group (UMC + chiropractic) also showed significant improvements in symptom bothersomeness, global perceived improvement, used less pain medication and reported higher average satisfaction compared to usual medical care alone.

Adverse Events:

19 adverse events (5.1%) were reported in patients in the control group (UMC). 43 adverse events (11.5%) were reported in the UMC + chiropractic group, 38 of which were described as muscle or joint stiffness attributed to chiropractic care ($n = 37$) or physical therapy ($n = 1$).

CLINICAL APPLICATION & CONCLUSIONS

This study confirms findings from previous studies in military (8) and civilian (7, 10) populations that demonstrated improvements in pain and disability in patients receiving chiropractic care for LBP. The findings provide additional support for the inclusion of chiropractic treatment as a component of comprehensive, multidisciplinary care for low back pain. Such care is currently recommended in guidelines from the American College of Physicians and the American Pain Society (11, 12).

As acknowledged by the authors, the study's limitations highlight the need for further research to help us understand longer-term outcomes as well as how intervention parameters and patient heterogeneity may affect patient responses to chiropractic care.

STUDY METHODS

This was a pragmatic, prospective, multisite, parallel-group comparative effectiveness clinical trial conducted at 3 sites: 1) Walter Reed National Military Medical Center,

Bethesda, Maryland; 2) Naval Medical Center San Diego, San Diego, California; and 3) Naval Hospital Pensacola, Pensacola, Florida.

Subject Eligibility:

Active-duty US military participants, aged 18-50 reporting LBP from a musculoskeletal source.

Exclusion Criteria:

Non-musculoskeletal source of LBP, recent spinal fracture, recent spinal surgery, diagnosis of post-traumatic stress disorder.

Treatment Allocation:

Randomized allocation was conducted using a computer-generated minimization algorithm to balance group assignment based on gender, age, LBP duration and intensity of worst pain in the 24 hours preceding enrollment.

Study Interventions:

1. Usual Medical Care (UMC): any care recommended or prescribed by non-chiropractic military clinicians to treat LBP. Options included self-management advice, physical therapy, pharmacologic pain management or pain clinic referral. Patients in this group were advised not to seek chiropractic care, unless directed by their clinician.
2. Usual Medical Care (UMC) + Chiropractic Care: UMC plus up to 12 chiropractic visits during the active care period. Chiropractic care consisted of spinal manipulative treatment to the affected and adjacent regions, based on diagnosis. Additional therapies included: rehabilitative exercise, interferential current therapy, ultrasound therapy, cryotherapy, superficial heat, and other manual therapies.

Blinding:

Participants and clinicians were not able to be blinded to treatment. All key study personnel and data analysts were blinded, however.

Outcomes:

The primary outcomes were: 1) the average LBP intensity during the week prior to assessment using a Numeric Rating Scale (NRS, rated 0-10); and 2) functional disability measured with the Roland Morris Disability Questionnaire.

Secondary outcomes were: 1) worst LBP intensity during the past 24 hours using NRS; 2) bothersomeness of LBP in the past week (1-5 scale); 3) pain medication use during the past week; 4) global LBP improvement using a 7-point scale; and 5) satisfaction with care using NRS (0-10).

Outcomes were assessed at baseline, as well as weeks 2, 4, 6 and 12.

Treatment Intervention Period:

The treatment interventions were provided over 6 weeks.

STUDY STRENGTHS/WEAKNESSES

Strengths:

- Pragmatic design: improves ability to understand the results as currently integrated and delivered in this specific population.
- Chiropractic treatment combined with UMC is consistent with how care is delivered in this setting/population.
- Racial and ethnic diversity among the population.
- Large sample size

Weaknesses:

- Difficulty in determining specific diagnosis of LBP (sub-grouping/classification remains an ongoing issue).
- Broad inclusion criteria (though this is a common strategy in pragmatic trials in an attempt to better represent general practice).
- Difficulty in masking/blinding participants (this is a problem in most manual therapy trials).
- Variations in participant numbers and treatment patterns across the varying sites.
- Difficult patient follow-up due to a highly transient (military) population.

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