in vivo *35*: 623-627 (2021)
doi:10.21873/invivo.12300

Repetitive Peripheral Magnetic Stimulation (rPMS) in Subjects With Lumbar Radiculopathy: An Electromyography-guided Prospective, Randomized Study

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Abstract. *Background/Aim: Lumbar radiculopathy refers to the disruption of one or more lumbosacral nerve root functions, usually causing radiating pain and functional impairments. Patients and Methods: We aimed to analyze the role of repetitive peripheral magnetic stimulation (rPMS) alone or in association with physiokinesiotherapy (PKT) in treating lumbar radiculopathy. A total of 41 patients diagnosed with lumbar radiculopathy were randomly allocated to the rPMS group and the rPMS plus PKT group. Subjects were then administered a total of 10 treatment sessions. Results: A statistically significant improvement was highlighted in both groups in terms of pain score, and electromyography (EMG) analysis depicted a far superior functional recovery in the rPMS plus PKT group. Conclusion: rPMS can constitute an effective treatment for subjects with lumbar radiculopathy and its association with a complex physical rehabilitation program could improve the outcome in these patients.*

This article is freely accessible online.

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Key Words: Repetitive peripheral magnetic stimulation, rPMS, lumbar radiculopathy, rehabilitation, low back pain.

Lumbosacral radiculopathy is one of the most common problems seen in neurorehabilitation consultation. The condition refers to impairments affecting the function of one or more lumbosacral nerve roots, with structural nerve root compression being the most frequent etiology. Severity of symptoms can range from transient radicular pain up to persistent, disabling motor deficits (1).

Available treatment options are broadly divided into pharmacologic, conservative, interventional and surgical (2). The Guidelines from the American Pain Society highlight that the risk-benefit analysis of invasive therapies in this condition is controversial and therefore, advises that it is more reasonable to first consider conservative management that focuses on appropriate pain control and functional recovery (3).

Repetitive peripheral magnetic stimulation (rPMS) is a non-invasive, highly tolerable therapy based on relatively painless electromagnetic stimulation. It refers to the use of high-power electromagnetic waves that have the special ability to deeply penetrate neural structures and initiate therapeutic effects through still unelucidated pain modulatory mechanisms (4, 5). Prior studies have reported therapeutic effects of rPMS on several types of musculoskeletal pain (6, 7) or posttraumatic neuropathies due to spinal or axonal damage injury (8). Yet, the application of rPMS in alleviating painful lumbar radiculopathies has not been properly investigated.

The purpose of this study was to investigate the influence of the rPMS technique on electrophysiological parameters and pain reduction in lumbar radiculopathy patients, with a randomized controlled design.

Patients and Methods

Participants. The present study prospectively included patients diagnosed with lumbar radiculopathy, who met the following inclusion criteria: 1) clinical signs of lumbar radiculopathy at the time of examination; 2) EMG diagnosis of lumbar radiculopathy; 3) ages between 18 and 80 years. Exclusion criteria consisted of: 1) people over 80 years old, who normally have changes in the electrophysiological parameters; 2) comorbidity with diabetes or any other polyneuropathies; 3) pregnancy; 4) medical implanted devices (cardiac pacemaker); 5) simultaneous treatment with analgesic medication, nonsteroidal anti-inflammatory drugs (NSAIDs) or AIS. All subjects were examined between January and June 2019 in a random order of arrival at the Medical Rehabilitation Department of Elias University Hospital. The study was approved by the Ethics Committee of the Elias Emergency University Hospital (no. 9829; 10.06.2019) and all patients gave written, informed consent.

Methods. A total number of 41 patients (male: women=1: 2.5) aged between 40 and 65-year-old were enrolled in the study. There were 7 cases of withdrawal unrelated to the disease or treatment and 34 patients completed the study. Patients were randomly assigned to receive rPMS as monotherapy or rPMS in association with PKT (Physiotherapy and Kinesiotherapy) procedures. Both groups underwent 10 sessions over a 2-week time span. All patients were assessed at baseline and after 10 sessions of treatment.

Patients were treated with rPMS using a magnetic field generated by an elliptical Racetrack RT-120 coil of 90×200×26 mm size transversally positioned in the lumbar area with the help of a metal arm. A MagVenture MagPro R100 stimulator was used and the stimulation protocol consisted of 200 trains of 5 pulses at a frequency of 10 Hz, followed by a 5 sec inter-train interval. A magnetic field strength of about 50-60% was emitted, generating a mild painless contraction of the lumbar paravertebral muscles. All subjects participated in 10 rPMS therapy sessions of 15 min per session.

PKT procedures were administered according to the standard protocol used in our clinic for the treatment of lumbar radiculopathies: 30-min therapy sessions, 1 time a day, 5 times a week, for 2 weeks.

Assessment tools

• Electromyography (EMG) was used to assess peripheral nerve regeneration. It was performed in Elias University Hospital Electrophysiology Laboratory using a Nicolet Compass Meridian device and consisted of examination of bilateral lumbosacral paraspinal muscles (only at initial testing, to certify the nerve root lesion) followed by examination of the distal muscle innervated by the affected root. Concentric Dantec DCN EMG needles of 50 mm length and 0.46 mm width were used. The muscles were tested at rest, at light voluntary contraction and maximum contraction. To record the results into a database, the following numerical notation and identification system was used:

(i) For spontaneous activity: 0 – the absence of spontaneous activity; 1 – the presence of spontaneous activity.

(ii) For motor unit action potential (MUAP) analysis, the device's software provided data about the number of turns and the number of phases, and the degree of polyphasia was noted as follows: 0 – normal MUAP; 1 – unstable MUAP; 2 – MUAP with 4-5 phases; 3 – MUAP with more than 6 phases.

(iii) The estimation of the recruitment pattern at maximum contraction it was noted as follows: 1 – simple; 2 – intermediary; 3 – interferential.

• A visual analogue scale (VAS) and the painDETECT Questionnaire (PDQ) were used for the assessment of pain score. VAS represents a straight linear pain measuring tool that is marked with "0" on the left and "10" on the right end. Patients are asked to mark the place which best represents the intensity of the pain. The score is noted in mm on a 0-100 mm scale or in cm on the 0-10 cm scale (9). PDQ is a screening tool for neuropathic pain, based on the self-report of symptoms. It consists of 9 questions about the location, evolution, and nature of the pain, irradiation area, presence of paresthesia and numbness. A score below 11 indicates the absence of neuropathic pain, between 11 and 19 the presence is uncertain, whereas a score exceeding 19 is considered characteristic for the existence of a neuropathic pain component (10). VAS and PDQ were assessed at the baseline and immediately after the 10 sessions of treatment.

Statistical analysis of the collected data was performed by utilizing the nonparametric method. The Mann-Whitney test was employed to compare the two groups at baseline. Wilcoxon signed-rank test was used to correlate the evolution of pre- and post-treatment parameters. A p-value <0.05 was considered statistically significant. SPSS version 21.0 (IBM SPSS, Armonk, NY, USA) was used for all statistical analyses.

Results

The two groups were compared in terms of EMG parameters - MUAP phases and recruitment pattern at maximum contraction, as well as in terms of pain scores -VAS and PDQ (Figure 1). The nonparametric Mann-Whitney test showed there were no statistically significant differences in baseline characteristics between the two groups.

In the group that received only rPMS therapy, the results were as follows: a number of 22 patients were enrolled, 8 men and 14 women, which registered a statistically significant difference in the evolution of EMG parameters, with an increase in the MUAP number of phases (m1=0.82, m10=1.45, p=0.024) and an improvement in the recruitment pattern at maximum contraction (m1=2.29, m10=2.71, p=0.002). Large, statistically significant differences were depicted in the pain score evolution for VAS (m1=4.95, m10=1.27, p=0.000) and PDQ (m1=13.09, m10=7.00, p=0.00).

In the group that received rPMS + PKT therapy, the results were as follows: 12 patients were enrolled, 8 men and 4 women, which registered a statistically significant difference in the evolution of EMG parameters, with a higher degree of polyphasic MUAPs (m1=0.33, m10=1.83, p=0.005) and an enhanced performance of the recruitment pattern at maximum contraction (m1=2.33, m10=2.83, p=0.014). Again, large, statistically significant differences were registered in pain score evolution for VAS (m1=5.00, m10=1.17, p=0.003) and for PDQ (m1=13.75, m10=6.42, p=0.006).

By comparing the evolution of the two groups, a statistically significant improvement was highlighted in both groups in terms of pain score and EMG parameters. Remarkably, in terms of nerve regeneration activity expressed through the MUAP morphology score, a far superior recovery was

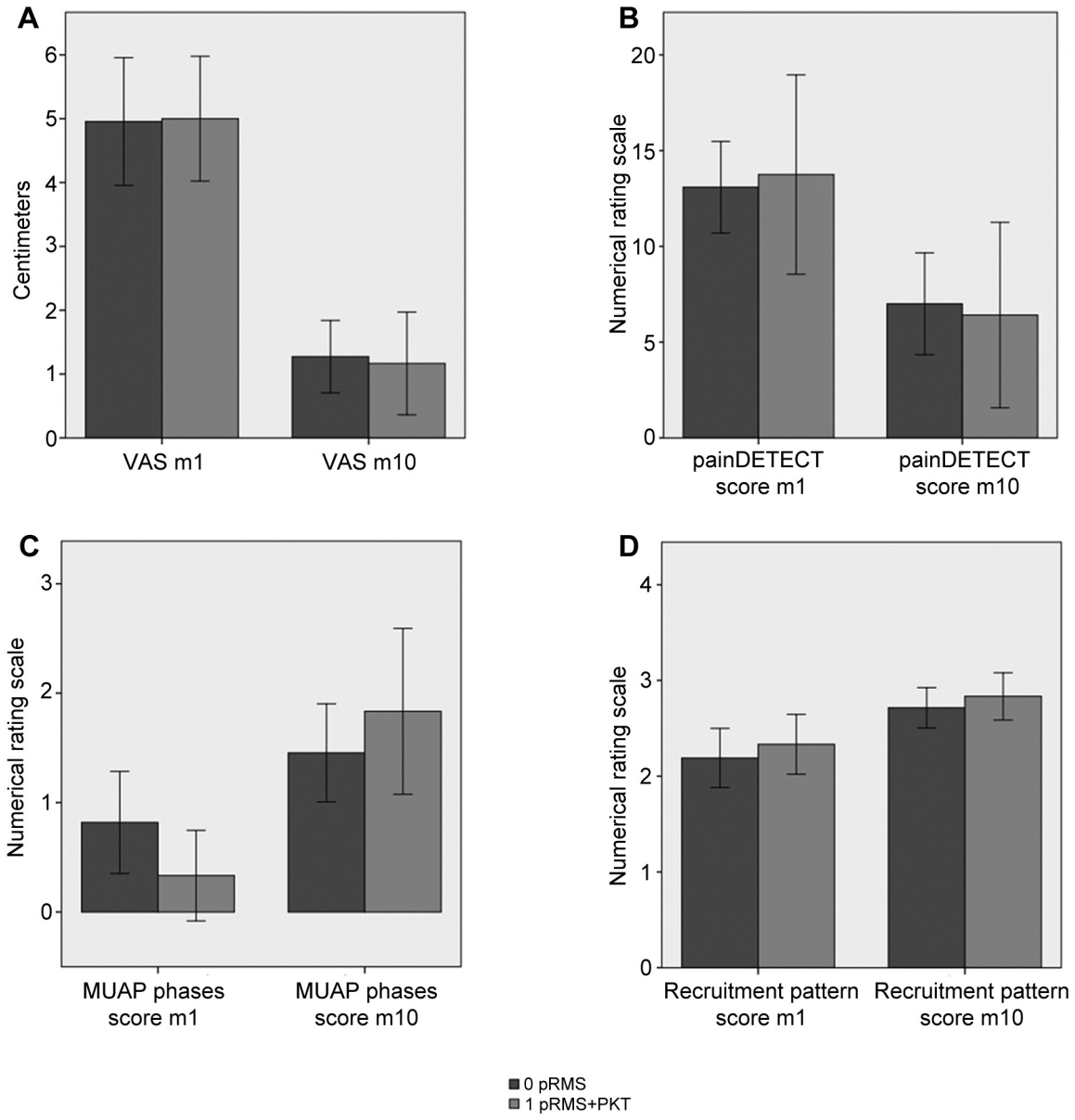

Figure 1. *Graphical representation of the VAS (A), PDQ (B), MUAP (C), and recruitment pattern score (D) in both arms at baseline (m1) and post-treatment (m10). The darker bars depict the rPMS group whereas the lighter bars depict the rPMS + PKT group. VAS: Visual analogue scale; PDQ: painDETECT questionnaire; MUAP: motor unit action potential; rPMS: peripheral repetitive magnetic stimulation; PKT: physiotherapy, and kinesiotherapy.*

achieved in the rPMS + PKT group, with an increase of 454% in the rPMS + PKT group *vs*. a 76.8% increase in the rPMS group alone (Table I). VAS and PDQ substantially decreased in both groups, highlighting that the two groups significantly improved in terms of pain reduction. Interestingly, in terms of EMG parameters, the MUAP score achieved an impressive 454% increase in the rPMS + PKT group, compared to an only 76.8% increase in the rPMS monotherapy group.

Discussion

The results were encouraging in both groups in terms of pain relief, with the VAS score decreasing by 74% in the rPMS group and by 76% in the rPMS + PKT group. Considering that there were no statistically significant differences between the two groups at baseline, we can state that rPMS therapy can be successfully used as monotherapy for the treatment of lumbar

Table I. *Evolution of VAS, PDQ and electromyography parameters - Comparative analysis between the two groups.*

Parameters	rPMS	rPMS+PKT
VAS	–74%	–76%
PDQ	–46%	–53%
MUAP phases score	+76.8%	+454%
Recruitment pattern	+23.7%	+21.4%

VAS: Visual analogue scale; PDQ: painDETECT questionnaire; MUAP: motor unit action potential; rPMS: repetitive peripheral magnetic stimulation; PKT: physiokinesiotherapy.

radiculopathy. Our results are consistent with the ones found in the literature. Radackovic *et al*. conducted a similar study, comparing the effectiveness of classical physio-kinesiotherapy *versus* rPMS plus physiokinetic therapy procedures for treating inflammation and pain along the path of the sciatic nerve. Their workgroup concluded that functional magnetic therapies combined with other physiotherapeutic approaches can improve outcome in patients with degenerative or traumatic sciatica syndrome (11). Also, in a randomized, placebo-controlled study, Lo and collaborators showed that a single session of repetitive spinal magnetic stimulation resulted in significant alleviation of pain caused by lumbar spondylosis (mean pain reduction of 63% in VAS score after the first session, followed by 17.4% after the 4th session) (12).

The therapeutic effect of rPMS in pain management was also confirmed by the PDQ score analysis which showed slightly higher improvement in the rPMS + PKT group (53% *vs*. 46% in the rPMS group). It should be noted that if the mean score at the start of treatment was approximately 13, a neuropathic component at group level being possible at that value, at the end of the treatment in the two groups a mean score of 7 was registered. This excluded the presence of neuropathic pain and pointed towards the nociception mechanism type instead (13).

An element that adds particular value to this study is the use of EMG, considering its essential role in evaluating electrophysiological activity (14, 15), therefore, in assessing the way peripheral damaged nervous system responds to rPMS. The analysis showed an increase in MUAP phases in both groups, particularly in the rPMS + PKT group where the evolution was fulminant, with the number of phases increasing by up to 4.5 times (454%). On the other hand, in the monotherapy group, the increase was of only 75%.

The mechanism by which MUAPs are more polyphasic (MUAPs with more than four phases are referred as polyphasic) compared to baseline is still unclear. Growing evidence shows that biological phenomena such as nerve reinnervation or nerve sprouting could serve as an explanation (16, 17).

First, the distance from the lesion site to the examination site is very long (at least 1 meter), which could have not allowed the reinnervation as a result of nerve repair. Neurobiological studies have shown that injured nerves have the capability of regenerating their axons in an extremely slow-rate of 1 mm/day. At such rate of regeneration, achievement of reinnervation should take months or years (18, 19). In the context of a 10-day study, this is virtually impossible, but re-evaluating patients at around 100 days (3-4 months) would be beneficial in order to better assess the effect of the high-powered electromagnetic fields on nerve regeneration. It would also be useful to re-evaluate the paravertebral muscles, considering that the lumbar proximal muscles are the first to benefit from the reinnervation phenomenon.

As for the theory of peripheral nerve regeneration through collateral sprouting of distal nerve fibers, this might have been induced by the classic physiokinesiotherapy procedures, which are well-known for their repairing and bio-stimulatory effects (20). Histological studies are, however, needed to confirm whether nerve fiber density at the distal level has increased or not.

Regarding the statistically significant discreet improvement in the recruitment pattern at maximum contraction in both groups (23.7% in the RMS group *vs*. 21.4% in the RMS + PKT group), this may be attributed to the fact that patients tended to be more cooperative once improvements in pain management were achieved. More in-depth studies are needed to establish if there is a possible root-repair effect.

This study had several limitations: First of all, the limited number of patients and the lack of a comparative placebo group should be mentioned. We enrolled a relatively small number of patients in a single hospital, thus, the generalization of the results may have some limitations. Another limitation of the study is related to the duration of protocol and re-examination after a short course of treatment. We only assessed the immediate effects and the possible long-term benefits require further evaluation.

Conclusion

To our knowledge, this is the first study to use EMG assessment in conjunction with VSA and PDQ for monitoring the evolution of patients with lumbar radiculopathy. The results confirm that rPMS is effective as monotherapy for the treatment of lumbar radiculopathy, but it is preferred to be used in conjunction with a complex physical rehabilitation program given the significant improvements achieved in the combined therapy group. Large-scale studies will ultimately be required to assess the medium and long-term efficacy. Nevertheless, the possible mechanisms through which rPMS can improve electromyographic parameters remain to be elucidated.

Hence, further research on the impact of magnetic fields on the nerve regeneration microenvironment is warranted.

Conflicts of Interest

The Authors declare that they have no competing interests in relation to this study.

Authors' Contributions

SES was responsible for the study design, electromyography analysis, determinations and writing of the manuscript. CB was responsible for the statistical analysis. CB, MNP, IB and NB were responsible for writing, reviewing and editing of the manuscript. AI and SES were responsible for the recruitment of patients and performed the electromyography examination. MMM, LGP, MB and NB made substantial contributions to the conception or design of the work. MNP and MB were responsible for the recruitment of patients, provided scientific advice and critically reviewed the manuscript. MNP was responsible for the project administration. All Authors read and approved the final manuscript.

References

1 Tarulli AW and Raynor EM: Lumbosacral radiculopathy. Neurol Clin *25(2)*: 387-405, 2007. PMID: 17445735. DOI: 10.1016/j.ncl.2007.01.008

2 Zhang X, Zhang Z, Wen J, Lu J, Sun Y and Sang D: The effectiveness of therapeutic strategies for patients with radiculopathy: A network meta-analysis. Mol Pain *14*: 1744806918 768972, 2018. PMID: 29651898. DOI: 10.1177/1744806918768972

3 Chou R, Loeser JD, Owens DK, Rosenquist RW, Atlas SJ, Baisden J, Carragee EJ, Grabois M, Murphy DR, Resnick DK, Stanos SP, Shaffer WO, Wall EM and American Pain Society Low Back Pain Guideline Panel: Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: An evidence-based clinical practice guideline from the American Pain Society. Spine (Phila Pa 1976) *34(10)*: 1066-1077, 2009. PMID: 19363457. DOI: 10.1097/BRS.0b013e3181a1390d

4 Sorrell RG, Muhlenfeld J, Moffett J, Stevens G and Kesten S: Evaluation of pulsed electromagnetic field therapy for the treatment of chronic postoperative pain following lumbar surgery: A pilot, double-blind, randomized, sham-controlled clinical trial. J Pain Res *11*: 1209-1222, 2018. PMID: 29950893. DOI: 10.2147/JPR.S164303

5 Pasek J, Pasek T, Sieroń-Stołtny K, Cieślar G and Sieroń A: Electromagnetic fields in medicine – The state of art. Electromagn Biol Med *35(2)*: 170-175, 2016. PMID: 26192151. DOI: 10.3109/15368378.2015.1048549

6 Beaulieu LD and Schneider C: Repetitive peripheral magnetic stimulation to reduce pain or improve sensorimotor impairments: A literature review on parameters of application and afferents recruitment. Neurophysiol Clin *45(3)*: 223-237, 2015. PMID: 26363684. DOI: 10.1016/j.neucli.2015.08.002

7 Zschorlich VR, Hillebrecht M, Tanjour T, Qi F, Behrendt F, Kirschstein T and Köhling R: Repetitive peripheral magnetic nerve stimulation (rPMS) as adjuvant therapy reduces skeletal muscle reflex activity. Front Neurol *10*: 930, 2019. PMID: 31507528. DOI: 10.3389/fneur.2019.00930

8 Zhivolupov SA, Odinak MM, Rashidov NA, Onischenko LS, Samartsev IN and Jurin AA: Impulse magnetic stimulation facilitates synaptic regeneration in rats following sciatic nerve injury. Neural Regen Res *7(17)*: 1299-1303, 2012. PMID: 25657659. DOI: 10.3969/j.issn.1673-5374.2012.17.003

9 Price DD, Staud R and Robinson ME: How should we use the visual analogue scale (VAS) in rehabilitation outcomes? II: Visual analogue scales as ratio scales: an alternative to the view of Kersten *et al*. J Rehabil Med *44(9)*: 800-801, discussion 803-804, 2012. PMID: 22915047. DOI: 10.2340/16501977-1031

10 Gudala K, Ghai B and Bansal D: Neuropathic pain assessment with the PainDETECT questionnaire: Cross-cultural adaptation and psychometric evaluation to Hindi. Pain Pract *17(8)*: 1042-1049, 2017. PMID: 28160414. DOI: 10.1111/papr.12562

11 Radaković T and Radaković N: The effectiveness of the functional magnetic stimulation therapy in treating sciatica syndrome. Open J Ther Rehabil *3*: 63-69, 2015. DOI: 10.4236/ojtr.2015.33009

12 Lo YL, Fook-Chong S, Huerto AP and George JM: A randomized, placebo-controlled trial of repetitive spinal magnetic stimulation in lumbosacral spondylotic pain. Pain Med *12(7)*: 1041-1045, 2011. PMID: 21668750. DOI: 10.1111/j.1526-4637.2011.01143.x

13 St John Smith E: Advances in understanding nociception and neuropathic pain. J Neurol *265(2)*: 231-238, 2018. PMID: 29032407. DOI: 10.1007/s00415-017-8641-6

14 Chung T, Prasad K and Lloyd TE: Peripheral neuropathy: Clinical and electrophysiological considerations. Neuroimaging Clin N Am *24(1)*: 49-65, 2014. PMID: 24210312. DOI: 10.1016/j.nic.2013.03.023

15 Kane NM and Oware A: Nerve conduction and electromyography studies. J Neurol *259(7)*: 1502-1508, 2012. PMID: 22614870. DOI: 10.1007/s00415-012-6497-3

16 Cobianchi S, de Cruz J and Navarro X: Assessment of sensory thresholds and nociceptive fiber growth after sciatic nerve injury reveals the differential contribution of collateral reinnervation and nerve regeneration to neuropathic pain. Exp Neurol *255*: 1-11, 2014. PMID: 24552688. DOI: 10.1016/j.expneurol.2014.02.008

17 Kingham PJ and Terenghi G: Bioengineered nerve regeneration and muscle reinnervation. J Anat *209(4)*: 511-526, 2006. PMID: 17005023. DOI: 10.1111/j.1469-7580.2006.00623.x

18 Sulaiman W and Gordon T: Neurobiology of peripheral nerve injury, regeneration, and functional recovery: From bench top research to bedside application. Ochsner J *13(1)*: 100-108, 2013. PMID: 23531634.

19 Teleanu RI, Gherasim O, Gherasim TG, Grumezescu V, Grumezescu AM and Teleanu DM: Nanomaterial-based approaches for neural regeneration. Pharmaceutics *11(6)*: E266, 2019. PMID: 31181719. DOI: 10.3390/pharmaceutics11060266

20 Tseli E, Boersma K, Stålnacke B-M, Enthoven P, Gerdle B, Äng BO and Grooten WJA: Prognostic factors for physical functioning after multidisciplinary rehabilitation in patients with chronic musculoskeletal pain: A systematic review and meta-analysis. Clin J Pain *35(2)*: 148-173, 2019. PMID: 30371517. DOI: 10.1097/AJP.0000000000000669

Received October 25, 2020
Revised November 19, 2020
Accepted November 20, 2020