

VU Research Portal

Effectiveness of spinal manipulation and myofascial release compared with spinal manipulation alone on health-related outcomes in individuals with non-specific low back pain

Boff, Taise Angeli; Pasinato, Fernanda; Ben, Ângela Jornada; Bosmans, Judith E.; van Tulder, Maurits; Carregaro, Rodrigo Luiz

published in

Physiotherapy (United Kingdom)

2020

DOI (link to publisher)

[10.1016/j.physio.2019.11.002](https://doi.org/10.1016/j.physio.2019.11.002)

document version

Publisher's PDF, also known as Version of record

document license

Article 25fa Dutch Copyright Act

[Link to publication in VU Research Portal](#)

citation for published version (APA)

Boff, T. A., Pasinato, F., Ben, Â. J., Bosmans, J. E., van Tulder, M., & Carregaro, R. L. (2020). Effectiveness of spinal manipulation and myofascial release compared with spinal manipulation alone on health-related outcomes in individuals with non-specific low back pain: randomized controlled trial. *Physiotherapy (United Kingdom)*, 107, 71-80. <https://doi.org/10.1016/j.physio.2019.11.002>

General rights

Copyright and moral rights for the publications made accessible in the public portal are retained by the authors and/or other copyright owners and it is a condition of accessing publications that users recognise and abide by the legal requirements associated with these rights.

- Users may download and print one copy of any publication from the public portal for the purpose of private study or research.
- You may not further distribute the material or use it for any profit-making activity or commercial gain
- You may freely distribute the URL identifying the publication in the public portal

Take down policy

If you believe that this document breaches copyright please contact us providing details, and we will remove access to the work immediately and investigate your claim.

E-mail address:

vuresearchportal.ub@vu.nl



Effectiveness of spinal manipulation and myofascial release compared with spinal manipulation alone on health-related outcomes in individuals with non-specific low back pain: randomized controlled trial

Taise Angeli Boff^{a,b}, Fernanda Pasinato^{b,c}, Ângela Jornada Ben^d,
Judith E. Bosmans^d, Maurits van Tulder^{d,e}, Rodrigo Luiz Carregaro^{a,b,c,*}

^a *Master in Rehabilitation Sciences, Universidade de Brasília (UnB), Campus UnB Ceilândia, Brasília, Brazil*

^b *Núcleo de Evidências e Tecnologias em Saúde (NETecS), Universidade de Brasília (UnB), Campus UnB Ceilândia, Brasília, Brazil*

^c *School of Physical Therapy, Universidade de Brasília (UnB), Campus UnB Ceilândia, Brasília, Brazil*

^d *Department of Health Sciences, Faculty of Science, Vrije Universiteit Amsterdam, Amsterdam Public Health Research Institute, The Netherlands*

^e *Department Physiotherapy & Occupational Therapy, Aarhus University Hospital, Aarhus, Denmark*

Abstract

Objective To investigate the effectiveness of spinal manipulation combined with myofascial release compared with spinal manipulation alone, in individuals with chronic non-specific low back pain (CNLBP).

Design Randomized controlled trial with three months follow-up.

Setting Rehabilitation clinic.

Participants Seventy-two individuals (between 18 and 50 years of age; CNLBP ≥ 12 consecutive weeks) were enrolled and randomly allocated to one of two groups: (1) Spinal manipulation and myofascial release – SMMRG; $n = 36$) or (2) Spinal manipulation alone (SMG; $n = 36$).

Interventions Combined spinal manipulation (characterized by high velocity/low amplitude thrusts) of the sacroiliac and lumbar spine and myofascial release of lumbar and sacroiliac muscles vs manipulation of the sacroiliac and lumbar spine alone, twice a week, for three weeks.

Main outcome measures Assessments were performed at baseline, three weeks post intervention and three months follow-up. Primary outcomes were pain intensity and disability. Secondary outcomes were quality of life, pressure pain-threshold and dynamic balance.

Results No significant differences were found between SMMRG vs SMG in pain intensity and disability post intervention and at follow-up. We found an overall significant difference between-groups for CNLBP disability (SMG-SMMRG: mean difference of 5.0; 95% confidence interval of difference 9.9; -0.1), though this effect was not clinically important and was not sustained at follow-up.

Conclusions We demonstrated that spinal manipulation combined with myofascial release was not more effective compared to spinal manipulation alone for patients with CNLBP.

Clinical trial registration number NCT03113292.

© 2019 Chartered Society of Physiotherapy. Published by Elsevier Ltd. All rights reserved.

Keywords: Manual therapy; Treatment outcome; Low back pain; Disability; Quality of life; Postural balance

* Corresponding author at: Universidade de Brasília (UnB), Campus UnB Ceilândia, Centro Metropolitano, Ceilândia Sul, Brasília/DF, CEP: 72220-275, Brazil.

E-mail address: rodrigocarregaro@unb.br (R.L. Carregaro).

Introduction

Chronic non-specific low back pain (CNLBP) is a condition characterized by pain, stiffness, and/or muscular tension between the lower rib margins and gluteal folds [1], and considered the main cause of years lived with disability [2]. In CNLBP, pain processing and modulation by the central nervous system may be altered [3]. Furthermore, the altered pressure pain-thresholds, balance and strength deficits can affect motor control [4,5], and might contribute to relapses [5,6].

Several conservative interventions are used for treating CNLBP, such as motor control exercises and manual therapy (e.g. spinal manipulation, which is characterized by high velocity/low amplitude thrusts, and myofascial release) [2,4,7–12]. Studies have suggested that decreases on intensity of pain after spinal manipulation are associated with changes in the central nervous system [4,13]. Additionally, stand-alone spinal manipulation was effective in decreasing pain and disability in the short-term (2–12 sessions) when compared to other interventions (e.g. sham manual therapy) or when combined with other therapies [14–16]. Findings from a systematic review and meta-analysis suggests that these studies presented moderate-quality evidence supporting the effectiveness of spinal manipulation in reducing pain and disability in individuals with CNLBP compared with active-controls (e.g. exercise, sham) [17].

Previous studies recommended the adoption of interventions focused on the soft-tissues, such as myofascial release [18,19], for the management of CNLBP. Although myofascial release alone reduced pain and disability compared to sham interventions [19], its effectiveness in individuals with CNLBP is controversial [18] and there is a paucity of high quality randomized controlled trials. Nevertheless, when myofascial release is combined with other treatments, it seems to be effective in reducing pain [18]. Most of the studies have investigated the isolated effects of spinal manipulation and myofascial release, though in clinical settings these modalities are commonly combined to optimize the interventions' effects [17,20]. Notwithstanding, the effectiveness of multimodal treatments (e.g. spinal manipulation plus myofascial release) as compared to stand-alone interventions is still unclear [18]. Furthermore, evidence on the impact of these treatments on quality of life of individuals with CNLBP is scarce [17]. This is a relevant topic considering that CNLBP can cause acute and/or persistent psychological distress affecting quality of life [21].

Therefore, the aim was to investigate the effectiveness of spinal manipulation plus myofascial release compared to spinal manipulation alone, on pain intensity and disability of individuals with CNLBP. It is hypothesized that the combination of spinal manipulation and myofascial release will be superior to spinal manipulation alone.

Method

Study design

A Randomized Controlled Trial was performed in which spinal manipulation plus myofascial release was compared to spinal manipulation alone in individuals with CNLBP. The interventions lasted three weeks (twice a week) with a follow-up of three months. The study was reported according to the CONSORT guidelines.

The trial was registered (Clinicaltrials.gov; NCT03113292) and approved by the Institutional Ethics Committee (FCE/UnB; protocol 2.399.669).

Participants

The participants were recruited at one public physiotherapy and occupational rehabilitation clinic located in the city of Brasilia. Participants who were willing to participate and had signed informed consent were assessed for eligibility.

The inclusion criteria were: (1) age between 18 and 60 years; (2) presence of CNLBP ≥ 12 consecutive weeks; (3) local pain; (4) radiating pain to one or both lower limbs but without neurological deficits.

Participants were excluded if they presented (1) radiating pain with neurological deficits; (2) infections/inflammations in the spine and upper and lower limbs in the last three months; (3) chest and abdominal surgeries in the last six months; (4) rheumatic and myopathic diseases; (5) spondylolysis; (6) history of fracture and/or trauma and lumbar spine surgery; (7) renal, digestive, and neurological diseases; (8) pregnancy; (9) use of anti-inflammatory drugs and analgesics in the two weeks prior to the intervention; and (10) manual therapy and exercise interventions in the three months prior to the study.

Participants who met the inclusion criteria were randomly allocated to one of two groups: (1) Spinal manipulation and myofascial release (SMMRG), or (2) Spinal manipulation alone (SMG).

Randomization was conducted using a random numbers table (Random Allocation Software version 2.0[®]). Randomization was stratified by gender (ratio of 4 men: 1 woman). Treatment allocation was concealed by using opaque and sealed envelopes, containing cards with the names of the interventions. The randomization procedure was performed by a researcher who was not aware of the objectives of the study. Due to the nature of the interventions, it was not possible to blind the therapist and participants. However, the therapist was blinded concerning the results of outcome measurements. Pain, disability and quality of life were self-reported. Assessment of pressure pain and dynamic balance were performed by two trained researchers, blinded for group allocation. The statistician was also blinded, having received the spreadsheets with groups/individuals numerically coded.

Description of the interventions

Interventions were planned by two Physiotherapists and one Chiropractor. The protocol was standardized regarding the definition and execution of the techniques (spinal manipulation and myofascial release), aiming at homogenizing possible professional variations. The interventions were performed by the chiropractor, who was an experienced clinical practitioner. Both groups were offered six treatment sessions. Treatment-related adverse events were monitored at the end of each session.

Spinal manipulation group (SMG)

Spinal Manipulation was performed on the sacroiliac and lumbar spine. The therapist selected the segment to be manipulated based on the presence of hypomobility, confirmed by static and dynamic palpation, and pain complaint in stress tests (compression test, Gaenslen's test, Gillet test, and standing flexion test). According to Laslett [22], pain-provoking tests for the sacroiliac joint are reliable and clinically valid. Manipulation of the sacroiliac region was done with the participant lying on their side with the most affected side up and positioned to reach the restrictive joint barrier. Concomitantly, the therapist applied thrust manipulation at high speed and low amplitude.

In the lumbar spine, the vertebrae to be manipulated were detected and the participant was placed in side-lying position with the side of rotation of the spinous process in contact with the massage table. The therapist stood in front of the participant and positioned himself to apply the manipulation. A detailed description is presented in supplementary Appendix 1 (online resource).

Spinal manipulation and myofascial release group (SMMRG)

The procedures started with myofascial release on the lumbar and sacroiliac muscles. The spinal erector, lumbar, gluteal, and piriformis muscles were palpated in order to identify trigger points. Myofascial release of the lumbar region was performed by means of deactivation of trigger points, Fig. 1 characterized by constant pressure with the thumb for 30 seconds and repeated three times at each point. The pressure intensity was controlled by the participant's tolerance [23]. Then, the fascia was released by continuous sustained pressure in the restrictive tissue barrier for 90 seconds, which was repeated three times in the right and left paravertebral muscles [24]. Myofascial release of the sacroiliac region was performed by active release technique (thumb pressure at the pain site), while the participant performed abduction, external rotation, and anterior tilt of the pelvis [25]. Each movement was repeated three times for 20 seconds. At the end of the myofascial release, spinal manipulation was performed on the sacroiliac and lumbar spine, same as described for the SMG.

Outcomes

Participants were evaluated at different time-points: (1) Baseline; (2) Post intervention (one week after completion of intervention) and (3) Three months post intervention (follow-up). The following variables were collected at baseline: age and gender; body mass, height, and Body Mass Index; and prognosis of chronic and debilitating LBP using the STart-Back Screening Tool (classified as low – good prognosis; medium – less-favorable prognosis; high risk – unfavorable prognosis) [26,27]. We used a validated and cross-culturally adapted version of the STartBack Screening Tool (SBST-Brazil) [28].

Primary outcomes

Disability was measured using the Quebec Back Pain Questionnaire [29], which contains 20 items that assesses the difficulty in performing routine activities (e.g., walking, sitting, turning in bed). Each question has six answers, ranging from zero (no difficulty) to five (unable to perform). The final score ranges from zero (no disability) to 100 (maximum disability). The reliability of this questionnaire was considered strong (intraobserver and interobserver intraclass correlation coefficients, respectively, of 0.93 and 0.96; and Cronbach- α of 0.97) [29].

Pain intensity was evaluated using the visual analogue scale, presented as a 10-cm line ranging from '0' (absence of pain) and '10' (worst pain). Participants were instructed to place a mark on the line (measured in centimeters), regarding pain on the previous week.

Secondary outcomes

Quality of life was measured using the EQ-5D-3L questionnaire, validated for the Brazilian population [30]. This instrument has five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has three possible answers (no problems/some problems/extreme problems), allowing to describe 243 health states. The health states were converted into utility values using a Brazilian tariff [30]. The utility represents a measure of quality of life ranging from '0' (death) to '1' (perfect health) [31].

Pain pressure-threshold was measured with a digital algometer [32] on the spinous processes of L4, L5, and S1 and paravertebral muscles (L4/L5, right/left). Initially, a familiarization was performed on the anterior muscles of the forearm. The algometer was positioned perpendicular to the skin and, subsequently, pressure was applied. The participant was instructed to verbalize when the pressure became painful. For the assessment, participants were positioned in prone on a massage table. All points assessed were marked with a pen and three measurements were taken at each site, with a 30-seconds interval between them [32]. The mean of the three measurements was used for analysis.

Dynamic balance was assessed using the Y-Balance Test (YBT) [33], which measures the displacement of the lower

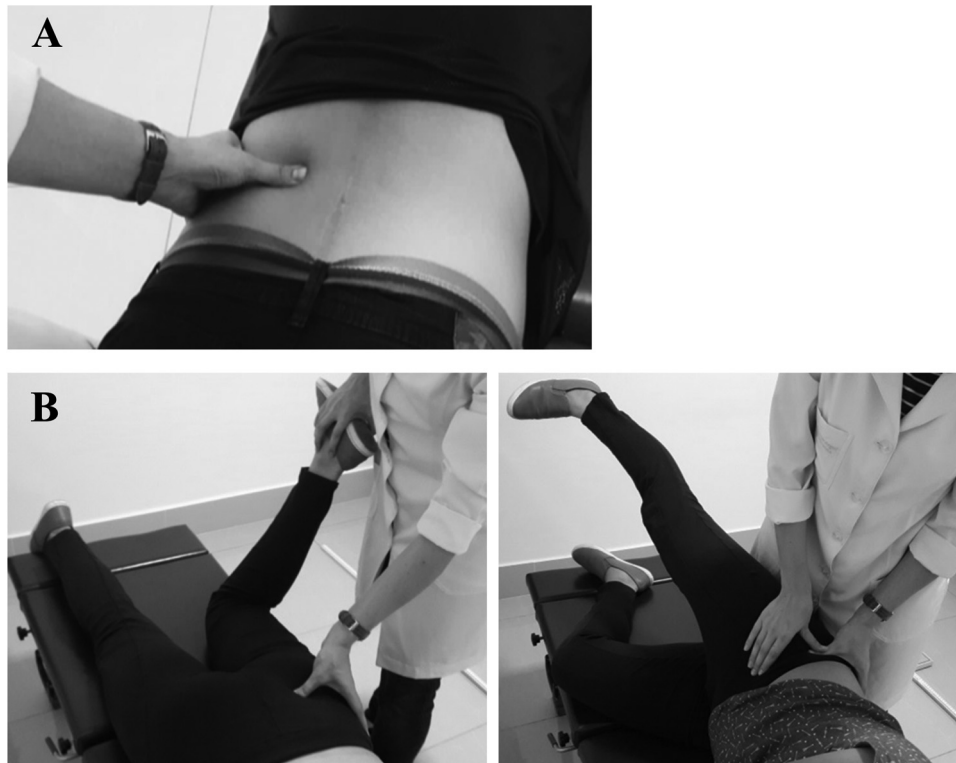


Fig. 1. Illustration of the myofascial release intervention: (A) deactivation of trigger points; (B) active release technique.

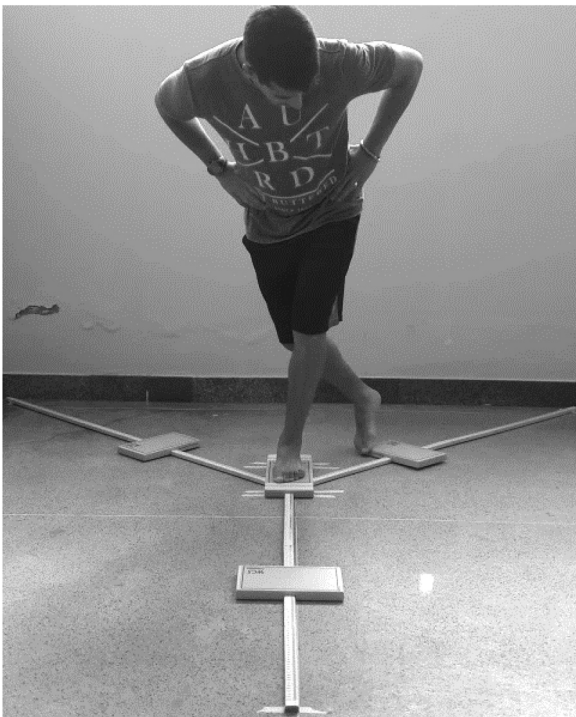


Fig. 2. Illustration of the Y-Balance Test, postero-medial direction.

limbs in the anterior, posterolateral, and posteromedial directions (Fig. 2). The YBT is a valid measure of dynamic balance [34], and is able to detect balance deficits in people with

LBP [33]. The test device is a Y-shaped board with a central fixed platform and three poles with distance marking in centimeters. On each pole there is a movable box. Participants were instructed to stand on their dominant leg on the fixed platform, with bare feet and slide the movable box as far as possible, in each direction, with the non-dominant foot. During sliding, participants placed their hands on their waist and were instructed to return to the starting position immediately after the maximum reach. Three successful attempts were collected for each direction, with a 30-second interval between them [33]. Measurements were normalized by the length of the dominant limb ($[\text{distance reached}/\text{limb length}] \times 100$). For the analysis, the mean of the three distances was used (data presented as percentages).

Due to logistic problems, pain pressure-threshold and balance were assessed only at baseline and post intervention.

Sample size

Sample size calculation was performed using GPower version 3.1.9.2, and based on a repeated-measures ANOVA model, power of 80%, and alpha of 5% to find a difference between groups of effect size = 0.3 for pain intensity. The calculation indicated a sample size of 62 participants ($n = 31$ per group). Considering a dropout of 15%, a sample size of 70 participants was needed ($n = 35$ per group).

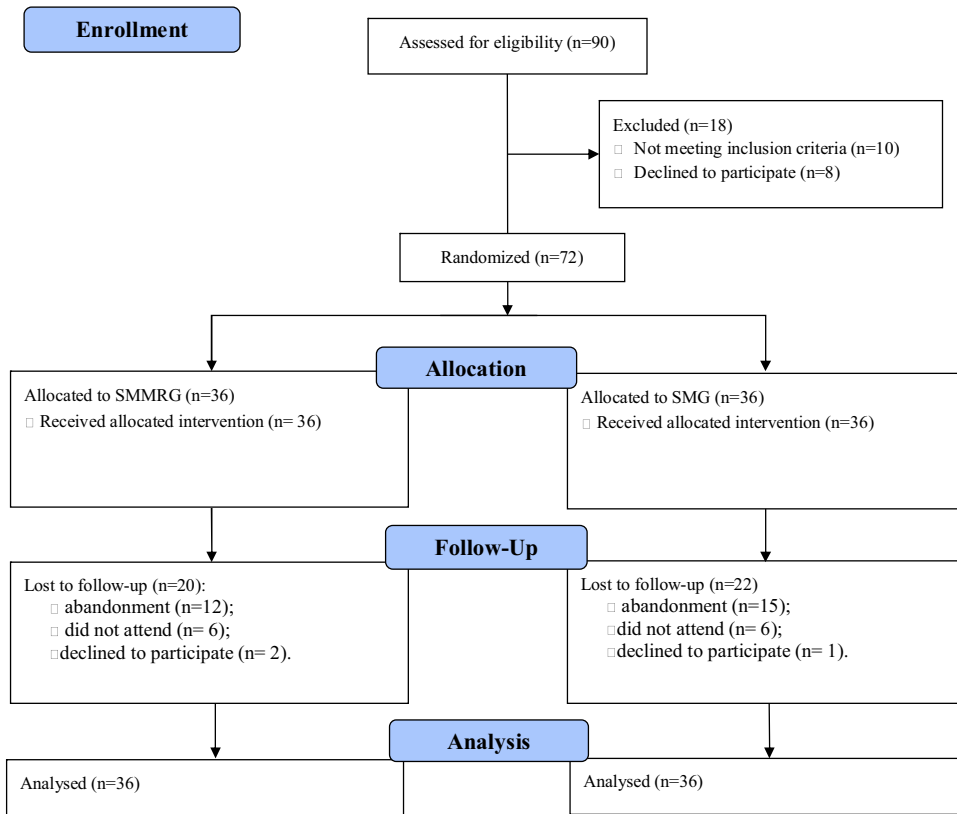


Fig. 3. Study flowchart.

Statistical analysis

The analyses were conducted according to intent-to-treat principles using STATA version 14.0. The variables collected at baseline were described by group. Means (standard deviations) were calculated for continuous outcomes; absolute and relative frequencies were calculated for categorical outcomes. The normality assumptions were confirmed by the Kolmogorov–Smirnov test.

Missing data were imputed using multiple imputation, assuming a missing at random (MAR) pattern. Variables associated with missing data and outcomes were included in the model. The number of imputed datasets was 10 to reach a fraction of missing information less than 5% [35].

The effectiveness was analyzed using linear mixed model, including a between-groups differences at each time-point and an overall effect difference. A within time-points analysis was also performed using linear mixed model to assess differences in the outcomes between post intervention vs baseline and follow-up vs baseline, in both groups. The STartBack score at baseline was included as covariate to adjust the effects to the prognosis of CNLBP.

Results

Ninety individuals were assessed for eligibility, but eighteen were excluded (ten did not meet the inclusion criteria and

Table 1
Baseline characteristics of the participants.

	SMMRG (n = 36)	SMG (n = 36)
Age – years; \bar{X} (SD)	38.1 (7.0)	38.7 (6.8)
Gender		
Female – n (%)	7 (19)	6 (17)
Male – n (%)	29 (81)	30 (83)
BMI – kg/m ² ; \bar{X} (SD)	26.5 (3.0)	26.7 (3.8)
SBST – n (%)		
Low risk	18 (50)	21 (58)
Medium risk	13 (36)	11 (31)
High risk	5 (14)	4 (11)

\bar{X} : mean; SD: standard deviation. BMI: Body Mass Index. SBST: STart-Back Screening Tool.

eight refused to participate). The remaining seventy-two were included and randomized. One participant in the SMMRG did not attend the post intervention assessment. All participants completed the interventions as originally assigned (Fig. 3).

Of the 72 participants, 92% (n = 66) attended all sessions, 7% of the participants (n = 5) attended five sessions, and 1 participant attended three sessions. Of the six participants who were not completely adherent to the treatment protocol, five were in the SMG and one in the SMMRG. No adverse effects were reported.

The participant’s characteristics are presented in Table 1. No relevant differences were found at baseline.

The results on the primary outcomes and quality of life are shown in Table 2. No between-group differences were found

Table 2

Results on the outcomes measured at baseline, post intervention, and follow-up (primary outcomes and quality of life).

	SMMRG	SMG	Mixed model effects			
			Mean (SE)	Mean (SE)	Between-groups ^a B (CI 95%)	P-value
Pain (cm)						
Baseline	3.0 (0.4)	3.0 (0.3)	–	–	–	–
Post intervention	1.9 (0.3)	1.7 (0.3)	0.1 (–1.0; 1.3)	0.8	–1.2 (–2.0; –0.4)	0.003
Follow-up	2.9 (0.6)	3.2 (0.5)	–0.3 (–1.8; 1.2)	0.7	0.2 (–0.9; 1.2)	0.7
Overall effect	n.a	n.a	–0.1 (–0.9; 0.8)	0.9	n.a	–
Disability (score)						
Baseline	20.3 (2.0)	24.9 (1.8)	–	–	–	–
Post intervention	16.5 (2.2)	16.67 (1.5)	0.8 (–6.2; 7.7)	0.8	–8.2 (–12.0; –4.5)	<0.001
Follow-up	17.4 (2.9)	21.3 (2.7)	4.4 (–0.9; 9.7)	0.1	–3.6 (–8.9; 1.7)	0.2
Overall effect	n.a	n.a	–5.0 (–9.9; –0.1)	0.04	n.a	–
Quality of life (utility)						
Baseline	0.64 (0.02)	0.60 (0.03)	–	–	–	–
Post intervention	0.69 (0.02)	0.68 (0.02)	–0.04 (–0.11; 0.03)	0.3	0.08 (0.03; 0.13)	0.002
Follow-up	0.67 (0.04)	0.65 (0.03)	–0.02 (–0.11; 0.07)	0.6	0.04 (–0.02; 1.04)	0.2
Overall effect	n.a	n.a	0.04 (–0.02; 0.11)	0.1	n.a	–

SMMRG: Spinal manipulation combined with myofascial release; SMG: Spinal manipulation alone. SE: standard error. CI 95%: confidence interval of 95%; n.a: non-applicable. Overall effect: mean difference between groups over time.

^a Mean difference in the outcome between groups.

^b Mean difference in the outcome over time, compared with baseline. Because there were no differences between the groups, we combined the groups in the within time-point analysis.

for pain and quality of life post intervention or at follow-up. Nevertheless, for disability, we found a significant overall effect difference between groups. Pain, disability, and quality of life improved significantly post intervention in both groups, but returned to baseline values at follow-up.

Data for the secondary outcomes are presented in Table 3. No significant differences were found between-groups. The within time-points analyses showed that only the dynamic balance improved significantly in both groups at post intervention vs baseline.

Discussion

The aim was to investigate the effectiveness of spinal manipulation plus myofascial release compared with spinal manipulation alone in individuals with CNLBP. We demonstrated that spinal manipulation plus myofascial release was not more effective compared to spinal manipulation alone. Moreover, we found that although both interventions somewhat improved pain and disability post-intervention, the effects were small and cannot be considered clinically relevant, except for quality of life.

Our findings demonstrated that the addition of myofascial release did not provide better effects compared to a stand-alone intervention. The only significant difference was the overall effect on disability, in which the SMMRG had a significant improvement of –5 points compared to the SMG. However, this difference was not clinically important (i.e. a minimum difference in the score of an outcome, from the patient perspective), as we found a mean difference less than 20 points [36]. This may be explained by the relatively low severity at baseline. Contrary to our findings, a previous

study [37] demonstrated that myofascial release plus segmental exercises were more effective compared to a myofascial release-sham intervention on the improvement of pain and disability. The discrepancy might be explained by the number of sessions, as the authors adopted twenty-four while we adopted six. Also, the effect found by Ajimsha *et al.* [37] may be due to the segmental exercises and not to myofascial release.

Another aspect that might explain our findings is the myofascial release protocol. Previous studies are heterogeneous regarding duration, frequency and intensity of the techniques [19,20,37]. Notwithstanding, Arguisuelas *et al.* [19] showed that myofascial release alone, compared to a sham-group, was more effective to improve pain and disability at 3-month follow-up in individuals with CNLBP. They applied a longitudinal sliding technique in more sites (including the iliopsoas muscle), and sessions of 40 minutes (exclusively for myofascial release). The protocol used by Ajimsha *et al.* [37] also lasted 40 minutes and was performed in several sites, including the thoraco-lumbar region, while in our study it lasted 20 minutes. It is possible to assume that our dosage and number of selected muscles may not have been enough to provide effects on pain and disability. The spinal manipulation effects include release of adhesions, improvement in vertebral mobility, distension of hypertonic muscles, and stimulation of mechanoreceptors, which may influence the proprioceptive response, resulting in increased mobility and decreased pain [10,11]. Thus, we speculate that such effects occurred in both groups, and the additional effects of myofascial release was small [19].

Despite the positive, post intervention effects, our findings on the primary outcomes were not maintained at follow-up and were not clinically important (less than 1.8 points

Table 3

Results on the secondary outcomes measured at baseline, and post-intervention.

	SMMRG	SMG	Mixed model effects			
	Mean (SE)	Mean (SE)	Between-groups ^a B (CI 95%)	P-value	Within time-points ^b B (CI 95%)	P-value
AlgS1 (kgf)						
Baseline	6.94 (0.45)	6.86 (0.42)	–	–	–	
Post intervention	7.81 (0.50)	6.98 (0.37)	0.75 (–0.09; 1.60)	0.08	0.11 (–0.48; 0.70)	0.7
Overall effect	n.a	n.a	0.11 (–1.06; 1.28)	0.8	n.a	
AlgL5 (kgf)						
Baseline	7.13 (0.44)	6.69 (0.33)	–	–	–	
Post intervention	7.47 (0.47)	6.80 (0.34)	0.28 (–0.60; 1.17)	0.5	0.10 (–0.52; 0.73)	0.7
Overall effect	n.a	n.a	0.47 (–0.59; 1.53)	0.4	n.a	
AlgRL5 (kgf)						
Baseline	8.91 (0.47)	8.42 (0.49)	–	–	–	
Post intervention	9.36 (0.53)	8.87 (0.51)	–0.02 (–1.03; 0.98)	0.9	0.47 (–0.24; 1.18)	0.2
Overall effect	n.a	n.a	0.51 (–0.85; 1.87)	0.5		
AlgLL5 (kgf)						
Baseline	8.77 (0.53)	8.24 (0.46)	–	–	–	
Post intervention	9.28 (0.65)	9.06 (0.48)	–0.34 (–1.56; 0.88)	0.6	0.83 (–0.03; 1.68)	0.06
Overall effect	n.a	n.a	0.58 (–0.86; 2.02)	0.4	n.a	
AlgL4 (kgf)						
Baseline	6.86 (0.39)	6.84 (0.32)	–	–	–	
Post intervention	7.73 (0.50)	6.77 (0.34)	0.95 (0.17; 1.73)	0.02	–0.07 (–0.62; 0.47)	0.8
Overall effect	n.a	n.a	0.03 (–1.03; 1.09)	0.9	n.a	
AlgRL4 (kgf)						
Baseline	8.80 (0.48)	8.38 (0.44)	–	–	–	
Post intervention	9.44 (0.52)	8.85 (0.50)	0.17 (–0.79; 1.23)	0.7	0.47 (–0.19; 1.14)	0.2
Overall effect	n.a	n.a	0.43 (–0.89; 1.75)	0.5	n.a	
AlgLL4 (kgf)						
Baseline	8.60 (0.55)	8.35 (0.42)	–	–	–	
Post intervention	10.22 (0.76)	8.73 (0.42)	1.24 (0.21; 2.69)	0.09	0.39 (–0.63; 1.41)	0.5
Overall effect	n.a	n.a	0.28 (–1.21; 1.80)	0.7	n.a	
YBTant (%)						
Baseline	55.8 (1.4)	56.1 (1.4)	–	–	–	
Post intervention	59.3 (1.1)	58.7 (1.4)	0.9 (–1.1; 3.0)	0.4	2.6 (1.2; 4.0)	<0.001
Overall effect	n.a	n.a	–0.4 (–3.7; 3.0)	0.8	n.a	
YBTpl (%)						
Baseline	73.2 (1.9)	73.8 (1.9)	–	–	–	
Post intervention	77.8 (1.5)	82.6 (1.9)	–4.2 (–8.6; 0.1)	0.06	8.8 (5.8; 11.9)	<0.001
Overall effect	n.a	n.a	–0.6 (–5.5; 4.2)	0.8	n.a	
YBTpm (%)						
Baseline	77.9 (1.7)	78.7 (1.7)	–	–	–	
Post intervention	83.4 (14.5)	86.3 (1.5)	–2.2 (–5.6; 1.2)	0.2	7.6 (5.2; 10.0)	<0.001
Overall effect			–0.8 (–5.0; 3.3)	0.7	n.a	

SMMRG: spinal manipulation combined with myofascial release; SMG: spinal manipulation alone. SE: standard error. CI 95%: confidence interval of 95%; n.a: non-applicable. Overall effect: mean difference between groups over time.

AlgS1: Algometer S1. AlgL5: Algometer L5. AlgRL5: Algometer right paravertebral muscle L5. AlgLL5: Algometer left paravertebral muscle L5. AlgL4: Algometer L4. AlgRL4: Algometer right paravertebral muscle L4. AlgLL4: Algometer left paravertebral muscle L4. YBTant: Y-balance test anterior. YBTpl: Y-balance test postero-lateral. YBTpm: Y-balance test postero-medial.

^a Mean difference in the outcome between groups.

^b Mean difference in the outcome over time, compared with baseline. Because there were no differences between the groups, we combined the groups in the within time-point analysis.

for pain and 20 points for disability) [38,36]. This may be explained by a low severity of symptoms at baseline. We did not investigate psychosocial factors, but they influence the perception of pain and aggravate the biological components along with disability [39]. Therefore, it is suggested that therapists should include interventions that target on psychosocial factors in a multimodal manual therapy approach for patients with CNLBP.

Quality of life was not different between-groups, however, it improved significantly at the post intervention in both interventions, but returned to baseline values in the follow-up. The post intervention difference was clinically important, as a previous study demonstrated that effects higher than 0.03 points were deemed to be sensitive to the intervention [40]. We found effects ranging from 0.03 to 0.13 points (95%CI), demonstrating that participants were benefited by both interventions. Similarly, spinal manipulation improved quality of life in the short-term (4 months), but not in the long-term (10 months) as compared to a sham-group, in individuals with CNLBP [10]. Our results differ from those of Castro-Sánchez *et al.* [20], who found no differences in quality of life when comparing spinal manipulation vs functional technique. The authors proposed three sessions of manipulation, whereas we adopted six, which may explain the difference. There are few studies investigating quality of life in manual therapy interventions, hence we were limited in comparing our results to the literature. Based on recent reviews [1,17], it was not possible to determine the evidence of spinal manipulation on quality of life in people with CNLBP. We assume that the improvement in pain and disability had a positive influence, as pain severity and disability in individuals with CNLBP might negatively affect quality of life [41].

Pain pressure-threshold was not different between-groups, except for the pressure at L4 (AlgL4). This finding indicates a hypoalgesic effect and corroborates the central modulation of pain when manipulation is applied [4,42]. Spinal manipulation decreases excitability to mechanical, tactile, and non-nociceptive stimuli of neurons located in the dorsal horn of the spinal cord by stretching joint capsules, ligaments, and muscles near the joints [3,43]. A previous study [13] demonstrated that spinal manipulation increased pain pressure-threshold and substance P levels (neurotransmitter that mediates inflammatory processes), indicating that some hypoalgesic effects may be attributed to substance P. However, the difference was not clinically important (i.e. improvements higher than 15%) [42], which might be explained by the low sensitivity to pressure at the baseline.

Likewise, balance presented no between-groups differences, but we found significant post intervention increases in the directions, on both groups. The maintenance of balance is due to sensory information, central processing, and neuromuscular activity [5,11]. Individuals with CNLBP use varied postural control strategies [6], and postural instability can be explained by a compromised proprioception [6]. There is evidence that spinal manipulation modifies paravertebral muscle activation patterns by stimulating proprioceptors and, thus,

positively influencing postural control [11,43]. Hence, we attribute our findings to the decrease in pain and lumbopelvic mobility generated by both interventions, but comparisons were limited as we did not find studies on spinal manipulation that assessed dynamic balance.

Clinical guidelines have suggested combining exercises with manual therapy [44,45]. We suggest that future studies should investigate the effectiveness of adding exercise following a short-term manual therapy intervention, to provide greater retention effects.

Some limitations should be acknowledged. First, the therapist performing the interventions was not blind. Secondly, many participants reported doing intense exercise, owing to a positive perception of improvement during the interventions, which may have influenced the outcomes due to the presence of delayed onset muscle pain. Lastly, even though an appropriate sample size calculation was performed, caution should be exerted as any studies with human participants might be limited to detect large effects.

Conclusion

We demonstrated that the addition of myofascial release to a spinal manipulation intervention was not effective as compared to spinal manipulation alone on the pain intensity and disability in individuals with CNLBP.

Key messages

- Myofascial release did not provide additional benefits to a spinal manipulation intervention;
- A short-term manual therapy intervention improves pain and disability, but without retention effects after three-months follow-up.

Ethical approval: Institutional Ethics Committee FCE/UnB; n. 2.399.669).

Funding: This study was financed in part by the Coordenação de Aperfeiçoamento de Pessoal de Nível Superior - Brasil (CAPES) - Finance Code 001.

Conflict of interest: None to declare.

Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:<https://doi.org/10.1016/j.physio.2019.11.002>.

References

- [1] Rubinstein SM, van Middelkoop M, Assendelft WJJ, de Boer MR, van Tulder MW. Spinal manipulative therapy for chronic

- low-back pain. *Spine (Phila Pa 1976)* 2011;36:E825–46, <http://dx.doi.org/10.1097/BRS.0b013e3182197fe1>.
- [2] Yeganeh M, Baradaran HR, Qorbani M, Moradi Y, Dastgiri S. The effectiveness of acupuncture, acupressure and chiropractic interventions on treatment of chronic nonspecific low back pain in Iran: a systematic review and meta-analysis. *Complement Ther Clin Pract* 2017;27:11–8, <http://dx.doi.org/10.1016/j.ctcp.2016.11.012>.
 - [3] Nijs J, Clark J, Malfliet A, Ickmans K, Voogt L, Don S, et al. In the spine or in the brain? Recent advances in pain neuroscience applied in the intervention for low back pain. *Clin Exp Rheumatol* 2017;35:S108–15.
 - [4] Coronado RA, Gay CW, Bialosky JE, Carnaby GD, Bishop MD, George SZ. Changes in pain sensitivity following spinal manipulation: a systematic review and meta-analysis. *J Electromyogr Kinesiol* 2012;22:752–67, <http://dx.doi.org/10.1016/j.jelekin.2011.12.013>.
 - [5] Ruhe A, Fejer R, Walker B. Is there a relationship between pain intensity and postural sway in patients with non-specific low back pain? *BMC Musculoskelet Disord* 2011;12:162, <http://dx.doi.org/10.1186/1471-2474-12-162>.
 - [6] Mok NW, Brauer SG, Hodges PW. Hip strategy for balance control in quiet standing is reduced in people with low back pain. *Spine (Phila Pa 1976)* 2004;29:E107–12, <http://dx.doi.org/10.1097/01.BRS.0000115134.97854.C9>.
 - [7] Cowan P. American Chronic Association. Guidelines for low back pain: consumer's guide. The American Chronic Pain Association; 2008.
 - [8] Castro-Sánchez AM, Matarán-Peñarocha GA, Arroyo-Morales M, Saavedra-Hernández M, Fernández-Sola C, Moreno-Lorenzo C. Effects of myofascial release techniques on pain, physical function, and postural stability in patients with fibromyalgia: a randomized controlled trial. *Clin Rehabil* 2011;25:800–13, <http://dx.doi.org/10.1177/0269215511399476>.
 - [9] Airaksinen O, Brox JI, Cedraschi C, Hildebrandt J, Klüber-Moffett J, Kovacs F, Mannion AF, Reis S, Staal JB, Ursin H, Zanoli G. European guidelines for the management of chronic low back pain. *Eur Spine J* 2006;15:192–300.
 - [10] Senna MK, MacHaly SA. Does maintained spinal manipulation therapy for chronic nonspecific low back pain result in better long-term outcome? *Spine (Phila Pa 1976)* 2011;36:1427–37, <http://dx.doi.org/10.1097/BRS.0b013e3181f5dfe0>.
 - [11] Wilder DG, Vining RD, Pohlman KA, Meeker WC, Xia T, DeVocht JW, et al. Effect of spinal manipulation on sensorimotor functions in back pain patients: study protocol for a randomised controlled trial. *Trials* 2011;12:161, <http://dx.doi.org/10.1186/1745-6215-12-161>.
 - [12] Sullivan PO. Diagnosis and classification of chronic low back pain disorders: Maladaptive movement and motor control impairments as underlying mechanism. *Man Ther* 2005;10(4):242–55, <http://dx.doi.org/10.1016/j.math.2005.07.001>.
 - [13] Molina-Ortega F, Lomas-Vega R, Hita-Contreras F, Plaza Manzano G, Achalandabaso A, Ramos-Morcillo AJ, et al. Immediate effects of spinal manipulation on nitric oxide, substance P and pain perception. *Man Ther* 2014;19:411–7, <http://dx.doi.org/10.1016/j.math.2014.02.007>.
 - [14] Balthazard P, de Goumoens P, Rivier G, Demeulenaere P, Ballabeni P, Dériaz O. 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. *BMC Musculoskelet Disord* 2012;13:162, <http://dx.doi.org/10.1186/1471-2474-13-162>.
 - [15] Ruddock JK, Sallis H, Ness A, Perry RE. Spinal manipulation vs sham manipulation for nonspecific low back pain: a systematic review and meta-analysis. *J Chiropr Med* 2016;15:165–83, <http://dx.doi.org/10.1016/j.jcm.2016.04.014>.
 - [16] Ferreira ML, Ferreira PH, Latimer J, Herbert RD, Hodges PW, Jennings MD, et al. Comparison of general exercise, motor control exercise and spinal manipulative therapy for chronic low back pain: a randomized trial. *Pain* 2007;131:31–7, <http://dx.doi.org/10.1016/j.pain.2006.12.008>.
 - [17] Coulter ID, Crawford C, Hurwitz EL, Vernon H, Khorsan R, Sutorp Booth M, et al. Manipulation and mobilization for treating chronic low back pain: a systematic review and meta-analysis. *Spine J* 2018;18:866–79, <http://dx.doi.org/10.1016/j.spinee.2018.01.013>.
 - [18] Ajimsha MS, Al-Mudahka NR, Al-Madzhar JA. Effectiveness of myofascial release: systematic review of randomized controlled trials. *J Bodyw Mov Ther* 2015;19:102–12, <http://dx.doi.org/10.1016/j.jbmt.2014.06.001>.
 - [19] Arguisuelas MD, Lisón JF, Sánchez-Zuriaga D, Martínez-Hurtado I, Doménech-Fernández J. Effects of myofascial release in nonspecific chronic low back pain. *Spine (Phila Pa 1976)* 2017;42:627–34, <http://dx.doi.org/10.1097/BRS.0000000000001897>.
 - [20] Castro-Sánchez AM, Lara-Palomo IC, Matarán-Peñarocha GA, Fernández-de-las-Peñas C, Saavedra-Hernández M, Cleland J, et al. Short-term effectiveness of spinal manipulative therapy versus functional technique in patients with chronic nonspecific low back pain: a pragmatic randomized controlled trial. *Spine J* 2016;16:302–12, <http://dx.doi.org/10.1016/j.spinee.2015.08.057>.
 - [21] Hartvigsen J, Hancock MJ, Kongsted A, Louw Q, Ferreira ML, Genevay S, et al. What low back pain is and why we need to pay attention. *Lancet* 2018;6736, [http://dx.doi.org/10.1016/S0140-6736\(18\)30480-X](http://dx.doi.org/10.1016/S0140-6736(18)30480-X).
 - [22] Laslett M. Evidence-based diagnosis and treatment of the painful sacroiliac joint. *J Man Manip Ther* 2008;16:142–52, <http://dx.doi.org/10.1179/jmt.2008.16.3.142>.
 - [23] Takamoto K, Bito I, Urakawa S, Sakai S, Kigawa M, Ono T, et al. Effects of compression at myofascial trigger points in patients with acute low back pain: a randomized controlled trial. *Eur J Pain (United Kingdom)* 2015;19:1186–96, <http://dx.doi.org/10.1002/ejp.694>.
 - [24] Barnes MF. The basic science of myofascial release. *J Bodyw Mov Ther* 1997;1:231–8.
 - [25] Robb A, Pajaczkowski J. Immediate effect on pain thresholds using active release technique on adductor strains: pilot study. *J Bodyw Mov Ther* 2011;15:57–62, <http://dx.doi.org/10.1016/j.jbmt.2010.04.004>.
 - [26] Fritz JM, Beneciuk JM, George SZ. Relationship between categorization with the STarT back screening tool and prognosis for people receiving physical therapy for low back pain. *Phys Ther* 2011;91:722–32, <http://dx.doi.org/10.2522/ptj.20100109>.
 - [27] Hill JC, Dunn KM, Lewis M, Mullis R, Main CJ, Foster NE, et al. A primary care back pain screening tool: Identifying patient subgroups for initial treatment. *Arthritis Care Res* 2008;59:632–41, <http://dx.doi.org/10.1002/art.23563>.
 - [28] Pilz B, Vasconcelos RA, Marcondes FB, Lodovichi SS, Mello W, Grossi DB. The Brazilian version of STarT back screening Tool-translation, cross-cultural adaptation and reliability. *Braz J Phys Ther* 2014;18(5):453–61.
 - [29] Rodrigues MF, Michel-crosato E, Cardoso JR, Traibert J. Psychometric properties and cross-cultural adaptation of the Brazilian Quebec Back Pain Disability Scale Questionnaire. *Spine (Phila Pa 1976)* 2009;34(13):E459–64, <http://dx.doi.org/10.1097/BRS.0b013e3181a5605a>.
 - [30] Menezes Rde M, Andrade MV, Noronha KV, Kind P. EQ-5D-3L as a health measure of Brazilian adult population. *Qual Life Res* 2015;24:2761–76, <http://dx.doi.org/10.1007/s11136-015-0994-7>.
 - [31] Whitehead SJ, Ali S. Health outcomes in economic evaluation: the QALY and utilities. *Br Med Bull* 2010;96:5–21, <http://dx.doi.org/10.1093/bmb/ldq033>.
 - [32] Frank L, McLaughlin P, Vaughan B. The repeatability of pressure algometry in asymptomatic individuals over consecutive days. *Int J Osteopath Med* 2013;16:143–52, <http://dx.doi.org/10.1016/j.ijosm.2012.10.004>.
 - [33] Hooper TL, James CR, Brismée J-M, Rogers TJ, Gilbert KK, Browne KL, et al. Dynamic balance as measured by the Y-Balance Test is reduced in individuals with low back pain: a cross-sectional comparative study. *Phys Ther Sport* 2016;22:29–34, <http://dx.doi.org/10.1016/j.ptsp.2016.04.006>.

- [34] Gribble PA, Hertel J, Facsm À, Plisky P. Using the star excursion balance test to assess dynamic postural-control deficits and outcomes in lower extremity injury: a literature and systematic review. *J Athl Train* 2012;47(3):339–57, <http://dx.doi.org/10.4085/1062-6050-47.3.08>.
- [35] White IR, Wood AM. Tutorial in Biostatistics Multiple imputation using chained equations: issues and guidance for practice. *Stat Med* 2010;30:377–99, <http://dx.doi.org/10.1002/sim.4067>.
- [36] Ostelo R, Deyo R, Stratford P. Interpreting change scores in pain and functional status in low back pain. *Spine (Phila Pa 1976)* 2008;33:90–4.
- [37] Ajimsha MS, Daniel B, Chithra S. Effectiveness of Myofascial release in the management of chronic low back pain in nursing professionals. *J Bodyw Mov Ther* 2014;18:273–81, <http://dx.doi.org/10.1016/j.jbmt.2013.05.007>.
- [38] Hägg O, Fritzell P, Nordwall A, Swedish Lumbar Spine Study Group. The clinical importance of changes in outcome scores after treatment for chronic low back pain. *Eur Spine J* 2003;12:12–20, <http://dx.doi.org/10.1007/s00586-002-0464-0>.
- [39] Kamper SJ, Apeldoorn AT, Chiarotto A, Smeets RJ, Ostelo RW, Guzman J, *et al.* Multidisciplinary biopsychosocial rehabilitation for chronic low back pain: cochrane systematic review and meta-analysis. *BMJ* 2015;350:1–11, <http://dx.doi.org/10.1136/bmj.h444>.
- [40] Soer R, Reneman MF, Speijer BLGN, Coppes MH, Vroomen PCAJ. Clinimetric properties of the EuroQol-5D in patients with chronic low back pain. *Spine J* 2012;12:1035–9, <http://dx.doi.org/10.1016/j.spinee.2012.10.030>.
- [41] Mutubuki EN, Beljon Y, Maas ET, Huygen FJPM, Ostelo RWJG, van Tulder MW, *et al.* The longitudinal relationships between pain severity and disability versus health-related quality of life and costs among chronic low back pain patients. *Qual Life Res* 2019, <http://dx.doi.org/10.1007/s11136-019-02302-w> [Epub ahead of print].
- [42] Voogt L, de Vries J, Meeus M, Struyf F, Meuffels D, Nijs J. Analgesic effects of manual therapy in patients with musculoskeletal pain: a systematic review. *Man Ther* 2015;20:250–6, <http://dx.doi.org/10.1016/j.math.2014.09.001>.
- [43] Herzog W. The biomechanics of spinal manipulation. *J Bodyw Mov Ther* 2010;14:280–6, <http://dx.doi.org/10.1016/j.jbmt.2010.03.004>.
- [44] Koes BW, van Tulder M, Lin CW, Macedo L, McAuley J, Mather C. An update overview of clinical guidelines for the management of non-specific low back pain in primary care. *Eur Spine J* 2010;20:75–94.
- [45] Dagenais S, Tricco AC, Haldeman S. Synthesis of recommendations for the assessment and management of low back pain from recent clinical practice guidelines. *Spine J* 2010;10:514–29, <http://dx.doi.org/10.1016/j.spinee.2010.03.032>.

Available online at www.sciencedirect.com

ScienceDirect