LETTER TO THE EDITOR

Dual-wavelength high-power laser therapy and neuromuscular manual therapy in chronic neck pain: a randomized clinical trial

G. Barassi[1], M. Supplizi[1], L. Prosperi[1], G. Irace[1], A. Younes[1], M. Della Rovere[1], A. Rabini[2], A. Colombo[2] and A. Di Iorio[3]

[1]Center for Physiotherapy, Rehabilitation and Re-education (CeFiRR) Training Center, "G. d'Annunzio" University of Chieti-Pescara, Chieti, Italy; [2]Department of Cardiovascular Pathologies, University Hospital "A. Gemelli", Campobasso, Italy;[3]Department of Aging Sciences, "G. d'Annunzio" University of Chieti-Pescara, Chieti, Italy

Received January 26, 2021 – Accepted April 1, 2021

To the Editor,

Chronic Myofascial Neck Pain (CMNP) is one of the main manifestations of musculoskeletal disorders and frequently requires the intervention of the physiotherapist (1). In particular, CMNP constitutes a frequent cause of pain, disability, absence from work and reduced quality of life. About two-thirds of the population declared to have experienced Neck Pain (NP) during their lifetime, with an increase of prevalence during adulthood and in the elderly (2). The annual prevalence of the problem reaches 30% of the general population and 50% of acute NP cases tend not to undergo spontaneous resolution, creating a relapsing and highly invalidating problem for the people concerned (2, 3) and assuming, over time, the characteristics of chronic pain (4).

Recently, the clinical relevance of the duration of NP has been questioned, as it seems to be a poor indicator of disability when the intensity of NP tends to be low (5). A strong correlation between NP intensity and disability has been observed (5), which may be a problem in presence of chronic NP, due to the fact that, when the NP intensity reaches moderate to high levels, the lengthening of the problem can lead to an equally long-lasting disability condition for the patient.

Several studies have been carried out, demonstrating the effectiveness of Manual Therapy (MT) in the treatment of Myofascial Trigger Points (MTrPs) responsible for NP. Simons highlighted, in his study, an important correlation between the development of Myofascial Trigger Points (MTrPs) in muscles such as the sternocleidomastoideus, the levator scapula, the upper trapezius and the splenius capitis and the genesis of pain at the cervical level, known as NP (6).

Bodes-Pardo et al. (7), in a randomized pilot clinical study, experienced how MT, targeting on MTrPs of the sternocleidomastoid muscle, was able to reduce NP and headache, compared to a sham therapy. Javier et al. (8) in their case report on a girl with NP, showed how ischemic compression of MTrPs responsible for NP was able to determine improvements in pain and mobility after just a single treatment session. Ischemic compression has been shown to be as effective as hydrocortisone phonophoresis and ultrasound therapy in the treatment of MTrPs of the upper trapezius muscle (9).

Key words: musculoskeletal manipulations; manual therapy; laser therapy; neck pain; physical therapy modalities; rehabilitation; trigger points

Corresponding Author:
Dr Giovanni Barassi,
Center for Physiotherapy,
Rehabilitation and Reeducation (CeFiRR) Training Center,
Gabriele d'Annunzio University of Chieti-Pescara,
Chieti, 66013, Italy
e-mail: coordftgb@unich.it

0393-974X (2021)

Generally, the most recent scientific evidence has supported the use of MT as a moderately effective approach in the management of NP, particularly in association with other types of treatment such as exercise and instrumental methods (10). Among the instrumental methods used for NP, a relevant role could be assumed by High-Power Laser Therapy (HPLT), which differs from the typical Low-Level Laser Therapy (LLLT) for a clearly higher power application (expressed in units of W instead of hundreds of mW), able to guarantee a stronger and deeper biological stimulation at the application site level.

Recent studies have highlighted the ability of HPLT to improve the symptoms deriving from NP, improving the functional limitation of the cervical tract, increasing mobility and reducing the pain perceived by patients (11-12), in particular with the use of Neodymium-doped Yttrium Aluminum Garnet (Nd:YAG) type lasers with a wavelength of 1064 nm (11). However, it must be considered that also other type of laser, characterized by wavelengths in the order of 810 nm and administered with low power (≤500 mW), have proven to be effective in the management of pain (13), advancing the idea that a multiple-wavelength radiation could represent a valid therapeutic option in the treatment of pain at the level of the spine. A therapeutic window of effectiveness of laser therapy has been defined, falling in a range between approximately 600 nm and 1200 nm (14). Specifically, in the rehabilitation field, it is generally assumed that a laser working at 810 nm acts on a more superficial level, thus defining a mainly analgesic effect in terms of nociceptive inhibition; conversely 1064 nm lasers are characterized by greater penetration into tissues as well as biostimulating-reparative, decontracting and anti-inflammatory effects, especially at the muscle level (14).

Taking into consideration these premises, the present study aimed to compare two methods, namely Dual-Wavelenght High-Power Laser Therapy (DWHPLT) and Neuromuscular Manual Therapy (NMT), in the treatment of CMNP.

MATERIALS AND METHODS

This study was conducted at the Center for Physiotherapy, Rehabilitation and Re-education (Ce. Fi.R.R.), located at the University "Gabriele d'Annunzio" of Chieti-Pescara as part of the Centre of Sports Medicine. A clinical parallel study was performed in accordance with the Helsinki Declaration and Good Clinical Practice standards (15). All participants signed the informed consent for the experimental procedures, complying with ISO 9001-2015 standards for "Research and experimentation". The study was conducted, as far as possible, according to the CONSORT guidelines. All the evaluation and treatment methods used for this study, as well as the actual application procedures, are commonly used in the clinical-rehabilitative practice of the private rehabilitation center where the study was carried out, therefore, the normal ethics committee clearance was not required (16).

The study sample consisted of 20 subjects, diagnosed with CMNP associated to MTrPs present in the Upper Trapezius (UT) and in the Splenius Capits (SC). The diagnosis was carried out by a medical doctor specialized in physical medicine and rehabilitation, who was not involved in the study. The study sample consisted of 10 male and 10 female subjects, aged between 19 and 82 years (average 54.29 years).

The subjects were randomly divided into two study groups, with a 1:1 allocation ratio. The randomization was carried out by an operator different from the ones responsible for the assessments, for the treatments or for the statistical analysis of data. The random allocation of patients was carried out through the "List Randomizer" online tool of the website www.random.org. To randomize patients, also taking into account the distribution of the sample by gender, two list of 10 elements were made, one for male patients and one for female patients, with each list in turn comprising 5 nominal elements A and 5 nominal elements B, with reference to the treatment groups to which the subjects were assigned. The total 10 values for each list were then randomly sequenced by the tool used, providing a random list used to allocate suitable patients either to the A or B treatment group, following the order of admission. By creating two separate lists for male and female patients, an equal gender distribution was obtained for each treatment group. While it was impossible to blind the therapist and the patients in terms of treatment provided/received, due to completely different procedures adopted, it was

provided a blinding of evaluations, that were carried out by a different person then the one performing the treatment. Moreover, data analysis was blinded, making sure that the analyst was not informed of which treatment corresponded to the two groups.

Patients diagnosed with CMNP, associated to MTrPs present in the central belly of the UT and of the SC, were considered eligible for the study. Patients affected by infections, neurological symptoms, cancer and specific contraindications to NMT or DWHPLT were excluded from the selection. Patients were required to abstain from taking painkillers during the study.

Group A (10 patients) underwent NMT treatments of the cervical area, twice a week for 3 weeks, for a total of 6 treatments. Group B (10 patients) underwent DWHPLT treatments on the cervical area, twice a week for 3 weeks, for a total of 6 treatments.

Outcome measures and intervention

The selected subjects underwent an initial evaluation, at time T0, and a final evaluation, at time T1, at the end of the therapeutic protocol.

Assessments were conducted with the use of:

- Neck Disability Index (NDI) assessment questionnaire, recommended for the assessment of the disability of patients suffering from NP (17). This scale includes 10 items regarding activities of daily living; each question provides 6 possibilities of answer (from 0 = no disability to 5 = complete disability) based on the degree of functional limitation manifested by the examined subjects;
- Pressure Algometer on the MTrPs identified at the level of the UT and SC muscles on both the left and right side of the body (18), using an F-Meter (Storz Medical AG, Tägerwilen, Switzerland). The value read on the display of the instrument, expressed in pure numbers, with each unit corresponding to 200g, expresses the objective pressure pain threshold of the assessed point.

Patients in Group A were treated through 6 sessions of NMT, that is a global and advanced system of soft tissue manipulations that mainly deals with chronic myofascial pain and pain syndromes. This technique restores the homeostatic balance of the central nervous system and of the musculoskeletal system, using various massage therapy methods such as "brushing", "kneading" and "deep transverse friction", through which deactivation of MTrPs is obtained in muscles and their fascia, in tendons and in ligaments. A pressure on MTrPs, known as finger pressure technique, is used to rebalance the MTrPs themselves present in soft tissues. The relaxation of MTrPs frees patients from local and referred pain.

Patients in group A were treated with NMT techniques at the level of the cervical area, focusing, in particular, on the UT and SC muscles, concentrating the treatment at the level of MTrPs located in the area. The treatment consisted in the sequential use of touch, kneading, friction, ischemic compression (lasting about 30 seconds for each MTrP) and stretching techniques, for a total duration of treatment of approximately 30 minutes.

Patients in Group B were treated with 6 sessions of DWHPLT. The device used for this study was the Medilaser 15 ED (Medisport Srl, Latina, Italy), a Nd: YAG instrument for HPLT (maximum average power 15 W, class IV), capable of operating with two different wavelengths, in a ratio of 25% for 810 nm and 75% for 1064 nm, guaranteeing potentially greater therapeutic efficacy.

The effects provided by the device, which can be modulated in all emission parameters, include:

- analgesic effect, determined by the modulation of peripheral nervous system activity through the administration of pulsed stimuli, characterized by peak power and duration varying below the thermal stimulation threshold of the tissues (defined as "Stochastic emission" mode);
- anti-inflammatory and anti-edema effect, related to the deep cellular biological stimulation of the tissues, accompanied by phenomena vasodilation, due to the controlled release of nitric oxide, increased oxygen supply to the tissues and neoangiogenesis;
- biostimulating effect, related to the facilitation of cellular processes of collagen production and cellular ATP regeneration, in particular for pulses lasting more than 100 ms ("continuous" or "long-pulse" emission);
- muscle relaxant effect, due to the local increase in temperature and the release of oxygen from hemoglobin in muscle fibers in a state of hypoxic contraction.

The MTrPs present in the muscles of the cervical tract (UT and SC) of patients in group B were treated by applying a 3-step program, to combine an intense analgesic activity with biostimulating and decontracting

actions, according to the following application scheme:

- Phase 1: analgesic application in "Stochastic emission" (a randomly pulsed mode) on the right cervical tract between the trapezius and the sternocledomastoid muscle, focusing the application on MTrPs of UT and SC, with an average power of 10 W and a duration of 3 minutes, with a manual scanning movement using a pen applicator in contact with the skin, with prolonged stops (about 5-7 seconds) in the areas of MTrPs;
- Phase 2: analgesic application in "Stochastic emission" mode on the left cervical tract between the trapezius and the sternocledomastoid muscle, using the same modalities exploited in Phase 1 for the right hemisome;
- Phase 3: biostimulating/decontracting application in "Continuous" mode on the entire cervical tract between the trapezius and the sternocledomastoid muscle, with average power of 8 W and energy density of 60 J/cm^2 (with a variable duration depending on the personal extension of the cervical tract to be treated, considered as an isosceles triangle with the base corresponding to the distance between the two acromions and the height corresponding approximately to the distance between the C7-T1 spinal tract and the upper nuchal line) manually applied with a scanning movement using a pen in contact with the skin, with enough rapid movements to avoid the local overheating perceived by the patient.

The total cervical treatment through the DWHPLT lasted between 7 and 10 minutes, depending on the duration of the phase 3.

RESULTS

Differences in the outcome measures between groups, at baseline and at follow-up, were tested by mixed models analysis of covariance. The advantage of this statistical approach is improvement in the precision of the effects estimate by using all available information and, at the same time, allow for handling missing data. For brevity, only the *p*-value for the fully adjusted model with the interaction term between time and type of intervention was reported. Classical Akaike's Information Criterion (AIC) and Bayesian Information Criterion (BIC) were used to examine improvement in model fit. All statistical analysis were carried out with SAS software (release 9.4). The significance for the *p*-value was set at ≤0.05.

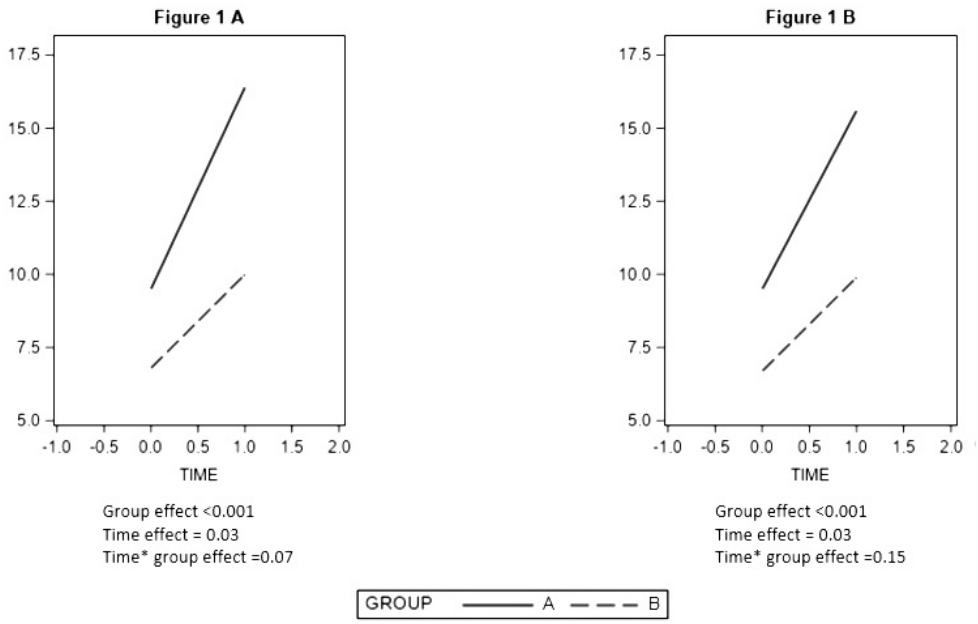

Fig. 1. *Linear Mixed Model. Variation of nociceptive level through study times (p value shown), according to algometric measurements on the UT in study groups.* ***A****)Right hemisome;* ***B****) left hemisome; 1 unit ≈ 200g).*

Regarding the algometric measurements of the UT, a general significance was detected for data variations in terms of group effect and time effect, but not for the time*group effect of both sides. As a matter of fact, a pressure pain reduction could be demonstrated of 72.6% in the right side and 64.2% in the left side for Group A and a pressure pain reduction of 47.1% in the right side and 47.8% in the left side for Group B.

With regard to algometric measurements of the SC, a general significance was detected for data variations in terms of group effect and time*group effect, while no significant variations were detected for time effect of the two hemisomes. A pressure pain reduction of 98.3% on the right side and 98.4% on the left side was calculated for Group A, and of 57.1% on the right side and 31.4% on the left side for Group B.

Finally, observing the NDI assessment questionnaire, a significant reduction was observed, in terms of time effect but not in terms of group effect and time*group effect, in the level of subjectively perceived disability both in group A (-60.2%) and in group B (-75.2%), with DWHPLT highlighting

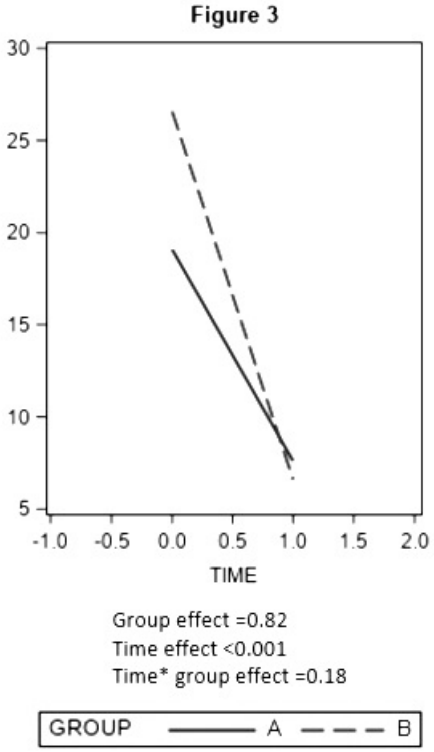

Fig. 3. *Linear Mixed Model. Variation of NDI score through study times (p value shown), according to study groups.*

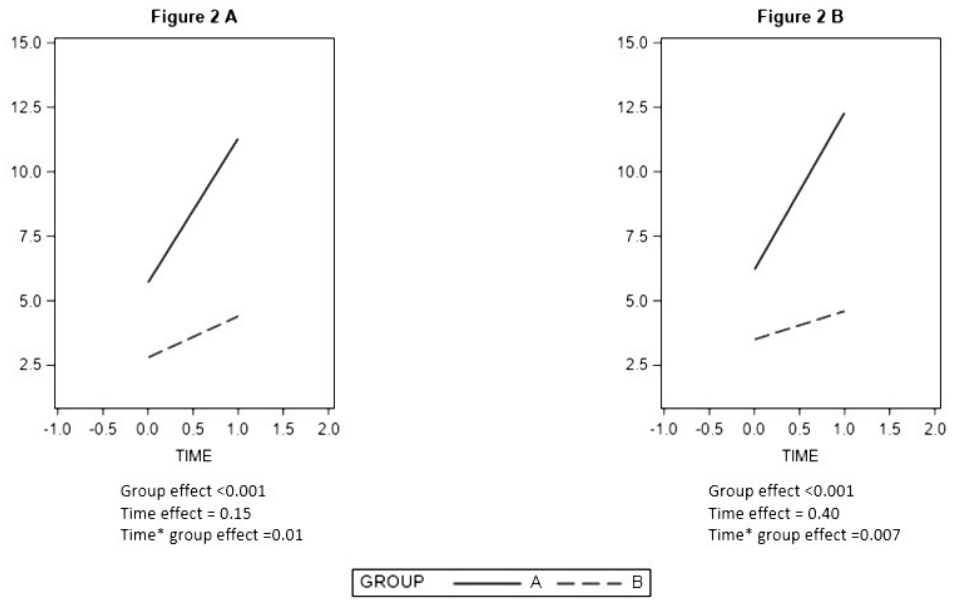

Fig. 2. *Linear Mixed Model. Variation of nociceptive level through study times (p value shown), according to algometric measurements on the SC in study groups. **A**) Right hemisome; **B**) left hemisome; 1 unit ≈ 200g).*

a superior effect, compared to NMT, in reducing disability related to CMNP.

DISCUSSION

Algometric measurements showed an improvement of pain tolerance with both the rehabilitation protocols, highlighting the effectiveness of NMT and DWHPLT in improving pressure related hyperalgesia associated with CMNP. More specifically, NMT showed a superior efficacy, especially for the SC. As already reported in a previous study, manual ischemic compression on MTrPs is able to increase the pain pressure threshold (8). The reason for this reaction should be found in the ischemic compression ability to promote a rapid acceleration of local blood flow after its release, therefore causing an increase in blood perfusion of the treated area and in tissue healing (20). It is also possible to hypothesize that NMT may have guaranteed a greater analgesic effect in terms of pressure pain due to a more intense stimulation of Aβ fibers and a subsequent inhibition of pain perception induced by Aδ and C fibers (10), which would explain the more instantaneous and intense effect of NMT on pain modulation compared to DWHPLT. However, it can be highlighted that this superiority of NMT in the inhibition of pressure pain appears completely in contrast with the perception of pain and disability in daily life by patients enrolled in our study.

Indeed, the DWHPLT-treated group showed a greater reduction in the NDI score, related to the reduction of the complications determined by NP in everyday life of patients. This condition identifies the DWHPLT as an instrument that induces an improvement in terms of influence of pain on daily life, as well as being capable of inducing improvement of functional limitations induced by NP. Several scientific studies showed that laser therapy, both low and high power, could be successfully used in the treatment of painful myofascial syndromes because of its therapeutic effects (21, 22). Furthermore, several studies have shown a great efficacy of different wavelengths in the treatment of pain syndromes of myofascial nature, in particular wavelengths of 1064 nm (11, 12, 14) and 810 nm (14) which, based on current knowledge, would seem to be the most effective light emissions for the control of myofascial pain, probably related to the biostimulating and neuromodulating properties of these types of laser radiation (11, 12, 14). Specifically, DWHPLT may be able to provide tissues with a more effective analgesic and reparative stimulus due to the combination of different levels of stimulation, (14) which mainly combines analgesic and superficial effects of the 810 nm wavelength with the predominantly biostimulating and anti-inflammatory effect of the 1064 nm wavelength, (14) thus obtaining a contemporary analgesic and reparative effect, not limiting the treatment to a short-term therapeutic efficacy, but promoting an actual healing and resolution process of somatic musculoskeletal dysfunctions, in the specific case in patients with CMNP.

In conclusion, the results demonstrated that both NMT and DWHPLT have proven to be effective methods in the treatment of CMNP. In the future, it would be desirable to further explore the proposed topic, with the assumption of a numerically larger and homogeneous study sample in terms of age and basal level of disability from NP, in order to reduce the influence of potential confounders or epidemiological bias. Furthermore, the hypothesis of prospectively evaluating the duration of the benefits and results obtained in both treatments, achievable by increasing the number of sessions and by inserting a follow-up assessment, could be really important to identify variability in response times of biological tissues, particularly in biostimulant therapies, such as DWHPLT, compared to other mechanical approaches, such as NMT.

The main limitations of this study are represented by the small dimension of the study sample, by the impossibility to blind operative procedures to the operator and to the patient, due to the completely different nature of the two proposed approaches, and, finally, by the lack of registration of the following trial in the clinicaltrials.gov registry.

REFERENCES

1. Zimoli A, Testa M. Il Dolore Cervicale: Guida alla

valutazione e al trattamento. Edra Masson. Milano, 2015.
2. Cohen SP. Epidemiology, diagnosis, and treatment of neck pain. In Mayo Clinic Proceedings, Elsevier. Amsterdam, 2015; Vol. 90, No. 2, pp. 284-99.
3. Falla D. Unravelling the complexity of muscle impairment in chronic neck pain. Man Ther 2004; 9(3):125-33.
4. Merskey HE. Classification of chronic pain: descriptions of chronic pain syndromes and definitions of pain terms. Pain 1986.
5. Fejer R, Hartvigsen J. Neck pain and disability due to neck pain: what is the relation? Euro Spine J 2008; 17(1):80-8.
6. Simons DG. Myofascial pain syndrome due to trigger points. J Rehabil Med 1988; 686-723.
7. Bodes-Pardo G, Pecos-Martín D, Gallego-Izquierdo T, Salom-Moreno J, Fernández-de-las-Peñas C, Ortega-santiago R. Manual treatment for cervicogenic headache and active trigger point in the sternocleidomastoid muscle: a pilot randomized clinical trial. J. Manip Physiol Ther 2013; 36(7):403-11.
8. Montañez-Aguilera FJ, Valtueña-Gimeno N, Pecos-Martín D, Arnau-Masanet R, Barrios-Pitarque C, Bosch-Morell F. Changes in a patient with neck pain after application of ischemic compression as a trigger point therapy. J Back Musculoskelet 2010; 23(2):101-4.
9. Sarrafzadeh J, Ahmadi A, Yassin M. The effects of pressure release, phonophoresis of hydrocortisone, and ultrasound on upper trapezius latent myofascial trigger point. Arch Phys Med Rehabil 2012; 93(1):72-7.
10. Hidalgo B, Hall T, Bossert J, Dugeny A, Cagnie B Pitance L. The efficacy of manual therapy and exercise for treating non-specific neck pain: A systematic review. J Back Musculoskelet Rehabil 2017; 30(6):1149-69.
11. Dundar U, Turkmen U, Toktas H, Solak O, Ulasli AM. Effect of high-intensity laser therapy in the management of myofascial pain syndrome of the trapezius: a double-blind, placebo-controlled study. Lasers Med Sci 2015; 30(1):325-32.
12. Pekyavas NO, Baltaci G. Short-term effects of high-intensity laser therapy, manual therapy, and Kinesio taping in patients with subacromial impingement syndrome. Lasers Med Sci 2016; 31(6):1133-41.
13. Cotler HB, Chow RT, Hamblin MR, Carroll J. The use of low level laser therapy (LLLT) for musculoskeletal pain. MOJ Orthop Rheumatol, 2015; 2(5).
14. Notarnicola A, Solarino G, Covelli I, Rifino F, Moretti B. Temperature controlled high energy adjustable multi-mode emission laser therapy in the treatment of the chronic low back pain. Am J Arthritis 2018; 2(1):1010.
15. World Medical Association. WMA Declaration of Helsinki–Ethical principles for medical research involving human subjects, 2018. Internet: https:// www. wma. net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects.
16. Winter EM, Maughan RJ. Requirements for ethics approvals. J Sports Sci 2009; 27:985.
17. Vernon H. The Neck Disability Index: state-of-the-art, 1991-2008. J Manipulative Physiol Ther 2008; 31(7):491-502.
18. Fischer AA. Pressure algometry over normal muscles. Standard values, validity and reproducibility of pressure threshold. Pain 1987; 30(1):115-26.
19. Oliveira-Campelo NM, de Melo CA, Alburquerque-Sendín F, Machado JP. Short-and medium-term effects of manual therapy on cervical active range of motion and pressure pain sensitivity in latent myofascial pain of the upper trapezius muscle: a randomized controlled trial. J Manipulative Physiol Ther 2013; 36(5):300-9.
20. Vigotsky AD, Bruhns RP. The role of descending modulation in manual therapy and its analgesic implications: a narrative review. Pain Res Treat 2017; 2017:1535473.
21. Simunovic Z. Low level laser therapy with trigger points technique: a clinical study on 243 patients. Lasers Surg Med 1996; 14(4):163-7.
22. Ceccherelli F, Altafini L, Lo Castro G, Avila A, Ambrosio F, Giron GP. Diode laser in cervical myofascial pain: A doubleblind study versus placebo. Clin J Pain 1989; 5(4):301-4.