

Dry Needling with the Use of FRSc Technique in Addition to Standard Rehabilitation Program for Chronic Low Back Pain: A Randomized Controlled Trial Using Both PROMs and Measurement Tools

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Purpose: Dry needling (DN) has gained popularity for musculoskeletal conditions, but its commercial use often surpasses scientific evidence. The novel Five Regulatory Systems Concept (FRSc) of DN shows potential therapeutic mechanisms, including chronic low back pain (LBP). However, rigorous clinical assessment with patient-reported outcome measures (PROMs) and objective measures are necessary. This study aimed to evaluate the effect of DN according to pain levels, postural control and selected gait parameters in patients with chronic LBP.

Patients and Methods: This prospective, double-blinded, randomized controlled study involved 30 patients with LBP allocated in the experimental (n=15, rehabilitation+ FRSc DN) or control group (n=15, rehabilitation + sham DN). The Roland-Morris questionnaire (RMQ) and Visual Analog Scale (VAS) were used as PROMs. Moreover, the posturography method for posture and balance control and the treadmill for gait analysis were used as objective tools. Measurements were taken before and immediately after the intervention and during 1- and 3-month follow up.

Results: There was a statistically significantly greater improvement in the RMQ in the experimental group compared to the controls (p=0.923 before and p<0.001 after treatment, as well as p<0.001 after 1 and 3 months). Despite the favorable analgesic effect, a significant advantage of the experimental group over the controls in this respect is worth noting (p=0.001 in favor of DN in all intergroup comparisons concerning results from the subjective assessment of pain (VAS)). A statistically insignificant post-treatment improvement in balance and postural stability was noted in both groups, although the effects appeared to be short-term. Surprisingly, again, DN had no advantage over sham interventions. In both groups, all changes in the swing phase were statistically insignificant (p=0.201 for the dominant and p=0.283 for the non-dominant side) for the initial swing phase. In both groups, all changes in the stance phase were statistically insignificant (p=0.480 for the dominant and p=0.410 for the non-dominant side of the body).

Conclusion: DN based on the FRSc appears promising as an effective adjunct to standard rehabilitation for LBP, showing improvements in functional performance and pain reduction.

Keywords: low back pain, dry needling, rehabilitation, postural control, gait analysis

Introduction

Over recent years, dry needling (DN) has been gaining popularity as a treatment method for musculoskeletal conditions.¹⁻³ Yet, it cannot be disregarded that the commercial use of that therapy significantly outpaces reliable scientific evidence. Moreover, there is no recognized and uniform clinical practice protocol, which further hinders the reliable application of dry needling according to the principles of Evidence-Based Physiotherapy.

As mentioned above, there are many ways to apply this method in daily practice. One interesting technique is applying needle therapy according to the novel Five Regulatory Systems Concept (FRSc). This is a novel method, which, however, requires substantial scientific validation. Regrettably, both basic research and recommended clinical papers of high methodological value on this subject are lacking. There are popular courses and training for FRSc. It is a popular method used in the practice of physiotherapists.

Its advocates generally believe that FRSc is based on therapeutic mechanisms such as the release of fascial structures and relaxation within the surrounding tissues, stimulation of local outflow of lymph, venous blood, and extracellular fluid, as well as analgesic effects and stimulation of proprioceptive perception.^{4,5} Unfortunately, these mechanisms have not been unambiguously confirmed by a considerable number of animal experiments, *in vitro* or *in vivo*.

In 2022, results from the world's first clinical study of DN according to the FRSc concept were published by our research team, indicating the relatively significant efficacy of this application in cases of chronic low back pain (LBP) treatment and its suitability as a complement to the standard physical rehabilitation protocol.⁶ This method could be helpful in everyday practice. However, despite the promising results from the pilot study, further clinical trials should be conducted, and the therapeutic effects should be tested against a wide variety of patient-reported outcome measures (PROMs) and objective measurement tools.⁷⁻⁹

In addressing a recognized gap in the existing literature on DN interventions, our study focuses on the innovative FRSc. With limited scientific validation available for this method, our research aims to contribute to the field by conducting a meticulous clinical assessment, incorporating patient-reported outcome measures and objective tools. The study's emphasis lies in evaluating the therapeutic efficacy of DN, specifically within the context of chronic LBP. This research seeks to provide valuable insights into the application of DN based on FRSc and contribute to the evolving understanding of DN interventions for LBP. Therefore, this study aimed to evaluate the effect of DN according to FRSc on subjective physical performance and pain levels, sense of balance, and postural stability, as well as selected components and parameters of gait in patients with chronic LBP treated with the standard rehabilitation program.

Materials and Methods

Ethics

The research project was conducted from December 2020 to January 2022 at the outpatient clinic at the Institute of Health Sciences of the University of Opole. Ethical approval was obtained from the Institutional Review Board (KB/91/FI/2018). All participants gave written informed consent to take part in the study. This study complies with the Code of Ethics of the World Medical Association (Declaration of Helsinki) and was prospectively registered (ISRCTN16627714). This manuscript was prepared in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines.

Design

This trial was a prospective, double-blinded, randomized controlled study with 3-month follow-up. Participants were randomized at a 1:1 ratio to the two study groups: the experimental group (rehabilitation program + DN) and the control group (rehabilitation program + sham DN). Participants were randomly allocated to comparative groups (experimental or control) by simple randomization with a 1:1 ratio through a computerized random sequence on the random.com website. All screening tests and measurements were carried out by two physiotherapists who trained each other on the repeatability and accuracy of the procedures for four months prior to the study. The DN procedures, on the other hand, were performed by one experienced physiotherapist with instructor qualifications. The standard rehabilitation program was provided one-on-one and was delivered to all participants by certified therapists who also had practiced the course of each session four months in advance. The procedure is described in detail in our team's first paper from 2022 in Scientific Reports.⁶ Participants provided with therapy and measurements had no contact with the qualifying team and those who analyzed the final results. The identical therapist administered both DN and sham procedures, ensuring consistency in the application of interventions. Notably, the procedures took place in distinct locations on the campus, preventing participants from discerning their allocation. This approach aimed to maintain blinding and minimize any potential bias arising from participants' awareness of the treatment assignment.

Participants

Participants were qualified for the presented study by a team consisting of an internist, radiologist, neurologist, neurosurgeon, orthopaedist, and physiotherapist. Patients with degenerative lesions in the lumbosacral region, chronic pain (at least three months), and no previous spinal surgical intervention were included (M54.5). The participants were adults and had current magnetic resonance imaging (MRI) scans confirming the diagnosis of LBP syndrome (lesions of at least grade 2 according to the Modic classification at L5-S1). Eligible participants had no previous DN procedures. Exclusion criteria were the absence of pain or reduced mobility in the lumbosacral region, other spinal conditions such as spondyloarthritis (M45), fracture of the lumbar spine and pelvis (S32), thoracic fracture (S23), level undetermined spinal fractures (T08) spine cancer (D48), intervertebral disc infection (purulent) (M46.3), unspecified inflammation of the intervertebral disc (M46.4), other infectious diseases of the spine (M46.5) Other specific inflammatory diseases of the spine (M46.8), and unspecified inflammatory disease of the spine (M46.9) as well as hypertensive heart disease (I11), heart diseases not precisely defined and complications of heart diseases (I51), blood clotting disorders (D68), pregnancy (Z32), cauda equina syndrome (G83.4), other joint diseases (M25), dislocation, sprain and tear of joints and ligaments at the level of the ankle and foot (S93), unspecified organic or symptomatic mental disorders (F09), other non-organic psychotic disorders (F28), other anxiety disorders in the form of phobias (F40.8), other anxiety disorders in the form of phobias (F48.8), malignant tumors of independent (primary) multiple locations (C97), other specified malignant tumors of the lymphatic tissue, hematopoietic system and related tissues (C96.7), history of other cancers (Z86.0), pressure ulcer (L89), other and unspecified skin lesions (R23.8), bacterial infections of unknown location (A49), other viral diseases (B33), unspecified fever (R50.9), other specific fever (R50.8), other and unspecified gait and movement disorders (R26.8), sensory disturbances (R20), Parkinson's disease (G20), multiple sclerosis (G35), condition after stroke (I64), other cerebrovascular syndromes in the course of cerebrovascular diseases (G46.8), damage to the peripheral nerves of the lower limbs (I60–I67), unspecified secondary hypertension (I15.9), fear of needles, lack of consent to perform DN. **Figure 1** shows the participants' flowchart.

The patients in both groups were homogeneous in terms of pain sensations, severity of the condition, and initial functional status. A number of differential and functional tests were performed to obtain a representative population. The screening consisted of the following procedures:

- 1) Observation of movement patterns in sitting, lying, standing, bending,
- 2) Active movements (flexion, extension, lateral flexion, combined movements quadrant position, single-leg extension),
- 3) Passive movements (overpressure was applied at the end of the range of active movements, muscle length of psoas, hamstring and gluteals, hip quadrants),
- 4) Palpation of spinous processes over the zygapophyseal joints, inferior sulcus of the sacroiliac joint, over the iliolumbar ligament, paraspinal muscles, quadratus lumborum, gluteal muscles,
- 5) Special tests (straight leg raise/slump, prone knee bend/femoral slump, sacroiliac joint stress tests and active straight leg raise, Sorensen test, neurological examination).

Interventions

Thirty patients participated in a standard rehabilitation program, dedicating 45 minutes per day, five times a week (Monday to Friday) for a duration of one month. The therapeutic regimen incorporated musculo-fascial relaxation techniques, activation of the lumbosacral-iliac complex, exercises targeting specific back muscles, stimulation of the correct breathing path and diaphragm mechanics, exercises designed to activate the transverse abdominal muscle, and elements of postural training.

In the experimental group (n=15), DN procedures were additionally conducted according to the FRSc concept. The procedure is described in detail in our team's first paper from 2022 in Scientific Reports [6]. The procedures were performed twice a week (Monday and Thursday) for one month (8 treatments in total). A single application lasted 60 minutes. The FRSc technique was based on the following steps (**Figure 2**):

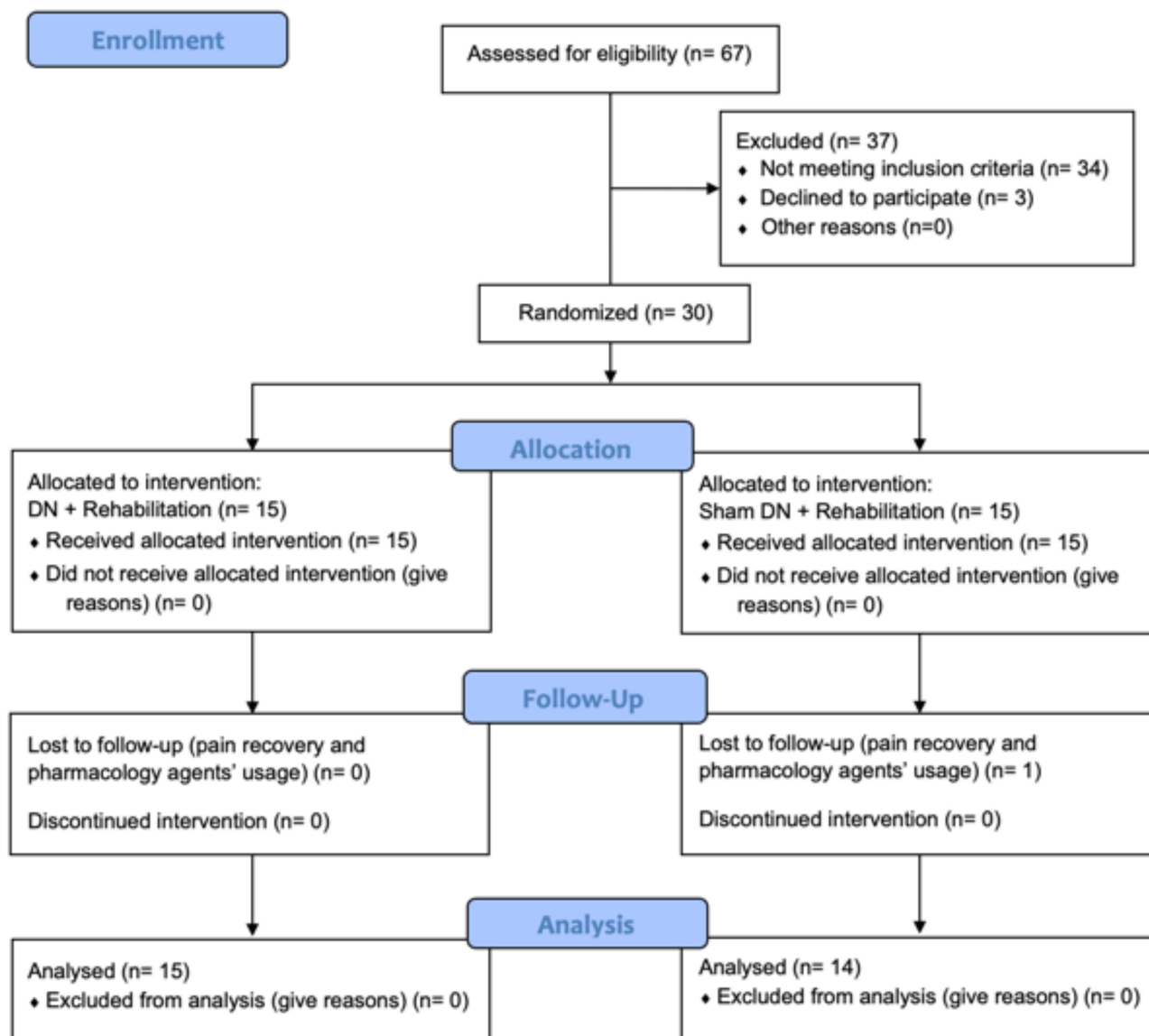


Figure 1 The CONSORT flowchart.

- 1) application to the area of the groove between the spinous processes and spinal erectors, in the caudal direction and towards the spine (needle length was 75 mm)
- 2) application within palpable connective tissue bands running transversely on the bulk of spinal erectors (needle length was 30 mm)
- 3) application to the neurocompartment of the superior gluteal nerve by puncturing and generating local twitch response (LTR) within the palpably tender areas of possible junctions of the course of the superior gluteal nerve (both upper and lower branches) with the gluteus maximus, gluteus medius and tensor fasciae latae muscles (needle length was 100 mm)
- 4) application to the area of the myogelosis of the piriformis muscle palpated as a tender fibrous thickening giving way under the fingers (needle length was 100 mm).

In the control group (n=15), on the other hand, sham techniques were performed using so-called telescopic needles, a method of blinding the actual dry needling, and an attempt to estimate the impact of the placebo effect. The design of the needles allowed them to be placed on the surface of the skin without piercing the integument.

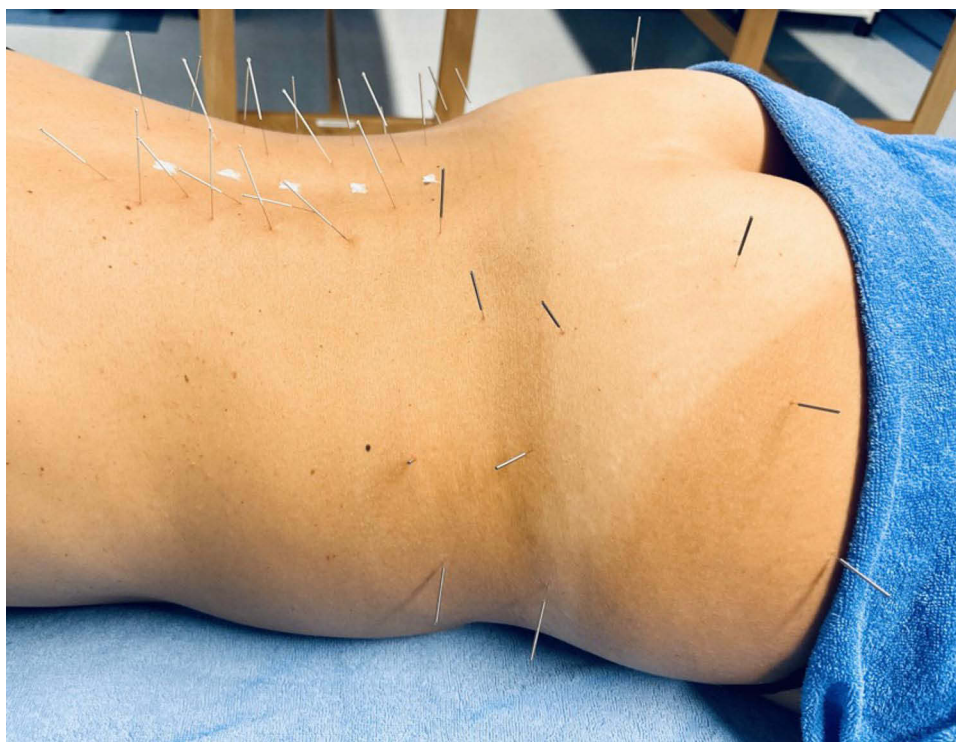


Figure 2 DN according to the FRSc concept in chronic LBP.

Outcomes

To analyze the therapeutic efficacy of the methods used, selected PROMs were used, ie, the Roland-Morris questionnaire, which was used to assess the degree of disability and consisted of 24 questions. Each item was ranked with a numerical score of 0 or 1. The higher the total, the more severe the degree of performance and functional impairment, and thus lower quality of life. The degrees of disability according to the presented questionnaire were 0–3 – no disability, 4–10 – low disability, 11–17 – moderate disability, and 18–24 – severe disability. Roland-Morris questionnaire represents sufficient internal consistency with Cronbach α of 0.89 and reliability of 0.85.¹⁰ The visual analog scale (VAS) was used to assess pain sensations, with the patient indicating pain intensity from 0 to 10 (0 – no pain, 10 – most severe pain). Reliability of the VAS ranges from 0.76 to 0.84.¹¹

Meanwhile, a strain gauge platform from AMTI AccuGait (Advanced Mechanical Technology Inc., USA) with Balance Clinic computer software was used to assess clinical outcomes objectively. The device was used to assess parameters evaluating posture. The computerized posturography tests allowed an objective assessment of balance control using repeatable measurements and served as an important diagnostic tool to assess the performance of the balance and proprioceptive systems, which are involved in maintaining a standing posture. Each patient was asked to take a relaxed standing position. The head was held upright, and the gaze was directed to a specific point at eye level approximately 1.5 meters away (wall marker). The feet were positioned hip-width apart, and the arms were positioned along the torso. It was also required to remove footwear. A single measurement lasted 30 seconds and was performed in two trials (with eyes open and closed) – **Figure 3**. The Area95% parameter was estimated, ie, the area of the ellipse delimited by 95% of the measurement points (deviations of the center of pressure (COP) marked on the field in the coordinate system formed on the X and Y, ie, frontal and sagittal axes) expressed as a unit of area, ie, cm^2 – **Figure 4**. With more efficient motor control and central stabilization, the area of the COP displacement record is more concentrated and assumes smaller values.

The Zebris FDM-T treadmill (Technomex Inc., Poland) was used to measure gait parameters objectively. It makes it possible to observe the different phases of the gait cycle at different speeds and the number of steps taken by the participant (**Figure 5**). Before data collection, every patient walked on the platform in order to familiarize themselves



Figure 3 The motor function and balance measurement on a stabilometry platform.

with the test procedures. Data were collected for five trials for each patient. On average, three good evaluations were considered for the results. A good evaluation was one in which a patient stepped with both feet at least three times on the platform and had no breaks in the gait cycle at a speed of 4 km/h. The two parameters that were recorded were swing time (%) and stance time (%). In the case of an abnormal gait which was in the process of normalization, there was a lengthening of the swing phase (when the foot is brought forward) and a shortening of the stance phase (when the foot is in contact with the ground) expressed as a percentage.

In both groups, all measurements were taken before and immediately after the treatment. During long-term follow-up, control measurements were conducted one and three months after the end of the therapeutic protocol. During this time, the participants did not receive any physiotherapeutic treatments or pharmacotherapy that could have affected further clinical outcomes.

Sample Size

The sample size was estimated using Statistica 13 (TIBCO Software Inc., USA). Sample size estimation was designed to detect a 2.5-point between-group difference in the scores of the primary outcome measure of disability, the Roland Morris Questionnaire. The sample size was estimated based on ten randomly selected results at the design stage of the

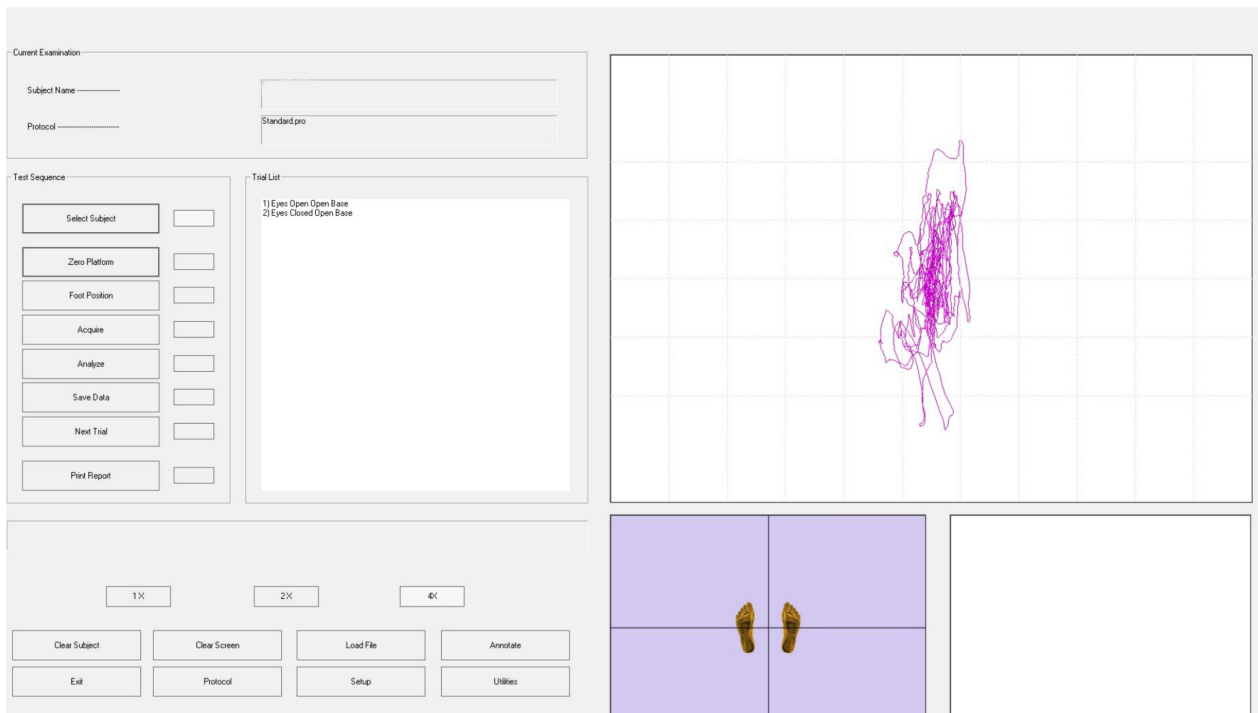


Figure 4 The sample result from the AccuGait device.

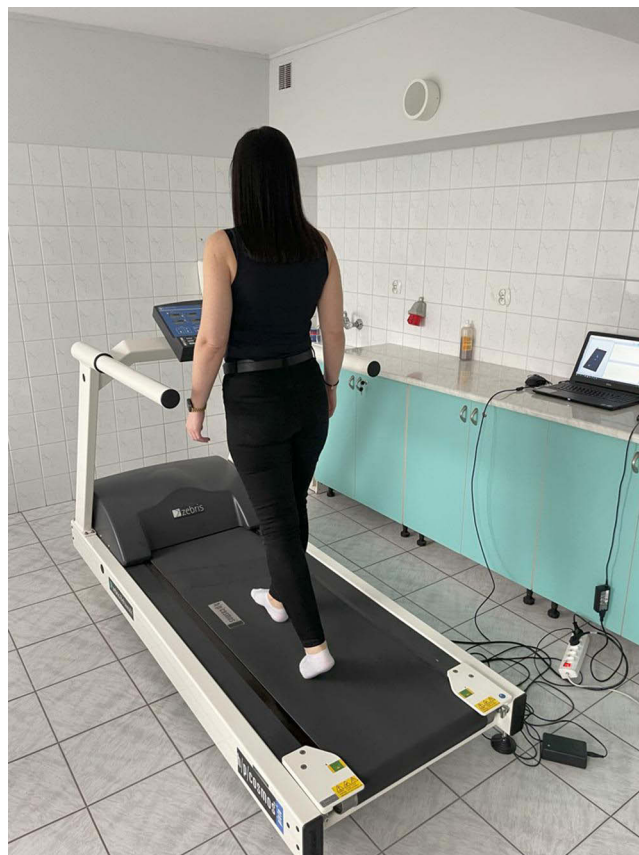


Figure 5 Gait analysis.

study (five from each group). The alpha level was set at 0.05, and the power of the test at 0.8 (for a two-sample *t*-test). It was also assumed that there is no correlation of evaluated variables, and a 2-sided null hypothesis was adopted.

Statistical Analysis

Statistical analysis was performed using Statistica 13 (TIBCO Inc., USA). Arithmetic means, medians, standard deviations, quartiles, and range of variation (extreme values) were calculated for measurable variables. Prevalence (%) was calculated for qualitative variables. All analyzed quantitative variables were verified using Shapiro–Wilk test to determine distribution type. Qualitative variables were compared between the groups using the Chi-squared (χ^2) test. Intra-group comparisons between the results obtained in the four measurements were performed using Friedman’s analysis of variance and a post-hoc test (Dunn’s test). Comparison of results between the treatment group and placebo was assessed using the Mann–Whitney *U*-test. The level of $\alpha=0.05$ was used for all comparisons.

Results

The experimental and control groups were homogenous in terms of anthropometrical characteristics (Table 1).

For disability scores using the Roland-Morris questionnaire, the DN-treated group scored 16.6 ± 2.8 , with a reduction to 5.75 ± 5.1 after one month of treatment ($p<0.001$, $d=2.637$). During long-term follow-up, the effect of improved physical performance persisted - 5.80 ± 5.2 at one ($d=2.586$) and 5.40 ± 5.3 at three months ($d=2.642$) after the completion of the therapeutic protocol. Interestingly, in the sham treatment group, the initial value was 16.4 ± 3.5 and only reduced to 16.1 ± 3.5 after treatment ($p=0.300$, $d=0.086$). One month after the completion of the study, the Roland-Morris questionnaire score increased to 17.4 ± 2.4 ($d=-0.333$), and after three months, it was at 16.9 ± 2.3 ($d=-0.169$). The above evidence clearly shows that there was a statistically significantly greater improvement in the patients’ subjectively perceived functional status in the experimental group compared to the control group ($p=0.923$ before and $p<0.001$ after treatment, as well as $p<0.001$ after one and three months in distant outcomes).

With regard to pain on the VAS scale, a mean value of 7.15 ± 0.9 before and 2.12 ± 1.6 after the therapeutic process was obtained ($p<0.001$, $d=0.888$) in patients provided with rehabilitation and dry needling. The analgesic effect was slightly reduced in the long-term follow-up, ie, 2.81 ± 2.4 after one month ($d=0.333$) and 3.11 ± 2.4 after three months ($d=0.172$). In contrast, patients receiving kinesitherapy and sham procedures had an initial pain sensation value of 7.32 ± 1.0 which was reduced to 5.10 ± 1.1 after the treatment ($p<0.001$, $d=-0.346$). During long-term follow-up, a value of 7.35 ± 1.3 was recorded one month after the completion of treatment ($d=0.019$), and 7.78 ± 1.4 after three months ($d=0.273$), meaning that the analgesic effect was markedly reduced. That said, despite the favorable analgesic effect in the majority of patients, a significant advantage of the experimental group over the control group in this respect is worth noting ($p=0.001$ in favor of DN in all intergroup comparisons concerning results from the subjective assessment of pain on the VAS scale).

Table 1 Characteristics of the Participants

	DN + Rehabilitation							Sham DN + Rehabilitation							p-value
	\bar{x}	Me	Min	Max	Q1	Q3	SD	\bar{x}	Me	Min	Max	Q1	Q3	SD	
Age [years]	62.6	64.3	48.3	81.0	51.0	72.6	21.7	56.8	59.5	36.0	74.0	47.0	64.0	11.5	0.110*
Body weight [kg]	72.6	72.9	57.5	85.2	61.8	88.2	13.0	72.3	71.5	54.0	92.0	62.5	82.5	11.7	0.950*
Body height [cm]	173.1	174.2	163.2	188.0	168.0	178.0	7.8	167.7	170.0	152.0	181.0	159.0	175.0	8.6	0.124*
BMI [kg/m ²]	25.2	24.9	20.4	32.3	23.7	20.8	5.1	25.6	26.0	19.0	30.1	22.8	28.1	3.2	0.228*
Sex	F – n=8 M – n=7							F – n=8 M – n=7							1.00**

Notes: *Mann–Whitney *U*-test; **chi-squared test.

Abbreviations: N, number of individuals; \bar{x} , mean; Me, median; Min, minimum value; Max, maximum value; Q1, lower quartile; Q3, upper quartile; SD, standard deviation; F, female; M, male; BMI, body mass index; DN, dry needling.

In conclusion, it should be stated that, according to the PROMs used in this study, the DN technique based on the FRSc concept provides effective support for the standard rehabilitation program with regard to the improvement of functional performance and reduction of pain in patients with LBP, and importantly also in long-term follow-up. This means that the clinical outcome appears to be permanent (up to 3 months) despite the discontinuation of further physiotherapy protocol.

Table 2 presents a comparison of the changes in the mean COP deviation area (the Area95% parameter) in the stabilometric test during the test with open eyes. In both groups, there was a favorable reduction in the area of COP deviations following treatment, although the changes were not statistically significant. Unfortunately, during long-term follow-up, this parameter returned to its initial values, indicating that the previous trends were short-lived. Very importantly, though, no intergroup differences were observed in the discussed changes ($p>0.05$).

The situation was similar for the test with closed eyes, as shown in Table 3. A statistically insignificant post-treatment improvement in balance and postural stability was noted in both groups, although the effects appeared to be short-lived at long-term follow-up. Surprisingly, again, there was no advantage of DN over sham interventions in this respect.

Relatively similar results were obtained for gait analysis. The experimental group recorded initial swing phase percentage scores of 28.08 ± 6.19 and 25.67 ± 4.36 for the dominant leg and non-dominant leg, respectively. After treatment, a slight increase in this gait phase was observed to a value of $29.45\pm6.34\%$ for the dominant leg and $27.60\pm4.04\%$ for the non-dominant leg. One month after the completion of rehabilitation and DN according to the FRSc concept, a gradual return to baseline values was noted, namely $29.89\pm6.04\%$ for the dominant leg and $26.88\pm4.89\%$ for the non-dominant leg. After three

Table 2 Changes in the Area95% Parameter in Both Groups (with Opened Eyes)

		DN + Rehabilitation							Sham DN + Rehabilitation						
		\bar{x}	Me	Min	Max	Q1	Q3	SD	\bar{x}	Me	Min	Max	Q1	Q3	SD
Area (cm ²)	Before	0.50	0.38	0.12	1.44	0.18	0.62	0.4	0.51	0.36	0.12	2.35	0.17	0.49	0.5
	After	0.32	0.28	0.11	1.00	0.16	0.44	0.2	0.34	0.28	0.12	0.83	0.17	0.45	0.2
	1-month follow up	0.51	0.34	0.15	2.58	0.14	0.34	0.6	0.42	0.38	0.12	0.84	0.12	0.46	0.2
	3-months follow up	0.56	0.39	0.12	0.87	0.19	0.48	0.2	0.58	0.42	-1.31	1.38	0.14	0.41	0.5
p-value (main effect)*		0.552							0.739						

Note: *Friedman's ANOVA.

Abbreviations: N, number of individuals; \bar{x} , mean; Me, median; Min, minimum value; Max, maximum value; Q1, lower quartile; Q3, upper quartile; SD, standard deviation; F, female; M, male; BMI, body mass index; DN, dry needling.

Table 3 Changes in the Area95% Parameter in Both Groups (with Closed Eyes)

		DN + Rehabilitation							Sham DN + Rehabilitation						
		\bar{x}	Me	Min	Max	Q1	Q3	SD	\bar{x}	Me	Min	Max	Q1	Q3	SD
Area (cm ²)	Before	0.73	0.44	0.00	1.09	0.15	0.47	0.3	0.66	0.38	0.09	0.80	0.16	0.61	0.2
	After	0.61	0.40	0.13	1.07	0.15	0.52	0.3	0.50	0.32	0.07	1.88	0.15	0.69	0.5
	1-month follow up	0.73	0.40	0.05	0.84	0.14	0.47	0.2	0.65	0.35	0.00	0.97	0.11	0.34	0.2
	3-months follow up	0.71	0.43	0.12	0.62	0.18	0.39	0.2	0.68	0.32	0.14	1.02	0.22	0.42	0.2
p-value (main effect)*		0.655							0.141						

Note: *Friedman's ANOVA.

Abbreviations: N, number of individuals; \bar{x} , mean; Me, median; Min, minimum value; Max, maximum value; Q1, lower quartile; Q3, upper quartile; SD, standard deviation; F, female; M, male; BMI, body mass index; DN, dry needling.

months, the swing time was $27.77\pm 6.09\%$ and $25.65\pm 4.88\%$, respectively. In both cases, all changes were statistically insignificant ($p=0.201$ for the dominant and $p=0.283$ for the non-dominant side of the body).

On the other hand, the control group had initial results for the swing phase (%) of 27.56 ± 6.89 for the dominant leg and 26.03 ± 4.77 for the non-dominant leg, respectively. After rehabilitation and quasi-DN treatments, the values were $28.89\pm 6.77\%$ after treatment, $28.12\pm 6.66\%$ after one month, and $27.34\pm 6.44\%$ after three months of long-term follow-up for the dominant leg, and $27.99\pm 4.66\%$ after treatment, $26.56\pm 4.03\%$ after one month and $26.04\pm 4.12\%$ after three months of distant follow-up for the non-dominant leg. Similar to the previous results in both cases, all changes were statistically insignificant ($p=0.267$ for the dominant and $p=0.270$ for the non-dominant side of the body).

Although not statistically significant, favorable changes were found for stance time (%). However, these were again short-lived and returned to baseline values in the follow-up.

In the experimental group, initial percentage scores for the stance phase of 71.76 ± 6.33 and 74.48 ± 5.02 for the dominant and non-dominant legs, respectively, were recorded. After treatment, a slight reduction in this gait phase was observed to a value of $70.51\pm 6.09\%$ and $72.03\pm 5.11\%$ for the dominant and non-dominant legs, respectively. One month after the completion of rehabilitation and DN according to the FRSc concept, a gradual return to baseline values was noted, namely $70.82\pm 6.11\%$ for the dominant leg and $73.13\pm 5.13\%$ for the non-dominant leg. After three months, the stance time was $72.01\pm 5.19\%$ and $74.03\pm 5.88\%$, respectively. In both cases, all changes were statistically insignificant ($p=0.480$ for the dominant and $p=0.410$ for the non-dominant side of the body).

Meanwhile, the control group had initial stance time (%) results of 72.06 ± 5.89 and 73.13 ± 4.97 for the dominant leg and non-dominant leg, respectively. After rehabilitation and quasi-DN interventions, the values were $71.09\pm 6.07\%$ after treatment, $71.27\pm 6.06\%$ after one month, and $72.33\pm 6.55\%$ after three months of long-term follow-up for the dominant leg, and $72.01\pm 5.06\%$ after treatment, $73.23\pm 5.13\%$ after one month and $73.44\pm 5.77\%$ after three months of distant follow-up for the non-dominant leg. Similar to the previous results in both cases, all changes were statistically insignificant ($p=0.412$ for the dominant and $p=0.423$ for the non-dominant side of the body).

In summary, the results obtained from the measurement tools (stabilometric platform and gait analysis treadmill) do not correspond to those obtained in the case of PROMs. Despite showing some favorable trends in the normalization of balance and posture and gait parameters in both groups, there was no therapeutic advantage of DN based on the FRSc concept compared to sham therapy, which does not confirm the assumption that needling techniques effectively support standard physiotherapy in the respects as mentioned above. Moreover, it appears that cessation of kinesiotherapy (long-term follow-up) leads to the return of measured parameters to the worse initial values.

Discussion

To date, this is the second publication on the use of DN based on the FRSc concept in treating LBP. In an earlier pilot report published in 2022,⁶ our team, relying only on subjective assessment of pain, disability, and range of motion in the lumbar spine, documented the therapeutic efficacy of the discussed needling technique. In the present study, further PROMs also support the significant usefulness of the FRSc method for chronic LBP.

Interestingly, the favorable impressions regarding patients' perceptions of pain and functional status do not translate into the parameters of balance, postural stability, and gait objectively measured using technologically recognized devices. This is particularly puzzling, especially since, theoretically, a significant reduction in pain should significantly affect qualitative improvements in gait phases or COP position focus. The fact that there were no intergroup differences between DN and sham therapy is intriguing, especially since, after all, many of the questions in the Roland-Morris questionnaire relate specifically to gait, stair climbing, activities of daily living, changes in postural alignment, and other spheres of life that are closely associated with issues measured on a treadmill or stabilometric platform. It is, therefore, very interesting why, in their own perception, patients experience a significant improvement under dry needling (despite the use of "blinding" and sham procedures), which, however, does not correlate clearly with the indicators measured with laboratory equipment.

This study was performed using the Roland-Morris questionnaire, which is an example of PROMs in LBP cases recommended in the literature.¹²⁻¹⁴ It has been estimated in various publications that the test-retest reliability value ranges from 0.86 to 0.91, depending on the severity of lower back pain. Similarly, subjective assessment of pain – despite

a number of limitations – is frequently used among patients with chronic LBP.^{15–17} Many authors have also recommended the use of the AccuGait stabilometry platform^{18,19} and the Zebris treadmill^{20–22} as modern measurement tools in various branches of medicine.

This means that the study used popular and recognized methods to assess clinical outcomes. Nonetheless, it is certainly necessary to expand the set of measurement tools in future studies to include a greater number of indicators and parameters so as to be able to answer the doubts that have arisen unambiguously. More instrumentation is needed to test the sensitivity of individual indicators and parameters, as the subjective feelings of patients may not be easy to measure and empirically express with laboratory equipment.

As mentioned above, there are no clinical studies in the available literature to which the results obtained in this study could be related. However, certainly, the subject of dry needling still needs scientific verification.

A recent meta-analysis published by Lara-Palomo et al in 2022²³ concluded that dry needling techniques applied to myofascial points (a methodology different from that used in this study) effectively reduced pain but only at short-term follow-up. It has also been noted that they do not have any beneficial effect in reducing disability (interestingly, in the present study, such an effect was observed for DN based on FRSc). The researchers relied on an analysis of eight randomized clinical trials (414 LBP patients in total).

Liu et al²⁴ on the other hand, based on a meta-analysis with a systematic review, found the level and strength of scientific evidence of dry needling of myofascial points to be moderate and noted the need for further clinical trials with good methodology and the search for the best protocol for performing DN.

This article shows that the results regarding pain and improvement of function are encouraging, especially in the opinion of the patients themselves, as indicated by PROMs indicators, while objective measures do not fully confirm such clinical effects. The FRSc method has insufficient scientific basis and should be used with caution and as an adjunct to rehabilitation. Therefore, the present authors hope that their further research work is in line with the latest trends and will help bring this issue closer to resolution and address existing uncertainties.

In considering the observed improvements in patient performance following DN based on the FRSc concept, it is crucial to delve into potential mechanisms that underlie these positive outcomes. While the precise physiological pathways remain a subject of ongoing research, several plausible explanations merit attention. DN, by targeting specific myofascial trigger points, may contribute to the release of muscle tension and promote relaxation, thereby alleviating pain and enhancing overall functional capacity. Additionally, the needling procedure might stimulate local neural pathways, leading to improved neuromuscular coordination and proprioception. These neurophysiological effects could play a role in the sustained positive impact observed in patients' subjective assessments of pain and functional status. However, further research is warranted to elucidate the intricate interplay between DN and the complex mechanisms influencing musculoskeletal function in individuals with chronic LBP.

Study Limitations

The study reported here is still a pilot study, as the number of patients in each group is small. It certainly should be extended to include a larger number of patients. As mentioned earlier, it is also worth using other measurement tools, which will allow a full verification of the usefulness of the presented method. The final challenge is to compare the efficacy of the FRSc concept to other popular therapeutic interventions, for example, extracorporeal shockwave therapy (ESWT), manual therapy, massage, Pilates, or acupuncture. Then the actual usefulness of this technique will be verified against other management modalities for LBP cases.

Clinical Implications

Due to the great popularity of practical use DN methods acc. FRSc is worth continuing research on its effectiveness. This method is not supported by appropriate scientific evidence, therefore the impact of FRSc should be examined based on other indicators and measures to comprehensively assess the usefulness and effectiveness of this method. An important aspect is to establish uniform treatment protocols that could be verified by other researchers. The challenge that arises is to compare FRSc-based DN with other established disease-specific treatment protocols.

For researchers, our findings offer a foundation for further investigations, encouraging the exploration of DN efficacy in diverse patient populations and conditions. Clinicians stand to benefit from insights into the potential of DN based on

FRSc as an adjunct to standard rehabilitation programs for chronic LBP patients, providing an additional tool for enhancing functional outcomes and reducing pain. Importantly, patients grappling with chronic LBP may find promise in the prospect of a comprehensive treatment approach that includes DN based on FRSc, potentially offering sustained relief and improved functional well-being. The study thus extends its impact beyond academia, striving to bridge gaps in both research and clinical practice for the betterment of patients and the healthcare community at large.

Future Recommendations

The study, albeit preliminary, indicates significant improvements in functional efficiency and pain reduction, as evidenced by PROMs. However, the objective measurements from stabilometric platforms and gait analysis fail to establish a clear advantage of DN over sham therapy. Future research should focus on expanding sample sizes, incorporating diverse outcome measures, conducting long-term follow-ups, and engaging in comparative effectiveness trials with other interventions. Standardizing treatment protocols and adopting a multidimensional assessment approach would contribute to a more robust understanding of DN's efficacy. Collaboration among researchers and clinicians can foster knowledge exchange, leading to refined techniques and evidence-based guidelines for managing chronic LBP with DN based on FRSc.

Conclusion

DN based on the FRSc concept emerges as a promising and innovative therapeutic approach, showcasing its effectiveness as a complementary intervention to standard rehabilitation programs for individuals with chronic LBP. The study, employing PROMs, underscores the positive impact of DN on enhancing functional efficiency and alleviating pain, both in the short and long term. Nevertheless, the objective assessments using a stabilometric platform and gait analysis treadmill reveal that, despite noticeable positive trends in normalizing balance, posture, and gait parameters across both treatment groups, DN based on FRSc did not demonstrate a distinct therapeutic advantage compared to sham therapy. Further research and exploration are warranted to delineate the nuanced effectiveness of DN in improving specific aspects of physical function in chronic LBP patients.

Data Sharing Statement

The data that support the findings of this study are available from the corresponding author [JR] upon reasonable request.

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Disclosure

The authors report no conflicts of interest in this work.

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