Magnetic therapy in acute and subacute non-specific back pain: Results of an open multicenter study

Andrey Karateev (1), Elena Polishchuk (2) Anatoliy D. Fesyun (2), Tatiana Konchugova (2), Ekaterina Filatova (1), Vera Amirdzhanova (1), Detelina Kulchitskaya (2), Alena Potapova (1), Marina Sukhareva (1), Alexander Lila (1,3), Elena P. Ivanova (2)

(1) The Federal State Budgetary Scientific Institution "NIIR named after V.A. Nasonova", Moscow, Russia; (2) Federal State Autonomous Educational Institution of Higher Education I.M. Sechenov First Moscow State Medical University, Ministry of Health of Russia, Moscow, Russia; (3) Department of Rheumatology «Russian Medical Academy of Continuing Professional Education» of the Ministry of Health of the Russian Federation, Moscow, Russia.

Abstract

Magnetic therapy (MT) is a non-drug method that improves the effectiveness of treatment of musculoskeletal pain, including:acute non-specific back pain (NBP). Objective of our study was to evaluate the results of complex treatment of patients with acute/subacute NBP at home using MT. The study group consisted of 339 patients with severe acute/subacute NBP. All patients received nonsteroidal anti-inflammatory drugs (NSAIDs). 166 patients (Group 1) received a course of MT (ALMAG+ device), 173 patients or a control group (Group 2) who did not receive MT. The dynamics of pain was significantly higher in group 1 than in group 2. So, the intensity of pain during movement (NRS) decreased from 7 [5;8] and 7 [5;8] to 0 [0;13] and 2 [1;3] after 1 month. ($p<0.001$). Significant differences between Groups 1 and 2 were observed in the dynamics of pain at rest and at night, overall health assessment (OHA), and sleep function and disorders. The average duration of NSAIDs use in Group 1 was 8.8±3.9, Group 2 – 11.8±5.7 days ($p<0.001$). The use of MT increases the effectiveness of treatment of acute/subacute NBP and reduces the need for NSAIDs use.

Key Words: Non-specific back pain; treatment; magnetic therapy; effectiveness.

Eur J Transl Myol 32 (3): 10686, 2022 doi: 10.4081/ejtm.2022.10686

Acute/subacute non-specific lower back pain (NBP) is the main reason for seeking medical help related to the pathology of the musculoskeletal system. According to the Russian MERIDIAN Study, which surveyed 5.926 medical practitioners in 61 cities in Russia, approximately half of patients go to polyclinics due to pain of various localization, and every second of them complains of back pain.[1] Almost every person in the world has experienced NBP at least once in their life. At the same time, according to a series of epidemiological studies, up to 60% of people who have had an episode of acute NBP suffer 1 or more relapses of this pathology within a year.[2] According to the Global Burden of Disease Study, which includese an assessment of the prevalence, mortality and disability due to 369 diseases and injuries for 204 countries, NBP is one of the main causes of disability in the most socially active individuals (age group 25-49 years). Among the pathologies that cause the greatest loss of disability-adjusted life years (DALY index), this pathology ranks 4th.[3] The pathogenesis of acute/subacute NBP is multifactorial and includes such elements as microtrauma (primarily of the ligamentous apparatus and spinal muscles), local inflammation, painful muscle spasm, peripheral hyperalgesia, central sensitization, and psychoemotional disorders. Background for the development of acute pain can be a variety of degenerative changes in the spine, myofascial syndrome and osteoarthritis (OA) of the facet and sacroiliac joints. An unfavorable combination of structural changes, nociceptive system dysfunction, depression and anxiety, as well as negative social factors creates prerequisites for the chronization of NBP.[1] This is why timely and effective treatment of acute/subacute NBP is so important: It is aimed not only at reducing suffering and improving the quality of life of patients, but also at

preventing the chronization of this pathology. According to Russian and foreign recommendations, treatment of acute/subacute NBP should be comprehensive. Non-steroidal anti-inflammatory drugs (NSAIDs) play a central role here, the rational use of which allows to stop back pain within 7-14 days in 80-90% of patients. Muscle relaxants such as tolperizone, tizanidine and baclofen are widely used in the treatment of NBP as a means of reducing the severity of painful muscle tension and enhancing the effect of NSAIDs. Equally important in the treatment of acute NBP is non-drug methods that can reduce pain, muscle tension, and accelerate the recovery of spinal function.[4] Physiotherapy and rehabilitation methods are of particular importance in the presence of comorbid diseases, which are often observed in older people and become a serious obstacle to the appointment of NSAIDs, which can cause various adverse reactions from the gastrointestinal tract (GIT), cardiovascular system (CVS) and kidneys.[5] In recent years magnetic therapy (MT) has attracted particular interest among physical therapy methods (MT), the use of which makes it possible to achieve a significant improvement in the condition of patients with NBP. The principal advantage of MT is a very favorable safety profile and the possibility of using it in serious comorbid diseases, when the use of NSAIDs has serious limitations or is contraindicated.[6] There is a large evidence base obtained in vitro and cell culture studies confirming the ability of low-intensity magnetic fields (primarily in pulsed mode) to exert anti-inflammatory and antinociceptive effects, as well as to promote the regeneration of damaged tissue.[7,8] The possibility of successful use of MT in clinical practice is confirmed by a series of randomized controlled trials (RCTs). So, recently T. Paolucci et al. (2020)[9] presented a meta-analysis of 21 RCTs (n=1101), which confirmed the effictiveness and safety of MT in various types of musculoskeletal pain. Similar results were demonstrated in the work of X. Yang et al. (202)[10], who conducted a meta-analysis of 15 RCTs (n=1212), which evaluated the effectiveness of MT in OA. The standardized mean difference (SMD) for pain reduction was -1.06 (95% confidence interval, CI 0.61 - 1.51), for stiffness 0.37 (95% CI 0.07 - 0.67), for function 0.46 (95% CI 0.14 - 0.78), and for quality of life 1.49 (95% CI -0.06 - 3.04). In their work of R. Andrade et al. (2016)[11] evaluated the total data of 6 MT RCTs for NBP (n=210). It was shown that, in contrast to placebo, this method provided a significant reduction in pain intensity, the dynamics of which averaged from 2.1 to 6.4 cm of the visual analog scale (VAS).

Although, as noted above, clinicians are clearly interested in the use of non-drug methods of treating NBP, in particular MT, there are a limited number of studies in our country devoted to the study of its effectiveness in real clinical practice. Thus the aim of our study was to evaluate the efficacy and safety of complex therapy with MT and short courses of NSAIDs for acute/subacute NBP.

Materials and Methods

The study is an open observational non-interventional comparative trial. We compared the results of treatment of two groups of patients with acute/subacute NBP who received either NSAIDs therapy in combination with MT (up to 20 daily procedures in accordance with the recommendations of the manufacturer of the MT device) (Group 1) and those who received only NSAIDs (Group 2).

This study that was part of the scientific topic "Pain control in rheumatic diseases: conservative therapy and surgical correction methods", was approved by the local ethics Committee of the Nasonova Research Institute of Rheumatology on 17.12.2020, meeting minutes No. 20. All patients gave informed consent to participate in the study. All adverse events (AES) that occurred during the treatment period were also taken into account

The inclusion criteria were:

1. Age over 18 years.
2. Diagnosis of acute /subacute NBP (duration <12 weeks) established in accordance with the recommendations of the Russian Society for the Study of Pain (RSSP) 2018 [1];
3. Pain intensity ≥5 on a numerical rating scale (HRSH, where " 0 "is the absence of pain," 10 " is the most pronounced pain);
4. Availability of indications for the use of MT and NSAIDs in accordance with the available recommendations, the opinion of the attending physician and the instructions of the manufacturer of the MT device;
5. Signed informed consent.

The exclusion criteria were:

1. The presence of " anxiety symptoms "("red flags") indicating the possibility of life-threatening diseases and pathological conditions as causes of back pain (trauma, signs of cancer, infectious, systemic inflammatory rheumatic diseases);
2. Signs of severe neurological pathology (motor and sensory disorders);
3. The presence of contraindications for MT.
4. Severe functional insufficiency or serious comorbid diseases that prevent regular visits to the doctor to assess the condition.

Participants of the study were 339 patients, 62.9% of women, 36.1% of men, mean age of 56.2±12,7 years, most of whom had episodes of NBP for several years – 8 [5;15], 44.6% had more than one relapse of NBP within the last year, many of whom had comorbid pathology: most often arterial hypertension (AH): 25.7%; diabetes mellitus (DM) type 2: 10.6%, chronic gastritis: 5,9%.

Since the distribution of patients in the study groups was determined by their deliberate consent to MT as an element of complex therapy or rejection of this

technique, the number of patients in groups 1 and 2 are different (206 and 133 people, respectively).

Table 1. *Biometric and clinical characteristics of the studied groups.*

Sign		Group 1 (n=166)	Group 2 (n=173)	p
Gender, W : M %		64.9 : 35.1	59.9 : 40.1	0.350
Age, years, M±σ		56.1±12.1	56.5±13.5	0.333
Age ≥ over 65 years, %		24.1	29.3	0.796
Work, %	Office	30.7	30.7	0.795
	Physical	19.8	23.3	
	Doesn't work	10.4	10.9	
	Pensioner	34.7	35.7	
	Disabled	person 4,5	2,3	
Changes in radiography, %	Hernias	71.2	76.6	0.984
	Spondylosis	45.9	48.7	0.317
	Osteophytes	44.7	51.4	0.650
	Facet joint OA	35.3	29.7	0.275
BMI, kg /m2		26.9±3.5	26.2±3.7	0.874874
BMI>> 30 kg/m2, %		17.24	19.9	0.547547
Taking NSAIDs, % Local forms Intramuscularly Oral		 64.1 59.7 79.1	 69.9 63.2 86.5	 0.265 0.525 0.015
Muscle relaxants, %		67.0	66.9,9	0.989
Vit Grup B, %		66.5	69.2	0.924
Proton pump inhibitors, %		15.5,5	17.3	0.671
Comorbidity, % AG Ulcer history Dyspepsia Gastroesophageal reflux Type 2 diabetes Chronic kidney disease Bronchial asthma		 26,7 7,8 2,4 5,3 10,2 0,49 4,4	 24,1 3,0 1,5 3,0 11,3 0,0 5,3	 0,587 0,069 0,559 0,307 0,752 0,421 0,705

The biometric and clinical characteristics of patients in groups 1 and 2 are presented in Table 1. Both groups did not differ in gender, age, BMI, or other parameters. The treatment was also similar: all patients received NSAIDs, most received muscle relaxants and B vitamins. The only difference between the groups was a large proportion of patients in group 2 who received NSAIDs orally. The latter is associated with a longer duration of NSAIDs use, noted in the second group, see below. MT was performed by patients at home on the doctor's recommendation using the ALMAG+ device (Manufacturer of JSC "Elatomsky Instrument Plant", license for the production and maintenance of medical equipment FS-99-04-000914-14 from 10.02.2014) in accordance with operating instructions. This device belongs to medical devices and is approved for use in medical practice (registration certificate No. RZN 2017/6194 of 08.09.2017). ALMAG+ is intended for physiotherapy treatment with low-intensity running and stationary pulsed magnetic field in medical and preventive institutions, as well as at home on the recommendation of a doctor. The device consists of a control unit and an emitter, which is four interconnected inductor coils used to influence individual parts of the body. Inductor coils have the ability to form radiating surfaces in the form of a "flexible radiating ruler "(consisting of 4 inductors) and a "flexible matrix" (2×2 inductors). The device provides operation in repeated-short-term mode for 8 hours: exposure time-20 minutes for all modes, 10 minutes – a break. The time of the magnetic treatment procedure for all modes is set automatically and is equal to 20 minutes ± 5%. The north pole of the magnetic field of all inductors corresponds to the "N" marking applied to the inductor housings. The choice of NSAIDs and other drugs for the treatment of acute/subacute NBP was determined by the attending physicians based on the clinical situation and

their own experience, in accordance with the recommendations for the treatment of this pathology.

Treatment outcomes were evaluated after 2 weeks and after 1 month after the start of treatment according to the following criteria:

- Dynamics of pain at rest, when moving, and at night (NRS 0-10, where " 0 "is the absence of pain," 10 " is unbearable pain)
- Dynamics of functional impairment (NRS 0-10, where " 0 " absence of disorders, "10" - inability to move in the spine)
- Sleep failure (NRS 0-10, where " 0 "is normal sleep," 10 " is complete insomnia)
- General health assessment, EHS (NRS 0-10, where "0" - excellent state of health, "10" - maximum poor state of health)
- Subjective assessment of the results of treatment by patients (scale Likert 1-5, where "1" - no effect or worse, "5" - excellent)
- Need for NSAIDs (average number of days of NSAIDs use over the entire course of treatment).

Patients were also asked to independently assess their condition daily using a special diary.

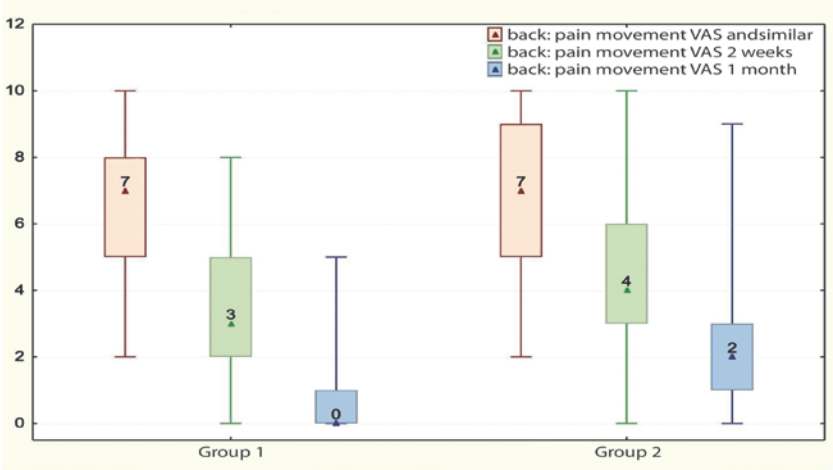

Fig 1. *Dynamics of pain during movement (HRV 0-10).*

Back pain	Group 1	Group 2	p
Andsimilar	7[5;8]	7[5;9]	0,815
After 2 weeks	3[2;5]	4[3;6]	0,000
After 1 month	0[0;1]	2[1;3]	0,000

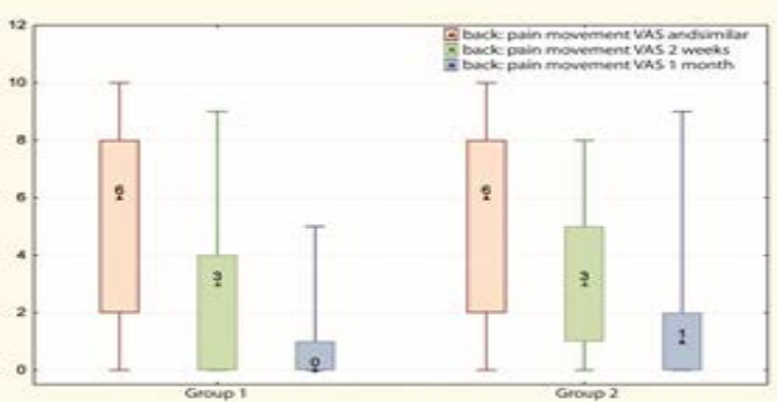

Fig 2. *Dynamics of pain during movement (HRV 0-10).*

Back pain	Group 1	Group 2	p
Andsimilar	7[5;8]	7[5;9]	0,815
After 2 weeks	3[2;5]	4[3;6]	0,000
After 1 month	0[0;1]	2[1;3]	0,000

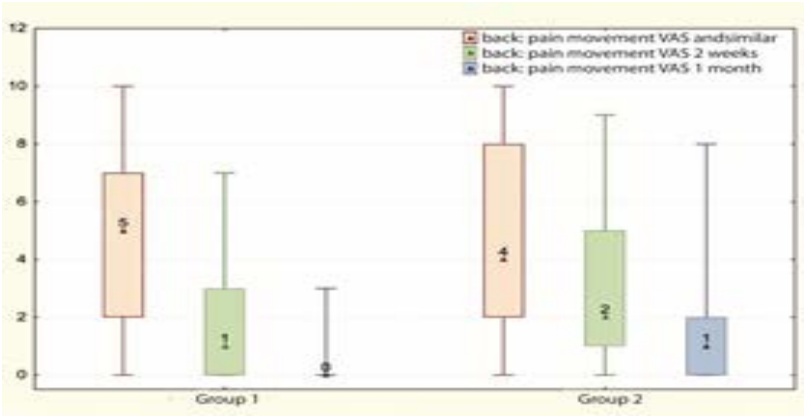

Fig 3. *Dynamics of pain during movement (HRV 0-10).*

Back pain	Group 1	Group 2	p
Andsimilar	6[2;8]	6[2;8]	0,648
After 2 weeks	3[0;4]	3[1;5]	0,023
After 1 month	0[0;1]	1[0;2]	0,000

For statistical processing of the obtained data, the SPSS17.0 program was used. Quantitative data are presented in the form of the average value and standard deviation (M±σ), in the absence of a normal data distribution – in the form of the median (Iu) and interquartile range [25th; 75th percentiles], qualitative data-in the form of a percentage ratio. When comparing the indicators over time, we used One-way analysis of variance (One Way ANOVA) and the Scheffe method of multiple comparisons. For pairwise comparison of quantitative values, the Wilcoxon test for related samples was used, and the Pearson's $\chi 2$ criterion was used to compare qualitative parameters. The differences were considered significant at $p < 0.05$.

Results

Almost all patients completed the course of treatment. In groups 1 and 2, one patient each dropped out of follow-up, and in group 1, two patients interrupted treatment due to the development of severe dyspepsia. During therapy, both groups showed a significant reduction in the severity of pain at rest, during movement, and at night (Figures 1, 2 and 3). Similarly, the positive dynamics of pain during movement was

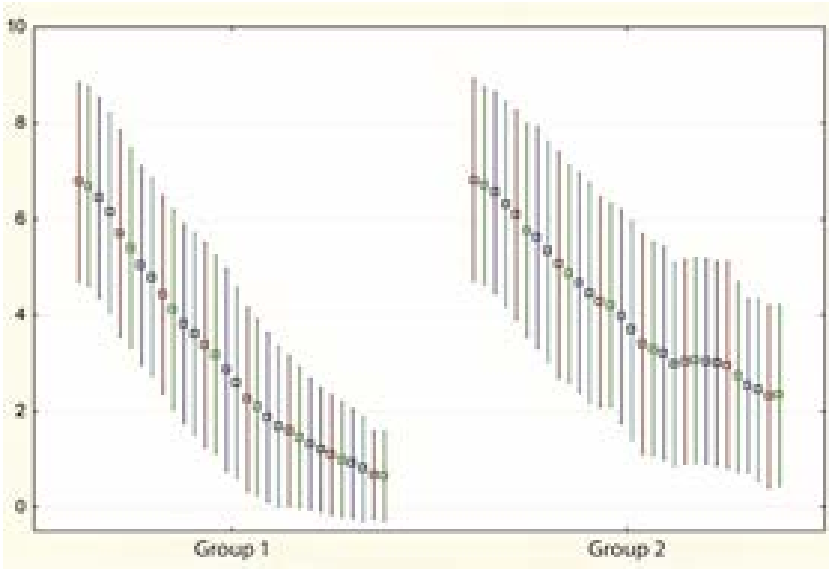

Fig 4. *Dynamics of pain during movement according to the patient's diaries.*

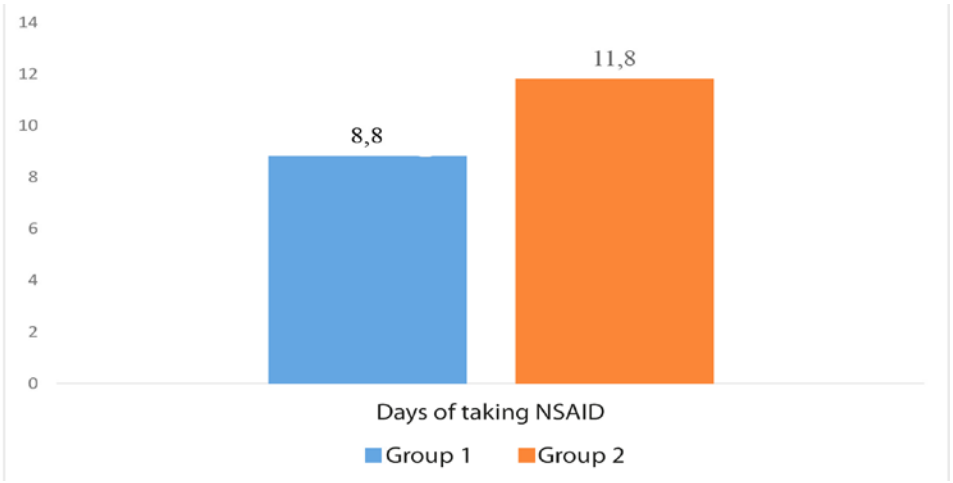

Fig 5. *Number of days of NSAIDs use required to achieve back pain control.*

noted according to the patient's diaries (Figure 4). At the same time, the dynamics of pain after 2 weeks. and after 1 month after the start of treatment-when moving, at rest and at night, was significantly higher in group 1 than in group 2 ($p<0.05$). Thus, the number of patients with reduced pain during movement >50% after 1 month was 99% in group 1 and 84% in group 2 ($p=0.001$).

A clear positive trend was observed in parameters functional disorders, general well-being, and the presence of sleep disorders (Table 2). For all these parameters, group 1 showed higher dynamics than in group 2. In group 1, the need for NSAIDs use was significantly lower compared to group 2. The number of days of taking these drugs was significantly lower in patients receiving combination therapy with MT - 8.8±3.9 than in the control group - 11.8±5.7, $p=0.000$ (Figure 5). The overwhelming majority of patients in group 1 gave a high assessment of the results of treatment: so, after a month. it was rated as "good" and "excellent" by 37.4% and 61.1% of patients. In group 2, only 25.4% and 11.5% of patients gave a similar assessment of the results of treatment. There were no serious life-threatening AES that required special treatment due to the independent use of the device at home. Among AES, the development or destabilization of arterial hypertension was most often noted (39.9% in group 1 and 32.7% in group 2, $p=0.236$). Blood pressure control was achieved by prescribing or correcting antihypertensive therapy. 1.9% of patients in group 1 and 5.3% of patients in group 2 ($p=0.061$) developed severe dyspepsia, which required the use of PPIs. As noted above, in two patients from group 1, dyspepsia caused an interruption of the course of treatment and an additional examination that did not reveal serious gastrointestinal damage.

Discussion

Our data indicate that the inclusion of MT in the treatment of acute/subacute NBP allows to achieve a more pronounced improvement than therapy based on the use of NSAIDs only with/without a muscle relaxants and vitamins group B. Although patients of group 2 were also noted a significant decrease in back pain during movement, at rest and during the night, and overall improvement of health, reduction of disorders of the spine and sleeping, however, in group 1 the dynamics of these clinical indicators was significantly higher. In particular, the dynamics of back pain during movement after 1 month in group 1 was 6 [4; 8], group 2: 4 [3; 6] HRV points ($p=0.000$). An important aspect of the use of MT was the reduction of the need for NSAIDs, which is of fundamental importance, given the

Table 2. *Dynamics of functional disorders, general assessment of the state and sleep disorders (HRV 0-10).*

Parameters	Group Parameters	Initially	p	After 2 weeks		p	After 1 month		p
Violation of the function	1	7[5;8]	0,511	3[2;4]		0,000	0[0;1]		0,000
	2	7[5;8]		4[3;5]			0[0;3]		
EHS	1	6[5;8]	0,261	3[2;4]		0,000	0[0;1]		0,000
	2	7[5;8]		4[2;5]			1[1;3]		
Sleep disturbance	1	5[2;7]	0,629	2[0;4]		0,005	0[0;0]		0,000
	2	5[2;7]		2[1;5]			1[0;2]		

serious comorbid background of many study participants. The advantages associated with the use of MT, also confirmed the subjective opinion of the study participants, which was reflected in the more pronounced dynamics of pain during movement according to the patient's diary. In addition, patients of group 1 gave a significantly higher assessment of the results of complex MT therapy, in comparison with group 2. Of course, the data obtained by us should be considered with certain limitations imposed by the open observational nature of the study. Studies based on this design usually show better results of the therapy under study than classical double-blind RCTs. The reason for this is the increased expectations of patients associated with the use of a new, promising treatment method. On the other hand, data from foreign researchers, including the results obtained in well-organized RCTs confirm the effectiveness of MT at the NBP. Thus, the work of Zdrodowska et al.,[12] compared laser therapy and MT in 120 patients with acute discogenic back pain (without signs of radiculopathy). Both methods of physical therapy were shown to effectively improve the condition of patients. At the same time, if laser therapy was more effective in relieving pain, then MT provided a better result in restoring the function of the spine. Good results of using MT in NBP were demonstrated in the work of Park et al.[13] During the RCT, 38 patients with NBP received real and fake MT for 2 weeks. Dynamics of back pain in the active MT group was 2.06±2.12, fake - 0.52±0.82 cm VAS ($p < 0,05$). In addition, the MT group showed significantly higher dynamics of the indexes Oswestry, SF-36, EQ-5D, and Roland-Morris. In the work of Lisi et al.[14] MT and fake MT in 42 patients with chronic NBP were compared. After 12 weeks dynamics of Oswestry index was significantly higher in patients receiving active treatment. Similar data were obtained by Elshiwi and co-authors (2019)[15] who compared the effect of true and fake MT in 50 patients with chronic NBP. After 4 weeks mean back pain intensity in the MT group decreased from 8.1 to 4.1 cm, while in the control group from 7.7 to 5.2 cm ($p<0.05$). Good results of MT application in NBP are also confirmed by works of Russian authors.[16-19] It should be noted that the advantages of MT as an effective and safe non-drug method of treating musculoskeletal pain (including those associated with NBP) were recorded in the results of the Council of Russian experts "Effectiveness and safety of magnetic therapy in osteoarthritis", held on June 3, 2020.[20]

Our data confirm effecacy and safety of MT as a method of non-drug therapy for acute/subacute NBP, because it was possible to achieve more effective pain control, restore function and reduce the need for NSAIDs.

List of acronyms

MT - Magnetic therapy
NBP - Non-specific back pain
NRS - Numerical rating scale
NSAIDs - Nonsteroidal anti-inflammatory drugs
OA - Osteoarthritis
RCT -.Randomized controlled trial
VAS - Visual Analog Scale

Contributions of Authors

KA, LA: Concept and design; PE, FE, SM: Collection and processing of materials; AV: Statistical processing; KA, PA: Writing the text; KT, FA, EI: Editing.
All authors have read and approved the final version.

Acknowledgments None.

Funding None.

Conflict of Interest

The authors declare no conflict of interests.

Ethical Publication Statement

We confirm that we have read the Journal's position on issues involved in ethical publication and affirm that this report is consistent with those guidelines.

Corresponding Author

Elena P. Ivanova, The Federal State Budgetary Institution «National Medical Research Center for Rehabilitation and Balneology» of the Ministry of Health of the Russian Federation, Moscow, Russia.
ORCID iD: 0000-0003-2627-1565.
E-mail: elenapivanova7@gmail.com

E-mails and ORCID iD of co-authors

Andrey Karateev: aekarat@yandex.ru
ORCID iD: 0000-0002-1391-0711
Elena Polishchuk: dr.pogozheva@gmail.com
ORCID iD: 0000-0001-5103-5447
Anatoliy D. Fesyun: fad68@yandex.ru
ORCID iD: 0000-0003-3097-8889
Tatiana Konchugova: umc-rnc@mail.ru
ORCID iD: 0000-0003-0991-8988
Ekaterina Filatova: es-filatova@mail.ru
ORCID iD: 0000-0002-2475-8620
Vera Amirdzhanova: amirver@yandex.ru
ORCID iD: 0000-0001-5382-6357.
Detelina Kulchitskaya: deti_ku@mail.ru
ORCID iD: 0000-0002-7785-9767
Alena Potapova: dr.aspotapova@gmail.com
ORCID iD: 0000-0002-8627-5341
Marina Sukhareva: marina-su@mail.ru
ORCID iD: 0000-0002-3871-0273
Alexander Lila: amlila@mail.ru
ORCID iD: 0000-0002-6068-3080

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Submission: June 16, 2022
Accepted for publication: June 23, 2022