Journal of Bodywork & Movement Therapies 42 (2025) 500–505

Contents lists available at ScienceDirect

Journal of Bodywork & Movement Therapies

journal homepage: www.elsevier.com/jbmt

Treatment for the central sensitization component of lower back pain using systemic manual therapy

Andres Aponte, MS, PTA, Adi Halili, PT, DPT, NCS *

Halili Physical Therapy, 268 E River Rd Suite 130, Tucson, AZ, 85704, USA

ARTICLE INFO

Handling editor: Dr Jerrilyn Cambron

Keywords:
Chronic
Low back pain
Central sensitization
Systemic manual therapy
Fascial counterstrain
Integrative manual therapy
Barral
Statins

ABSTRACT

Objective: The purpose of this study was to analyze treatments for central sensitization (CS) and other contributors to chronic lower back pain (CLBP), using systemic manual therapy (SMT) protocols based on the temporal model for CS (TMCS).

Design: Cohort retrospective multivariate analysis.

Methods: This study analyzed episode of care and rate of improvement data in 1053 patients, evaluating 715 protocol combinations of SMT.

Results: While 682 (68%) patients reported improvement in overall symptoms, only 583 (53%) reported improvement in the lower back pain complaint. Comorbidities with statistically significant ($p < 0.05$) association with worse lower back pain outcomes were statin use, anxiety, depression, digestive and urinary issues, smoking and prior surgery.

A significantly higher rate of improvement resulted from the use of 43 protocol combinations, which were composed of 19 protocols, a group that includes five protocols including urinary-drainage (UD), Diaphragm-cranial-sinus (DCS), Barral-abdominal-motility (Barral), lower-abdominal-urogenital (LAUG), and Cardiac-cervical-cranial-vascular (CCCV), which were all predicted to treat CS by the TMCS.

Discussion and conclusions: The results of this study support the use of SMT to treat CLBP and reinforce the TMCS hypothesis defining CS as a functional, multifaceted neurophysiological state rather than a purely structural adaptation of the CNS. The lower rate of improvement in CLBP compared to overall improvement and the correlations of worse outcome with certain comorbidities suggests that, in addition to SMT, a multimodal approach for CLBP should favor lifestyle improvements such as smoking cessation, lifelong exercise habits, and a balanced diet over medications and surgery.

1. Introduction

CLBP is a pervasive condition significantly impacting individuals' quality of life and functional capability worldwide. It is estimated that up to 85% of the global adult population is affected by chronic lower back pain, making it the most widespread musculoskeletal disorder (Nijs et al., 2015). The prevalence of CLBP varies with age and sex, increasing linearly from the third decade of life until 60 years of age and being more prevalent in women (Meucci et al., 2015). In the US, CLBP is considered one of the most significant expenditures in health care and a major public health burden (Roussel et al., 2013), as nearly 23% of adults with CLBP experience chronic manifestations associated with substantial disability and socioeconomic burden (Balagué et al., 2012). The intricate nature of chronic lower back pain often involves an interplay between physical, psychological, and environmental factors, making its management challenging for healthcare professionals. One pivotal aspect of CLBP that has gained considerable attention is its relationship to CS. CLBP is often accompanied by somatic hyperalgesia or enhanced pain from noxious stimuli, which are also found in central sensitization (Cervero and Laird, 1999).

While the etiology of CLBP can be multifaceted and complex, the neurophysiological phenomenon we call CS can be a significant contributor to the persistence and intensification of pain. In CS, the nervous system undergoes a process of heightened sensitivity to both painful and (normally) non-painful stimuli (Sanzarello et al., 2016). CS has been noted as one possible causal mechanism (among others) for CLBP (Verbrugghe et al., 2023). These mechanisms, characterized by intense activity of dorsal horn neurons, contribute to hyperalgesia,

* Corresponding author.
E-mail addresses: halilipt@msn.com (A. Aponte), halilipt@msn.com (A. Halili).

https://doi.org/10.1016/j.jbmt.2025.01.016
Received 19 June 2024; Received in revised form 10 December 2024; Accepted 12 January 2025
Available online 17 January 2025

allodynia, and referred pain.

(Roussel et al., 2013). Altered central processing of pain, as described by CS, has been linked to many chronic pain conditions (Roussel et al., 2013). CS in the context of CLBP represents a condition where the nervous system, undergoing a process of heightened response, becomes more responsive to nociceptive and non-nociceptive stimuli. This phenomenon is characterized by amplifying neural signaling within the central nervous system (CNS), leading to pain hypersensitivity. Studies highlight the multifaceted nature of CS in CLBP, revealing a spectrum of definitions, assessment methods, and prevalence estimates in the literature, reflecting the complexity and variability of this condition (Schuttert et al., 2022).

Past views on the traditional pain model focus mainly on tissue pathology as the source of the pain. However, this does not encompass enough information for assessing and treating pain, especially when it has persisted for over six months, as seen in chronic pain conditions. Nonetheless, other models try to explain that the pain level does not always dictate the state of tissue pathology; instead, pain is a combination of several factors. The immune system's response in the body has been known perhaps to be the originating source or the cause of the continuation of pain sensitization (Halili, 2021b). An individual's belief system of pain may also contribute to the perception of their prognosis, thus influencing the experience of pain.

Current treatment paradigms for CLBP are diverse, ranging from pharmacotherapy and physical therapy to psychological interventions, reflecting the multifactorial nature of the condition. For instance, a combination of lidocaine and ketamine which is known for modulating central sensitization, has demonstrated efficacy in reducing pain intensity and improving functional state in individuals with CLBP (Sugiharto et al., 2020). However, the effectiveness of these interventions can be limited, and the chronic nature of the pain often necessitates long-term management strategies. Recently, treatments targeting central sensitization have shown promise.

Halili (2023) proposed a temporal model for CS (TMCS). According to this model, CS occurs due to the confluence of metabolic stress and the continued propagation of that stress over time. In addition, the temporal model contains a template that can test for hypothetical mechanisms for pathophysiology as well as the efficacy of a proposed intervention. The pathophysiology component of Halili's temporal model describes five progressive stages of autonomic and CNS function, where CS is maintained at the fourth stage due to repeated trauma or self-reinforcing neurological loops. The temporal model further contains a proposed intervention for stabilizing CS using systemic manual therapy (SMT) (Halili, 2020b). The proposed treatment entails disrupting those self-reinforcing neurological loops using specific systemic manual therapy protocols.

Halili (2023) suggests that the null hypothesis can be rejected if the following conditions are met: The proposed protocols, including UD, DCS, CCCV, in addition to at least one of the following: LAUG, Barral, and gastro-urinary ovarian uterine (GUOU), will (1) effectively treat the lower back area, (2) be effective for overall symptoms, (3) do so regardless of the anatomical proximity to the treated region, and (4) result in sustained improvement over the episode of care. This null hypothesis rejection was previously demonstrated by meeting these conditions in treating the CS component of knee pain (Halili, 2024a). The purpose of this study is to attempt to replicate the knee pain study findings when treating primarily sensitized patients with CLBP complaints.

2. Methodology

This study was approved by the Argus Independent Review Board (www.argusirb.com) on July 21, 2021.

A retrospective chart analysis was done in a practice setting where SMT was used as the primary mode of treatment.

SMT protocols (Halili, 2020b) are a group of about 50 protocols that have been developed and standardized over the past few decades by incorporating individual techniques from several osteopathic and physical therapy methods, such as fascial counterstrain (FCS) (Tuckey, 2018), Barral (Barral and Mercier, 2005), integrative manual therapy (IMT) (Giammatteo and Weiselfish-Giammatteo, 2006) and muscle energy techniques (MET) (Mitchell and Mitchell, 2001). A protocol refers to a specific group of techniques that are performed in one treatment session. in the medical records a protocol is referred to by a group of letters (UD or DCS or CCCV etc.). Unless specified otherwise in the treatment record, a protocol is done in the exact same manner for each treatment. Prior work (Halili, 2021a) quantified the ability to achieve standardization in performance between trained treating clinicians. A protocol sequence refers to a series of protocols performed over several consecutive treatment sessions.

To identify which SMT protocols or protocol combinations were more effective than the oSOC (optimal standard of care), the Halili physical therapy statistical analysis tool (HPTSAT) (Halili, 2021a) was used. The HPTSAT is a software tool designed to control for a number of internal validity threats, such as repeated measurements error, when retrospective clinical data is analyzed as well as a placebo effect. One of the key functions of the tool is to measure the average rate of change (ARC5) during multiple treatment sessions. The tool then compares the rate during the period a specific protocol or protocol sequence was done and compares it to the rate during times other treatments were done. The tool identifies all protocols or sequences that met a specific quantitative differentiation criterion. The criterion uses both parametric and non-parametric tests as well as sample and effect size.

The HPTSAT analyzed 44915 blinded visit records of 2710 patients from the Halili physical therapy EMR (electronic medical records) system v. 2021, (HPT2021) between the dates of February 4, 2015 and 11/29/2022.

The inclusion criteria for the study were the presence of lower back pain as one of the patient's identified problems. The criteria used to exclude patients from the sample was if they receive less than two treatment sessions. The absence of identified CS or a younger age were not used for exclusion from the sample because they did not impact hypothesis testing process.

A study sample was created using the search terms "low back," "lower back," and "lumbar" in the patient's PIP list. The study sample included 1053 patients (722 female, 331 male, average age 60.4 range (8–95). The evaluating physical therapist identified CS as one of the differential diagnoses in 741 patients (70%). This determination was done using a methodology similar to the one outlined by Lluch et al. (2017) such as Widespread mechanical hyperalgesia and allodynia, thermal hyperalgesia, hypoesthesia and reduced vibration sense as well as other dynamic measures of CS. Forty-four patients were excluded from the study since they had less than two visits.

Among the 1009 patients, there were 1304 episodes of care (if 90 days have passed since the last visit, then the next visit is considered a new episode of care).

The specific outcome measure used for this study was the Patient Identified Problem (PIP) scale (Halili, 2020a). The PIP scale is a 1 to 10 (half point permitted) scale. The patient can score between 1 (which denotes that the problem is not currently active) and 10 (which indicates maximal intensity). Problems were examined both individually and as a cumulative score. The cumulative score was calculated according to the following formula: PIP = SUM (individual score/number of problems) $\times$ 10 (adding the scores of all individual problems, dividing the total by the number of individual problems, and then multiplying by 10). Symptoms were graded by the patient whenever possible to decrease the examiner's bias. Scoring was always performed at the next visit and not immediately after the treatment. The PIP scale had a specificity and sensitivity of 91.46% and 64.45%, respectively, and an ICC score of 0.96. Minimal clinically important change (MCID) for change observed in the whole scale is 3.8 (95% CI 1.4 to 8.2), and for an individual problem, score change is 0.89 (95% CI 0.33 to 1.5).

The HPTSAT located and analyzed 715 SMT protocols or protocol combinations. A protocol is a specific set of techniques performed in the same order in a single treatment session. A protocol sequence refers to several protocols performed over several sessions. The criteria for analyzing a protocol or a sequence of protocols is that they were found in the database at a frequency larger than five. Within this group, the tool identified the protocol and protocol sequences that met or exceeded the differentiation criteria discussed in the introduction. Further qualitative demographic and comorbidity information and the episode of care data were compiled and analyzed using both the HPTSAT (Halili, 2021a) and MedCalc software (Schoonjans, 2022).

3. Results

To gain some qualitative understanding of our study sample, we noted the following: The average time period a patient was followed in this study was 354 days. The average length of an episode of care was 161 days (95% CI 147 to 175); average visits per episode were 16 (95% CI 14 to 17); and average days between treatments were 10.

Changes in overall PIP scale scores over the study period were as follows: 682 patients (68%) reported improvement in overall PIP complaints, 81 patients (8%) either did not record or reported no change and 246 patients (24%) reported worsening of overall PIP scores. On average, the overall PIP scale score improved by 9.39 points (p, <0.001 STD 21.43, and 95% CI 10.71 to 8.07). This change exceeded the MCID of 3.8, including its 95% CI upper limits of 8.2 points. The average improvement at the end of the episode of care (161 days) was nearly identical to the average improvement noted at the end of the (354 days) study period (9.39 vs 9.22, $p = 0.83$).

The specific changes related to lower back pain complaints were: 538 patients (53%) reported improvement; 250 patients (25%) either did not record or reported no change; and 221 patients (22%) reported worsening of lower back pain score. On average, individual complaints of lower back pain improved by 1.04 points (p, STD, and 95% CI were <0.001, 2.49, 1.19, and 0.89, respectively). This change exceeded the MCID of 0.89. The average improvement over the study period (which included multiple episodes of care) was not significantly higher than the average improvement noted after a single episode of care (1.04 vs. 0.95 $p = 0.38$). The average starting score for the group that reported improved lower back pain was 6.3 points. This score was significantly higher ($p < 0.001$) than the group that reported no change (4.7 points) and the group that reported eventual worsening of symptoms ($p < 0.001$, 4.4 points).

Comorbidities that were found to have a statistically significant ($p < 0.05$) association with worse outcomes included use of statin medications, digestive and urinary issues (active as well as in past history), active depression, anxiety (both current and past), and history of orthopedic surgeries. Table 1 includes an expanded list of the effects of comorbidities. To better understand the relationship between statin use, the underlying conditions statins are used for, and the adverse effects on back pain, we wanted to understand if the difference of 0.46 between statin use and cardiovascular conditions is statistically significant. To do so, we conducted an additional post hoc *t*-test showing that it was not ($p = 0.11$).

All protocols mentioned in this section are described by Halili (2020b).

Of the 717 protocol combinations assessed, 43 combinations containing 19 distinct protocols passed the HPTSAT criteria to demonstrate a better treatment effect than the oSOC when evaluating the individual complaint of CLBP. Passing combinations are listed in Table 2.

The 19 individual protocols passing the HPTSAT criteria were CCCV, LAUG), Cardiovascular Venous Thoracic (CVVT), Upper Extremity Drainage Jones (UEDJ), Muscle Energy Technique Sacroiliac combined with Vascular protocol variations (METVAS), Side-Lying Modified Glides (SLMG or SLMGT [Top]), Seated Modified Glides (seated MG), UD, DCS, Sympathetic Nerve (SYMPN), Lower Extremity Drainage Jones

Table 1
Comorbidities associated with adverse effects on outcome.

Rx	n, control	Diff pt	SD (95% CI)	Welch	Hedges' g
statin medication use	**91, 922**	**−0.69**	**2.61 (3.15 to 2.08)**	**0.017**	**0.28**
IBS (active)	**366, 659**	**−0.58**	**2.44 (2.69 to 2.19)**	**< 0.001**	**0.23**
depression (active)	**247, 778**	**−0.57**	**2.48 (2.79 to 2.17)**	**0.002**	**0.23**
insomnia (active)	**337, 688**	**−0.57**	**2.52 (2.79 to 2.25)**	**< 0.001**	**0.23**
urinary dysfunction (active)	**262, 757**	**−0.53**	**2.47 (2.77 to 2.17)**	**0.003**	**0.21**
bowel/bladder problems (history of)	**614, 403**	**−0.48**	**2.44 (2.63 to 2.25)**	**0.003**	**0.19**
anxiety (active)	**293, 732**	**−0.47**	**2.56 (2.85 to 2.26)**	**0.008**	**0.19**
orthopedic surgeries	**446, 571**	**−0.45**	**2.43 (2.65 to 2.2)**	**0.004**	**0.18**
smoking history	**623, 400**	**−0.42**	**2.47 (2.66 to 2.27)**	**0.01**	**0.17**
insomnia (history of)	**545, 478**	**−0.4**	**2.57 (2.78 to 2.35)**	**0.012**	**0.16**
Neurological surgeries (history of)	209, 806	−0.35	2.52 (2.87–2.18)	0.076	0.14
Abdominal/Pelvic surgeries (history of)	636, 385	−0.32	2.54 (2.74–2.35)	0.052	0.12
Cardiac/ Respiratory	522, 501	−0.23	2.54 (2.76–2.32)	0.154	0.09
Neurological	532, 489	−0.22	2.53 (2.75–2.32)	0.159	0.09
Cancer (history of)	210, 803	−0.21	2.44 (2.77–2.11)	0.25	0.09
Male gender	345, 686	−0.13	2.35 (2.59–2.1)	0.417	0.05

Terms in bold indicate a statistically significant effect ($p < 0.05$).

LEDJ (all variations), Venous Thoracic Cardiopulmonary (VTCP), Barral, Spinal Drainage Jones - lumbar or cervical variations (SPDJL or SPDJC), Lower Extremity Nerve (LEN), Periosteal lower extremity (OST), Diaphragm Cranial Sinus - Dural version (DCD), Sinus Drainage - Jones version (SIDJ) and Genito-Urinary Drainage (GUD). All but two of the protocols (SIDJ and GUD) that passed the HPTSAT criteria for lower back pain were also found in the combinations that passed the criteria for effectiveness on overall change.

In accordance with the temporal model of central sensitization (Halili, 2023), five of the 19 passing protocols (CCCV, DCS, UD, Barral, and LAUG) were performed because of their hypothesized general effect on central sensitization.

Four protocols (METVAS, Seated MG, SLMG, and SPDJ) are considered to have a more direct effect on lower back pain.

The remaining ten protocols (CVVT, LEDJ, OST, LEN, GUD, VTCP, UEDJ, SYMPN, SIDJ, DCD) can improve symptoms by desensitization or other indirect regional mechanisms.

The effects of exercises performed during the therapy session (the HPTSAT controls for the effects of home exercises) did not show a statistically significant difference from the oSOC. The ARC5 for exercises was 0.14 vs 0.11 for oSOC $p = 0.52$ and an effect size of 0.01.

A nearly identical lack of difference over the oSOC was noted when balance activities were performed during the therapy session. The ARC5 for balance activities was 0.13 vs 0.11 for oSOC $p = 0.62$ and an effect size of 0.01.

Strain Counterstrain techniques (SCS) - which were a combination of FCS (Tuckey, 2018) and older Jones Strain-Counterstrain techniques (Jones et al., 1995), - were done using the more traditional pragmatic approach of seeking tender points and then treating them, and were also

Table 2
Passing combinations for lower back complaint.

Protocol/combinations	n	freq, control	ARC5	Rx, oSOC	SD (95% CI)	Welch	MW	ANOVA	Hedges' g
UD METVAS DCS	37	191, 84097	**1.09**	1.2, 0.11	2.02 (2.31–1.74)	<0.001	<0.001	<0.001	0.72
METVAS DCS BARRAL	21	116, 84172	**0.91**	1.02, 0.11	1.6 (1.89–1.31)	<0.001	<0.001	<0.001	0.6
UD METVAS DCS BARRAL	20	54, 84234	**0.85**	0.96, 0.11	1.76 (2.23–1.29)	<0.001	<0.001	<0.001	0.56
METVAS DCS	60	510, 83778	**0.74**	0.85, 0.11	1.97 (2.14–1.8)	<0.001	<0.001	<0.001	0.49
CVVT LAUG LEDJ	29	156, 84132	**0.66**	0.77, 0.11	1.82 (2.11–1.54)	<0.001	<0.001	<0.001	0.43
LAUG LEDJ OST UD	25	68, 84220	**0.64**	0.75, 0.11	1.62 (2.01–1.24)	0.002	0.002	<0.001	0.42
METVAS LAUG LEDJ LEN	30	82, 84206	**0.64**	0.75, 0.11	1.6 (1.95–1.26)	<0.001	<0.001	<0.001	0.42
METVAS BARRAL CCCV	23	119, 84169	**0.63**	0.74, 0.11	2.21 (2.61–1.82)	0.003	<0.001	<0.001	0.41
DCS BARRAL CCCV LAUG LEDJ	39	39, 84249	**0.63**	0.74, 0.11	1.93 (2.54–1.33)	0.049	0.038	0.01	0.41
METVAS Seated MG	24	204, 84084	**0.57**	0.68, 0.11	2.19 (2.49–1.89)	<0.001	<0.001	<0.001	0.37
LEDJ OST UD	30	158, 84130	**0.55**	0.66, 0.11	1.53 (1.77–1.29)	<0.001	<0.001	<0.001	0.36
LAUG LEDJ UD DCS BARRAL	84	83, 84205	**0.51**	0.62, 0.11	1.89 (2.29–1.48)	0.018	0.038	0.003	0.33
DCS LAUG CCCV METVAS	38	112, 84176	**0.51**	0.62, 0.11	2.34 (2.77–1.9)	0.024	0.01	<0.001	0.33
METVAS SLMG UD	35	200, 84088	**0.51**	0.62, 0.11	1.7 (1.93–1.46)	<0.001	<0.001	<0.001	0.34
CCCV METVAS SLMG	53	300, 83988	**0.5**	0.61, 0.11	1.74 (1.94–1.54)	<0.001	<0.001	<0.001	0.33
LAUG LEDJ UD METVAS	60	146, 84142	**0.5**	0.61, 0.11	2.29 (2.67–1.92)	0.013	<0.001	<0.001	0.32
METVAS GUD	24	191, 84097	**0.49**	0.6, 0.11	1.79 (2.05–1.54)	<0.001	<0.001	<0.001	0.32
UD METVAS LAUG	24	154, 84134	**0.49**	0.6, 0.11	1.73 (2–1.46)	<0.001	0.001	<0.001	0.32
LAUG LEDJ LEN UD	51	130, 84158	**0.47**	0.58, 0.11	1.7 (2–1.41)	0.002	0.007	<0.001	0.31
LEDJ UD DCS BARRAL	102	295, 83993	**0.46**	0.57, 0.11	2.16 (2.41–1.91)	<0.001	0.002	<0.001	0.3
BARRAL CCCV SLMG	20	109, 84179	**0.44**	0.55, 0.11	1.9 (2.25–1.54)	0.02	<0.001	0.003	0.28
METVAS VTCP UEDJ	34	152, 84136	**0.42**	0.53, 0.11	1.69 (1.96–1.42)	0.003	0.002	<0.001	0.28
LAUG CCCV METVAS	46	264, 84024	**0.4**	0.51, 0.11	2.1 (2.36–1.85)	0.003	<0.001	<0.001	0.26
CCCV LAUG CCCV	27	155, 84133	**0.39**	0.5, 0.11	1.84 (2.13–1.55)	0.01	0.029	0.002	0.25
METVAS VTCP	68	519, 83769	**0.39**	0.5, 0.11	1.58 (1.72–1.45)	<0.001	<0.001	<0.001	0.25
SLMG LAUG	27	225, 84063	**0.38**	0.49, 0.11	1.64 (1.86–1.43)	<0.001	<0.001	<0.001	0.25
BARRAL LEDJ	24	158, 84130	**0.38**	0.49, 0.11	1.62 (1.87–1.37)	0.004	0.004	0.002	0.25
LAUG LEDJ OST LEN	75	198, 84090	**0.37**	0.48, 0.11	1.53 (1.74–1.32)	0.002	0.002	0.002	0.22
LAUG LEDJ OST	115	555, 83733	**0.37**	0.48, 0.11	1.45 (1.57–1.33)	<0.001	<0.001	<0.001	0.24
METVAS LAUG LEDJ	79	401, 83887	**0.36**	0.47, 0.11	1.7 (1.87–1.53)	<0.001	<0.001	<0.001	0.24
LEDJ UD MET	78	406, 83882	**0.35**	0.46, 0.11	1.96 (2.15–1.77)	<0.001	<0.001	<0.001	0.23
SYMPN SPDJ	30	267, 84021	**0.35**	0.46, 0.11	1.33 (1.49–1.17)	<0.001	<0.001	<0.001	0.23
DCS BARRAL CCCV LAUG	59	166, 84122	**0.35**	0.46, 0.11	1.81 (2.09–1.54)	0.014	0.048	0.003	0.23
SIDJ	22	290, 83998	**0.35**	0.46, 0.11	1.5 (1.68–1.33)	<0.001	<0.001	<0.001	0.23
BARRAL CCCV LAUG LEDJ	48	139, 84149	**0.35**	0.46, 0.11	1.62 (1.89–1.35)	0.013	0.025	0.007	0.23
VTCP METVAS	53	456, 83832	**0.35**	0.46, 0.11	1.62 (1.77–1.48)	<0.001	<0.001	<0.001	0.23
UD LAUG LEDJ UD	30	149, 84139	**0.34**	0.45, 0.11	1.79 (2.07–1.5)	0.022	0.043	0.006	0.22
LAUG LEDJ UD DCS	144	350, 83938	**0.34**	0.45, 0.11	1.76 (1.94–1.58)	<0.001	<0.001	<0.001	0.22
LEDJ UD DCD	23	110, 84178	**0.34**	0.45, 0.11	1.43 (1.7–1.17)	0.017	0.049	0.022	0.22
LEDJ OST	141	1177, 83111	**0.32**	0.43, 0.11	1.45 (1.53–1.36)	<0.001	<0.001	<0.001	0.21
CCCV MET VTCP	27	151, 84137	**0.32**	0.43, 0.11	1.6 (1.86–1.35)	0.016	0.017	0.01	0.21
LEDJ UD SPDJ	34	180, 84108	**0.32**	0.43, 0.11	1.59 (1.83–1.36)	0.009	0.006	0.006	0.21
LEDJ LEN UD	61	331, 83957	**0.32**	0.43, 0.11	1.89 (2.1–1.69)	0.003	<0.001	<0.001	0.21

Key: **n**: number of times combination was done; **freq**: number of 1–5 measurements including this combination; **control**: number of 1–5 measurements not including this combination; **ARC5**: average rate of change over five measurements; **Rx**: ARC5 of freq; **oSOC**: ARC5 of optimal standard of care (control frequency); **SD**: standard deviation; **CI**: confidence interval; **Welch**: *p* of Welch's *t*-test; **MW**: *p* of Mann-Whitney test; **ANOVA**: *p* of Analysis of variance; **Hedges' g**: Hedges's g effect size; **LAUG**: Lower Abdominal Urogenital; **Barral**: Barral Abdominal Motility; **UD**: Urinary Drainage; **DCS**: Diaphragm Cranial Sinus; **DCD**: Dural Cranial Diaphragm; **SIDJ**: Sinus Drainage Jones **CCCV**: Cardiac Cervical Cranial Vascular; **VTCP**: Venous Thoracic Cardiopulmonary; **CVVT**: Cardiovascular Venous Thoracic; **SLMG**: Side-Lying Modified Glides; **Seated MG**: Seated Modified glides; **SPDJ**: Spinal Drainage Jones (all versions); **SYMPN**: sympathetic nerve; **METVAS**: muscle energy to SI joint and vascular combination; **UEDJ**: Upper Extremity Drainage Jones; **OST**: Lower Extremity Periosteum; **LEN**: Lower Extremity Nerves **LEDJ**: Lower Extremity Drainage Jones; **GUD**: Genito-Urinary Drainage.

statistically no better than the oSOC (the ARC5 for SCS was 0.16 vs. 0.11, $p = 0.20$, effect size = 0.03). It is important to note that because of the pragmatic manner in which these techniques are applied compared to the structured manner in which the SMT protocols are done, the efficacy of the treatment is more dependent on the treating clinician's decision-making and other skills. Therefore, inferences about the efficacy of Strain Counterstrain techniques are limited under this investigation format.

The complete performance of the remaining protocol combinations, the effects of comorbidities, additional post-hoc tests, and raw data tables are available in the accompanying dataset (Halili, 2024b).

4. Discussion and conclusions

The study's analysis of the TMCS hypothesis for pathology and treatment found that the results met the four conditions required to reject the null hypothesis and support the TMCS (Halili, 2023). A significant improvement over the episode of care met the first condition. The second condition was met by several protocols that were more effective than standard of care in reducing visceral input (LAUG, Barral, Barral-CVVT, VTCP), shifting humoral inflammatory activity (UD, DCS), and reducing oxidative stress (CCCV). These protocols were effective regardless of their proposed direct effect on lower back pain, meeting the third condition. Additionally, all these protocols passed the HPTSAT criteria for overall effects on the PIP scale, meeting the fourth condition.

Since this type of investigation does not directly measure physiological changes, rejection of the null hypothesis (which implies that chronic lower back pain is a localized problem treated with direct techniques), does not necessarily validate the hypothesis for mechanism and treatment proposed in the TMCS. However, if future studies investigating other body regions are able to replicate the results of this study, especially that treatment protocols theorized to address CS are effective even when applied in an area remote from the targeted region, and that the same protocols continue to exhibit benefit to the patient's overall symptoms, it would bring The pathology and treatment hypotheses discussed in the TMCS closer to validation.

For example, this study reinforces previous findings (Halili, 2024a, 2024b) as well as supporting the idea proposed by the TMCS that CS should be viewed as a functional, multifaceted neurophysiological state rather than a purely structural adaptation of the CNS.

Beyond confirming the efficacy of SMT in treating CS, it also identifies several SMT protocols that have a direct or regional influence on improving CLBP symptoms. However, the difference in improvement rates between overall symptoms (68%) and CLBP (53%) suggests that there may be specific factors related to CLBP that make it more challenging to treat. The study's analysis of comorbidities provides insights into this. Excluding comorbidities associated with CS, three factors remain: statins use, surgical history, and tobacco or alcohol use. These observations support early referral to physical therapy instead of elective surgery; smoking cessation; and adopting lifelong habits such as exercise and a healthy diet could reduce statin use (statins have been shown to worsen the ability to recover from back pain) and to generally improve the outcome of treatment for back pain.

The study's findings do not suggest that exercises are ineffective for CLBP. Instead, they indicate that the limited time in the clinic might be better spent on administering SMT techniques. As a standard practice, patients in this study were prescribed a home exercise program focused on cardiovascular fitness, such as interval-based walking, unless contraindicated.

Limitations and additional considerations.

- The findings that exercise during the therapy session were not better than average care does not mean that exercises are not beneficial for CLBP but rather that the limited time in the clinic is better spent with the administration of SMT techniques. As a general practice, unless contraindicated, patients in this study were given a cardiovascular-based home exercise program such as an interval walking program.
- Performing SCS and FCS in the more traditional pragmatic manner is dependent on the decision-making skills of the clinician. As such, their limited efficacy observed needs to be interpreted with caution.
- The poorer outcomes observed in the presence of certain comorbidities demonstrate correlation and not causation.
- Because of the moderate effect size observed when statins were used (0.28) and the observation that the difference between the effects of statins and simply having an underlying cardiovascular condition was close to reaching statistical significance ($p = 0.11$), statin use should be further scrutinized in patients with CLBP.
- Because of the statistically lower average starting point of the group that reported no change in lower back pain symptoms compared to the group that reported improvements, the possibility of a type II measurement error exists (improvement that occurred was not measured). This error is attributed to the floor effect of the outcome tool used (PIP scale) (Halili, 2020a). This error does not affect the outcome of the TMCS hypothesis tests but should be considered as an additional factor that could have contributed to the difference observed between the improvement in overall symptoms (68%) and improvement in lower back pain on its own (53%)

4.1. Future Implications

The results of this study strengthen the case for using SMT to treat CS and certain musculoskeletal conditions. They also support the idea that CS is a functional neurophysiological state, suggesting that a non-invasive, multimodal approach, including physical therapy in general and SMT specifically, may be more suitable than drugs or implanted devices like spinal cord stimulators or vagal stimulators.

Additionally, the study's findings favor a multimodal approach for CLBP treatment, combining SMT with smoking cessation, lifelong exercise habits, and a balanced diet over medication.

Key findings: The findings of this study are consistent with the hypothesis expressed in the TMCS that the sensitization component CLBP can be treated with success using SMT. It is hypothesized to do so because CS appears to be a functional not a structural adaptation of CNS. This study also found that comorbidities such as statin use, surgical history and smoking have an adverse effect on the outcome of treatment.

The findings of this study also support a multi-modal approach to treatment of chronic lower back pain.

CRediT authorship contribution statement

Andres Aponte: Writing – review & editing, Writing – original draft, Methodology. **Adi Halili:** Writing – review & editing, Writing – original draft, Methodology, Data curation.

Funding source

There were no external funding sources for this study.

Declaration of competing interest

There are no financial interest or other conflict to report for this manuscript.

References

Balagué, F., Mannion, A.F., Pellisé, F., Cedraschi, C., 2012. Non-specific low back pain. Lancet 379 (9814), 482–491. https://doi.org/10.1016/S0140-6736(11)60610-7.

Barral, J.P., Mercier, P., 2005. Visceral Manipulation. Eastland Press.

Cervero, F., Laird, J., 1999. Visceral pain. Lancet 353 (7221), 2145–2148. https://doi.org/10.1016/S0140-6736(62)91174-1.

Giammatteo, T., Weiselfish-Giammatteo, S., 2006. Integrative Manual Therapy for the Autonomic Nervous System and Related Disorders: Utilizing Advanced Strain and Counterstrain Technique. North Atlantic Books.

Halili, A., 2020a. Patient identified Problem (PIP) Scale, validity, reliability, responsiveness, likelihood ratio, and minimal clinically important difference. Phys. Ther. Rehabil. 7 (1), 4. https://doi.org/10.7243/2055-2386-7-4.

Halili, A., 2020b. Systemic Manual Therapy. Sun Bernardino. Kindle direct publishing, California, 2020.

Halili, A., 2021a. Control of internal validity threats in a modified adaptive platform design using Halili Physical Therapy Statistical Analysis Tool (HPTSAT). MethodsX 8, 101232. https://doi.org/10.1016/j.mex.2021.101232.

Halili, A., 2021b. Physical therapy for the treatment of respiratory issues using systemic manual therapy protocols. J. Bodyw. Mov. Ther. 27, 113–126. https://doi.org/10.1016/j.jbmt.2021.02.009.

Halili, A., 2023. Temporal model for central sensitization: a hypothesis for mechanism and treatment using systemic manual therapy, a focused review. MethodsX 101942. https://doi.org/10.1016/j.mex.2022.101942.

Halili, A., 2024a. Treatment for the central sensitization component of knee pain using systemic manual therapy. Douleurs. https://doi.org/10.1016/j.douler.2024.01.002.

Halili, A., 2024b. Treatment for the Central Sensitization Component of Lower Back Pain Using Systemic Manual Therapy. Mendeley Data, V1. https://doi.org/10.17632/b4zb9myy5d.1.

Jones, L.H., Kusunose, R.S., Goering, E.K., 1995. *Strain-counterstrain*. Boise, ID: Jones Strain-Counterstrain.

Lluch, E., Nijs, J., Courtney, C.A., Rebbeck, T., Wylde, V., Baert, I., Wideman, T.H., Howells, N., Skou, S.T., 2017. Clinical descriptors for the recognition of central sensitization pain in patients with knee osteoarthritis. Disabil. Rehabil. 40 (23), 2836–2845. https://doi.org/10.1080/09638288.2017.1358770.

Meucci, R.D., Fassa, A.G., Xavier Faria, N.M., 2015. Prevalence of chronic low back pain: Systematic review. Rev. Saude Publica 49, 1–10. https://doi.org/10.1590/S0034-8910.2015049005874.

Mitchell, F.L., Mitchell, P.K., 2001. The Muscle Energy Manual. MET Press, East Lansing, MI, Michigan.

Nijs, J., Apeldoorn, A., Hallegraeff, H., Clark, J., Smeets, R., Malfliet, A., Girbé, E.L., De Kooning, M., Ickmans, K., 2015. Low back pain: Guidelines for the clinical classification of predominant neuropathic, nociceptive, or central sensitization pain. Pain Physician 18 (3), E333–E346. https://doi.org/10.36076/ppj.2015/18/e333.

Roussel, N.A., Nijs, J., Meeus, M., Mylius, V., Fayt, C., Oostendorp, R., 2013. Central sensitization and altered central pain processing in chronic low back pain: Fact or myth? Clin. J. Pain 29 (7), 625–638. https://doi.org/10.1097/AJP.0b013e31826f9a71.

Sanzarello, I., Merlini, L., Rosa, M.A., Perrone, M., Frugiuele, J., Borghi, R., Faldini, C., 2016. Central sensitization in chronic low back pain: a narrative review. J. Back Musculoskelet. Rehabil. 29 (4), 625–633. https://doi.org/10.3233/BMR-160685.

Schuttert, I., Timmerman, H., Petersen, K.K., McPhee, M.E., Arendt-Nielsen, L., Reneman, M.F., Wolff, A.P., 2022. Reply to Jensen, O.K. On the Use of Quantitative Sensory Testing to Estimate Central Sensitization in Humans. Comment on "Schuttert et al. The Definition, Assessment, and Prevalence of (Human Assumed) Central Sensitisation in Patients with Chronic Low Back Pain: A Systematic Review.

J. Clin. Med. 11 (8), 11–12. https://doi.org/10.3390/jcm11082113. J. Clin. Med. 2021,10, 5931.
Schoonjans, F., 2022. MedCalc Statistical Software - Free Trial Available. MedCalc. Retrieved July 10, 2022, from. https://www.medcalc.org/.
Sugiharto, H., Haddani, Hasnawi, Fitria, Yuki, Rizal, Zainal, 2020. Efficacy of lidocaine and ketamine combination on Reduction of pain intensity, improvement of functional state and central desensitization of chronic low back pain. Bioscientia Medicina : Journal of Biomedicine and Translational Research 4 (4), 45–54. https://doi.org/10.32539/bsm.v4i4.167.
Tuckey, 2018. Counterstrain Fascial Introduction. Carlsbad. Jones institute, California, 2018.
Verbrugghe, J., Agten, A., Stevens, S., Vandenabeele, F., Roussel, N., Verbunt, J., Goossens, N., Timmermans, A., 2023. High intensity training improves symptoms of central sensitization at six-month follow-up in persons with chronic nonspecific low back pain: Secondary analysis of a randomized controlled trial. Braz. J. Phys. Ther. 27 (2), 100496. https://doi.org/10.1016/j.bjpt.2023.100496.