**Article Full Title**

Manual therapy followed by specific active exercises versus a placebo followed by specific active exercises on the improvement of functional disability in patients with chronic non specific low back pain: a randomized controlled trial

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**Paper Abstract**

Background: Recent clinical recommendations still propose active exercises (AE) for CNSLBP. However, acceptance of exercises by patients may be limited by pain-related manifestations. Current evidences suggest that manual therapy (MT) induces an immediate analgesic effect through neurophysiologic mechanisms at peripheral, spinal and cortical levels. The aim of this pilot study was first, to assess whether MT has an immediate analgesic effect, and second, to compare the lasting effect on functional disability of MT plus AE to sham therapy (ST) plus AE. Methods: Forty-two CNSLBP patients without co-morbidities, randomly distributed into 2 treatment groups, received either spinal manipulation/mobilization (first intervention) plus AE (MT group; n = 22), or detuned ultrasound (first intervention) plus AE (ST group; n = 20). Eight therapeutic sessions were delivered over 4 to 8 weeks. Immediate analgesic effect was obtained by measuring pain intensity (Visual Analogue Scale) before and immediately after the first intervention of each therapeutic session. Pain intensity, disability (Oswestry Disability Index), fear-avoidance beliefs (Fear-Avoidance Beliefs Questionnaire), erector spinae and abdominal muscles endurance (Sorensen and Shirado tests) were assessed before treatment, after the 8th therapeutic session, and at 3- and 6-month follow-ups. Results: Thirty-seven subjects completed the study. MT intervention induced a better immediate analgesic effect that was independent from the therapeutic session (VAS mean difference between interventions: -0.8; 95% CI: -1.2 to −0.3). Independently from time after treatment, MT + AE induced lower disability (ODI mean group difference: -7.1; 95% CI: -12.8 to −1.5) and a trend to lower pain (VAS mean group difference: -1.2; 95% CI: -2.4 to −0.30). Six months after treatment, Shirado test was better for the ST group (Shirado mean group difference: -61.6; 95% CI: -117.5 to −5.7). Insufficient evidence for group differences was found in remaining outcomes.

**NIH Risk of Bias Tool**

Quality Assessment of Controlled Intervention Studies

1. **Was the study described as randomized, a randomized trial, a randomized clinical trial, or an RCT**

Yes

1. **Was the method of randomization adequate (i.e., use of randomly generated assignment)?**

Yes

1. **Was the treatment allocation concealed (so that assignments could not be predicted)?**

Yes

1. **Were study participants and providers blinded to treatment group assignment?**

Yes

1. **Were the people assessing the outcomes blinded to the participants' group assignments?**

Yes

1. **Were the groups similar at baseline on important characteristics that could affect outcomes (e.g., demographics, risk factors, co-morbid conditions)?**

Yes

1. **Was the overall drop-out rate from the study at endpoint 20% or lower of the number allocated to treatment?**

Yes

1. **Was the differential drop-out rate (between treatment groups) at endpoint 15 percentage points or lower?**

Yes

1. **Was there high adherence to the intervention protocols for each treatment group?**

Yes

1. **Were other interventions avoided or similar in the groups (e.g., similar background treatments)?**

Yes

1. **Were outcomes assessed using valid and reliable measures, implemented consistently across all study participants?**

Yes

1. **Did the authors report that the sample size was sufficiently large to be able to detect a difference in the main outcome between groups with at least 80% power?**

No

1. **Were outcomes reported or subgroups analyzed prespecified (i.e., identified before analyses were conducted)?**

Yes

1. **Were all randomized participants analyzed in the group to which they were originally assigned, i.e., did they use an intention-to-treat analysis?**

Yes

**Key Finding #1**

The immediate analgesic effect of intervention was in favor of manual therapy over detuned ultrasound.

**Key Finding #2**

Manual therapy combined with active exercise (specifically the MT techniques and exercise type, dosage, and progression used in the study) can be efficient to decrease pain for CNSLBP.

**Key Finding #3**

There was insufficient evidence for the effect of manual therapy + active exercise on FABQ-wk, FABQ-pa and Sorensen scores.

**Key Finding #4**

The results of this pilot study need to be further confirmed by future studies with appropriate sample sizes.

**Please provide your summary of the paper**

This study was performed to assess whether manual therapy (MT) has an immediate analgesic effect and to compare the effect of MT combined with active exercise (AE) to a control group on functional disability. The experimental group consisted of MT + AE. The control group consisted of sham therapy (ST) and AE. The ST intervention relied on detuned ultrasound - meaning the ultrasound was inactivated and ineffective. There were several methods used to compare changes in pain and function, including a visual analogue scale (VAS), Oswestry Disability Index (ODI), fear-avoidance beliefs (Fear-avoidance Beliefs Questionnaire), Sorenson (erector spinae), and Shirado (abdominal muscles endurance). These outcome measures are reliable and were assessed before each treatment, after the 8th therapeutic session, and at 3 and 6 month follow ups. To the author’s knowledge, this study is the first controlled study to assess the efficacy of spinal manipulation/mobilization followed by specific active exercises. The findings confirm the immediate analgesic effect of manual therapy (MT) for patients with CNSLBP. It can be strongly suggested from the results of this study that the analgesic effect of MT combined with AE can be productive in decreasing pain for patients with CNSLBP. Furthermore, it has been proposed that MT may allow the patient to perform more accurate active exercises and provide better facilitation of muscle activation. There are limitations concerning the results (due to small sample size) and future testing with appropriate sample sizes are needed for confirmation of findings. There was insufficient evidence for the effect of MT + active exercise (AE) on FABQ-wk, FABQ-pa or Sorensen scores. Lastly, the process of finding patients was provided solely by the rheumatology clinic of a University hospital, which does not reflect the CNSLBP population as a whole.

**Please provide your clinical interpretation of this paper. Include how this study may impact clinical practice and how the results can be implemented.**

To begin, I believe the study provided strong evidence for the clinical relevance of MT, itself, and MT combined with AE in the use of treatment for patients with CNSLBP. The organization and plan of treatments, and the specification of interventions for MT/ST and exercises, provides clinicians with the ability to replicate these techniques in clinical practice. In saying this, I think the study could have provided an even greater impact in clinical practice by knowing which MT intervention, out of the three MT intervention(s), correlated most with a decrease in pain for patients with CNSLBP. Lastly, the findings of the study do need to be further assessed on a larger scale.