CLINICAL TRIAL REPORT

Fu's Subcutaneous Needling Combined with Kinematic Acupuncture versus Electroacupuncture in the Treatment of Cervical Spondylotic Radiculopathy: A Randomized Controlled Trial

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Background: Degenerative Cervical Myelopathy (DCM) is an overarching term that encompasses a broad spectrum of degenerative conditions affecting the cervical spine. Cervical Spondylosis Radiculopathy (CSR) represents a prevalent yet particularly severe type within the broader spectrum of Degenerative Cervical Myelopathy (DCM). Currently, conservative treatments, such as acupuncture, traction, physical therapy, and medication, are the standard methods used. As a widely applied physical therapy for musculoskeletal disease, Fu's Subcutaneous Needling (FSN) therapy could be considered when choosing treatment interventions for complement. Electroacupuncture, a commonly used acupuncture treatment, has been proven effective by multiple studies. The comparative analysis with electroacupuncture is specifically aimed at assessing the potential advantages and therapeutic efficacy of FSN therapy in the management of CSR. This is particularly pertinent in instances where conventional conservative interventions and traditional acupuncture techniques may fall short in providing adequate symptom relief.

Methods: The study was a single-centered study without blinding. 80 eligible patients were randomly assigned into two groups, with 40 in each group. The study group received FSN combined with Kinematic acupuncture, the control group received electroacupuncture treatment.

Results: The results after treatment demonstrated that the study group had significantly higher scores in VAS (P=0.001), NPQ (P=0.000), NDI (P=0.000), TY (P=0.000), SF-36 (P=0.000), Hand-numbness (P=0.004), total effective rate (P=0.004) and Analgesic effect time (P=0.001) compared to the control group. The follow-up results also indicated that the experimental group outperformed the control group in VAS (P=0.000), NPQ (P=0.000), NDI (P=0.000), SF-36 (P=0.000), NPQ (P=0.000), NDI (P=0.000), SF-36 (P=0.000), however, the results of Hand-numbness scoring showed no significant statistical difference between both two groups (P=0.302), neither did Relieve duration (P=0.562).

Conclusion: In general, Fu's Subcutaneous Needling combined with Kinematic acupuncture method is more effective in relieving symptoms and promoting recovery of CSR.

Trail Registration: The clinical trial has been registered at the Chinese Clinical Trial Registry (NO. ChiCTR2300068507). **Keywords:** Fu's Subcutaneous Needling, kinematic acupuncture, Cervical Spondylotic Radiculopathy, randomized controlled trial

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Introduction

Globally, degenerative cervical myelopathy (DCM) stands as the primary cause of spinal cord dysfunction among adults.¹ This disease is characterized by chronic and progressive dysfunction stemming from degenerative alterations in the cervical spine, which encompass disc degeneration, osteophyte formation, ligament hypertrophy or ossification, among others.^{2,3} Such degenerative processes may result in the compression of the spinal cord or nerve roots. Specifically, when nerve root compression induces localized pain and sensory abnormalities, the resultant disease is defined as Cervical Spondylotic Radiculopathy (CSR).⁴ Cervical Spondylotic Radiculopathy is a clinical disease characterized by unilateral pain radiation and numbness in the upper limb.⁵ It is commonly associated with the degenerative changes in the cervical disc and intervertebral joint, which can cause mechanical compression. Additionally, the compression of the overall incidence of cervical spondylosis, making it the most prevalent type.⁷ If the physiological curvature of the cervical spine remains altered for an extended period and is not corrected, local muscles in the neck will experience spasm and edema. This can lead to the cervical spine's local decompensation, worsening its adverse effects on the normal function of the cervical spine and the blood vessels, as well as local nutrient metabolism, eventually leading to the dynamic and static imbalance of the cervical spine, thus causing a vicious cycle.⁸⁻¹⁰

Currently, conservative therapy and surgical treatment are the primary treatments for cervical CSR. While surgical treatment has demonstrated definitive effects, it is often associated with high risk, cost, and recurrence rates.¹¹ As a result, conservative therapy, such as traction, physical therapy, and medication, is commonly preferred for CSR treatment.^{12–14} Existing research indicates that^{15–17} electroacupuncture, a modality of acupuncture, has been extensively validated for its efficacy in managing CSR. This technique amplifies the therapeutic stimulation by introducing a microcurrent to the acupuncture needles. Through the precise stimulation of acupoints with filiform needles and the strategic application of pulsatile currents, electroacupuncture demonstrably mitigates cervical muscle spasms, curtails the permeation of inflammatory mediators, augments local blood flow, and dissipates hematomas, consequently alleviating the compressive symptoms affecting the nerve roots.^{18–20} FSN is a form of physical therapy that using disposable floating needles to sway in subcutaneous tissues of skin around specific MTrPs (also known as myofascial trigger point) or adjacent limbs. The objective is to improve the ischemic state of the affected muscles, eliminate MTrPs, and promote muscle tissue recovery.²¹ Furthermore, multiple clinical studies have found that FSN can effectively manage musculoskeletal pain with long-lasting effect.²²⁻²⁴ Similarly, Kinematic acupuncture therapy is based on the theory of "movement cortex stimulation therapy" that involves patients moving their affected area or related parts during needle stimulation to increase the stimulation and then enhance the treatment's effectiveness.²⁵ The diversity and multi-modal nature of conservative treatment for CSR are advantageous. Therefore, this study aims to explore the clinical efficacy and basis of FSN combined with Kinematic acupuncture in treating CSR, which may provide additional options and guidance for clinicians in treating CSR.

Methods

Trail Design and Participants

This study was conducted at a single clinic and was randomized, but not blinded, aimed to recruit 80 patients diagnosed with CSR from the Acupuncture and Rehabilitation Department of the First Affiliated Hospital of Guangzhou University of Chinese Medicine, between February 2023 to July 2024. While patients in the study group received FSN combined with Kinematic acupuncture, the control group underwent electroacupuncture treatment. All participants provided written informed consent prior to their involvement in the study.

The trial complies with the Declaration of Helsinki and this research plan has been reviewed and approved by the Ethics Committee of the First Affiliated Hospital of Guangzhou University of Traditional Chinese Medicine (NO. K-2022-080), and it was registered with the Chinese Clinical Trial Registry as ChiCTR2300068507, Feb 21st, https://www.chictr.org.cn/.

Diagnosis, Inclusion and Exclusion Criteria

Based on the "Standard for diagnosis and efficacy evaluation of traditional Chinese medicine syndromes and diseases" issued by the State Administration of Traditional Chinese Medicine in 1994,²⁶ the diagnosis of CSR involvement should meet the following criteria: neck pain accompanied by upper limb pain, which worsens with neck extension; reduced sensation, muscle atrophy, abnormal tendon reflexes, and other indications in the area affected by the compressed nerve root; positive findings in the brachial plexus traction test (Eaton test) or neck compression test (Spurling test); cervical X-ray or CT imaging demonstrating narrowing of the nerve root canal.

Inclusion criteria: Inclusion requirements include patients who meet the above diagnostic criteria and are between the ages of 18 and 60, regardless of gender, have not received other treatment in the last three months, and demonstrate good compliance and willingness to participate in the study by signing the informed consent form.

Exclusion criteria: patients with CSR resulting from trauma or other causes, as well as patients with other types of cervical spondylosis such as myelocytic, sympathetic, and vertebral artery types. Patients with cognitive dysfunction or mental illness, severe cardiovascular, cerebrovascular, liver, or kidney dysfunction, and pregnant or lactating women were also excluded. Patients who were unwilling or unable to cooperate or complete the course of treatment due to other reasons were excluded. Additionally, those who had participated in any drug clinical trials in the six months prior to screening or were deemed unsuitable for the study by the researchers were excluded.

When it comes to the safety of subjects, participation in the study must be stopped as determined by the investigator if any of the following conditions arise: exacerbation of symptoms, occurrence of serious adverse events (such as pain, broken needle, fainting during acupuncture treatment, or infection), poor compliance, and the like.

Interventions

The study group underwent FSN combined with Kinematic acupuncture treatment using medium-sized disposable needles, produced by Nanjing Paifu Medical Technology Co., Ltd. During treatment, patients were seated and MTrP points and affected muscles were identified in the neck, shoulder, and forearm muscles.²¹ Procedure: To begin, identify the patient's MTrP point and mark the needle entry point 5–10cm away from it. Then, thoroughly disinfect and sterilize the skin at the needle entry point. Proceed by selecting a disposable needle and swiftly piercing the skin at an angle of 15–20 degrees. Once inserted, manipulate the needle back and sway for 5 minutes using the needle point as a fulcrum. During this time, the patient should engage in reperfusion therapy (passive resistance exercise) under the guidance of the doctor. After 3–5 treatments in each affected area, the patient should stand up and perform active exercises such as cervical spine forward flexion and extension, left and right rotation, left and right lateral flexion, arm lifting, and shoulder lifting. Once the pain is significantly relieved or localized muscle stiffness has subsided, the needle core can be safely withdrawn. Place a hose under the skin and secure it with a transparent dressing. The patient should be advised on precautions to take to keep the tube in place and rest as needed. The hose can be removed four hours later by a qualified healthcare provider. Treatment should be repeated once every other day, for a total of three sessions in one course. Two courses are recommended for optimal results.

The control group received electroacupuncture treatment using stainless steel needles that were 0.30×25mm (1 inch) or 0.30×40mm (1.5 inches) in size with Tianzhu, Fengchi, Jianjing, Binao, Quchi, Hegu and Jiaji acupoints corresponding to the cervical vertebrae segment. The steps were as follows: Sterile disinfection treatment was carried out on the acupoint local skin, and millineedles were inserted to achieve "Deqi." The G6805-2A electronic acupuncture treatment instrument was used for 10 minutes in dense wave mode followed by 20 minutes in disperse-dense wave mode with current intensity tolerated by the patient. Treatment was administered every other day for a total of three times per course. Two courses of treatment were observed. A one-month telephone follow-up was conducted after the treatment ended.

To evaluate the efficacy of both patient groups at three points in time, namely before treatment, immediately after treatment, and after follow-up.

Outcome Measures

Main Outcome Measures

The study utilized various outcome measures to evaluate the effectiveness of the treatment. The Visual analogue scale (VAS),^{27,28} Northwick Park (NPQ),²⁹ and total effective rate were the primary measures. Patients were instructed to use the VAS score to indicate the severity of their pain on a 10cm ruler, where 1cm equaled 1 point. The higher the score, the more severe the pain. The NPQ score, which reflects the quality of life of patients with neck pain, also indicated the severity of the pain. The total effective rate was calculated in accordance with the "Standard for diagnosis and efficacy evaluation of traditional Chinese medicine syndromes and diseases"²⁶ the Total Effective Rate = [number of (cure cases + remarkably effective cases + effective cases) / total number of cases] × 100%.

Secondary Outcome Measures

The Neck Disability Index (NDI),³⁰ Tanaka Yasuhisa symptom scale(TY),³¹ SF-36 mental component summary,³² Handnumbness score, Analgesic effect time and Relieve duration were used as secondary outcome measures. NDI measured cervical spine dysfunction, while TY assessed the severity of symptoms, signs, and hand function. The SF-36 scale assessed the quality of life of respondents, the Hand-numbness score reflected the degree of numbness experienced by patients, the scoring method for the Hand-numbness score was the same as that used for the VAS score. The Analgesic effect time recorded the time required from the start of treatment until the patient felt pain relief, and Relieve duration recorded the duration of pain relief after the patient received treatment, the data were continuously measured for a period of 7 days, and the average value of the 7-day period was utilized for data analysis.

Sample Size

Samples were collected from patients in both the ward and outpatient of Acupuncture and Rehabilitation Department of the First Affiliated Hospital of Guangzhou University of Traditional Chinese Medicine between February 2023 and July 2024. Sample estimation was carried out using the following equation: $n1=n2 = (U\alpha + U\beta)2 \times P(1 - P) / (P1 - P2)2$, with P= $(P1 \times n1 + P2 \times n2) / (n1 + n2)$, P indicates the Total Effective Rate, P1 indicates the effective rate of study group, P2 indicates the effective rate of control group. For our study, we chose α =0.05, which corresponds to a probability of type 1 error (U α =1.960), and β =0.2, which corresponds to a probability of type 2 error (U β =0.842). Referencing previous literature findings,³³ if n1= 41, P1= 95.12%, n2= 40, P2= 80%. Combining the two groups, the total effective rate of P was 88%, and the minimum sample size for each group was determined to be 36, factoring in the potential maximum shedding rate of 20% and considering constraints around time, funding, and minimum sample size. Ultimately, we selected a final sample size of 80 cases.

Randomisation

Patients who met the inclusion criteria were recruited and sequentially numbered from 1 to 80 in the order of their visit and randomly assigned to two groups using statistical software SPSS 26.0, with each group comprising 40 patients (Y. L and W. H), and then made a card and place it inside an opaque, sealed envelope (Q. J). Write the corresponding number on the outside of the envelope (L. S). Label the patients based on their treatment and hand them the envelope with the matching number (G. J). This will determine their corresponding random number and group.

Statistic methods

Statistical analysis of the data was performed using SPSS 26.0 (IBM, USA). The data were tested Normal Distribution Test, and baseline differences between groups were analyzed using the homogeneity of variance method. For quantitative data (such as height, weight, age and scores in this study), Mean \pm SD deviation was used, and homogeneity of data was determined by Independent Sample *t*-test. When there was non-conforming homogeneity of variance, Satterthwaite *t*-test was used. Quantitative data that did not meet the normal distribution were expressed through median and interquartile distance ([M (IQR)]), and the Wilcoxon signed rank test was used for nonparametric testing of differences between groups, the Mann–Whitney *U*-Test was used for nonparametric testing of differences between two groups. Qualitative data were expressed as a percentage (the Total

Effective Rate), and the Chi-square Test was utilized to compare the differences between the two groups. It indicates that there is a statistically significant difference between the two groups when P < 0.05.

Results

Participant Flow and Recruitment

The study evaluated 181 patients for a diagnosis of CSR, with 80 of them considered for inclusion. During the study, 117 patients were excluded (Figure 1). Finally, the data of 79 patients were analyzed, of which 39 were in the test group and 40 in the control group. One patient withdrew early due to being unable to tolerate the pain during the FSN course. Our study recruited 80 patients diagnosed with CSR from the Acupuncture and Rehabilitation Department of the First Affiliated Hospital of Guangzhou University of Chinese Medicine, between Feb 21st 2023 to July 21st 2024. And a follow-up survey was conducted two weeks after the end of the treatment.

Baseline Characteristic

There were no significant differences in general data (gender, age, height, weight, disease duration, and cervical joint mobility³⁴) between the treatment and control groups (P>0.05). Furthermore, the clinical data between the two groups were comparable (refer to <u>STable1</u>).

Numbers Analysed

For study group, 39 participants included in analysis, for control group were 40. The analysis was by original assigned groups (Figure 1).

Outcomes and Estimation

Comparison of the Total Effective Rate Between the Two Groups

Table 1 presents a comparison of the total effective rate between the study and control groups. The study group showed a better overall efficacy at total effective rate of 97.44%, 95% CI: [0.865, 0.999] (38/39) compared to the control group at 75.00%, 95% CI: [0.588, 0.873] (30/40). The difference was statistically significant.

Comparison of the Scoring Results Between the Two Groups

Prior to treatment, there were no significant differences (P > 0.05) in VAS, NPQ, NDI, TY, SF-36, and hand numbness scores between the two groups, as demonstrated by <u>STables 2</u> and <u>3</u>. After the treatment, both groups experienced significant improvement (P < 0.05), which indicated that both groups were effective (Table 2 and Figure 2). The study group exhibited considerable progress in all scores compared to the control group, with a statistically significant difference (P < 0.05). Specifically, concerning SF-36 scores, the study group surpassed the control group in elevating the scores for bodily pain, vitality, social function, and health transition, with a significant difference (P < 0.05). Physical functioning, general health, role emotional, and mental health scores, however, did not differ significantly (P > 0.05), as illustrated by Figure 3 and Table 3. Moreover, regard to Analgesic effect time, the effective time of the treatment in study group was shorter than that in control group, with a statistically significant difference (P < 0.05). For Relieve duration, Although the duration of remission in control group was relatively longer than that in study group, it did not differ significantly (P > 0.05)(Figure 4 and Table 4).

The results of the follow-up survey showed no significant differences (P>0.05) in VAS, NPQ, NDI, and TY scores between pre- and post-treatment scores within the group (refer to <u>STable 2</u>). This suggests that the therapeutic effects of both treatments on CSR pain symptoms and functional impairments did not decline significantly after treatment completion and remained stable However, the total SF-36 scores recorded post-treatment improved further during follow-up, indicating the continued betterment of patients' overall health status (refer to <u>STable 2</u>-SF-36 total score), and this difference was statistically significant. Moreover, the study group exhibited greater improvement in VAS, NPQ, NDI, TY, and SF-36 total score than the control group during follow-up (refer to <u>STables 2</u> and <u>3</u>). However, for hand numbness score, the situation differed. In the study group, the difference between follow-up and treatment results was statistically significant (t_3 Study group=-2.364, P_3



Figure I Process diagram of a randomized controlled trial of the efficacy of Fu's Subcutaneous Needling combined with Kinematic acupuncture for treating Cervical Spondylotic Radiculopathy.

Study group=0.023, P_3 Study group<0.05), while in the control group, it was not significant (t_3 Control group=1.778, P_3 Study group=0.083, P_3 Study group>0.05) (refer to STable 2-Numbness).

Harms

The potential harms and adverse events that arose in this trial include: a. pain resulting from needle puncture; b. needle breakage within the skin or body; c. syncope during acupuncture insertion; d. bleeding or subcutaneous

Group	Case	Recovery Rate (n, %)	Remarkable Rate (n, %)	Good Rate (n, %)	Non-Response Rate (n, %)	Total Rate (n, %)
Study group	39	4 (10.25)	8 (20.51)	26 (66.67)	l (2.56)	38 (97.44)
Control group	40	I (2.50)	5 (12.50)	24 (60.00)	10 (25.00)	30 (75.00)
χ ²						8.293
Р						0.004

Table I Comparison of Total Effective Rates Before and After Treatment Between Both Groups

 Table 2 Comparison of the Scoring Indicators Between the Two Groups (Mean±SD)

	Study Group (n=39)	Control Group (n=40)	95% CI	t	Ρ	
VAS						
Before	6.41±0.94	6.23±0.92	[-0.231, 0.601]	0.886	0.378	
After	2.31±1.20*	3.45±1.01*	[-1.638, -0.647]	-4.589	0.001	
Follow-up	2.31±0.92*	3.35±0.98*	[-1.468, -0.617]	-4.878	0.000	
NPQ						
Before	27.64±5.52	29.31±3.88	[-3.801, 0.461]	-1.560	0.123	
After	14.10±6.12*	19.65±4.42*	[-7.939, -3.162]	-4.627	0.000	
Follow-up	13.67±5.34*	19.65±4.33*	[-8.155, -3.800]	-5.467	0.000	
NDI						
Before	18.51±3.49	19.73±3.26	[-2.732, 0.291]	-1.608	0.095	
After	8.83±3.20*	13.06±3.35*	[-5.699, -2.759]	-5.727	0.000	
Follow-up	9.26±3.13*	13.23±3.25*	[-5.395, -2.530]	-5.510	0.000	
TY						
Before	14.49±1.39	13.63±2.46	[-0.036, 1.760]	1.912	0.060	
After	18.23±1.14*	17.00±1.50*	[0.633, 1.828]	4.101	0.000	
Follow-up	18.21±1.00*	16.95±1.57*	[0.663, 1.847]	4.224	0.000	
Numbness						
Before	1.26±0.68	1.26±0.68	[-0.286, 0.249]	-0.138	0.890	
After	0.54±0.60	0.88±0.40*	[-0.565, -0.108]	-2.929	0.004	
Follow-up	0.67±0.66*.**	0.80±0.46	[-0.389, 0.122]	-1.038	0.302	

Note: *The difference was statistically significant compared with the pre-treatment results in the same group (P<0.05), **The difference was statistically significant compared with the post-treatment results in the same group (P<0.05).

hematoma; e. peripheral nerve damage caused by needle puncture; f. infection during the course of tube indwelling period. Apart from one woman in the study group who withdrew from the trial due to pain intolerance, no evident harms or adverse reactions were observed in the remaining patients.



Figure 2 Line chart for comparison of scoring indicators before and after treatment between the two groups. Note: *The difference was statistically significant (P<0.05).



Figure 3 Histogram for comparing the scoring indicators before and after treatment between the two groups (SF-36).

Discussion

The proper curvature and movement of the cervical spine rely heavily on the strength and tone of the neck muscles. A decline in these qualities can result in abnormal motion and curvature of the spine, which negatively impact blood circulation and nutrient metabolism, as well as accelerating the pain of neck.^{8,9} This, in turn, can worsen cervical spine dysfunction. For this reason, it's crucial to improve the soft tissue tension surrounding the cervical spine and restore its physiological curvature in order to reduce pain and nerve root compression symptoms.

SF-36 score	Study Group (n=39)	Control Group (n=40)	95% CI	t	P
Physical functioning					
Before	72.23±3.42	72.00±1.28	[-4.722, 5.184]	0.094	0.925
After	76.18±3.77*	75.25±2.02*	[-3.779, 7.138]	0.622	0.537
Follow-up	76.05±3.54	75.20±1.99	[-3.574, 6.677]	0.612	0.544
Role-physical			•		
Before	73.51±5.36	73.90±0.96	[-2.100, 1.326]	-0.450	0.654
After	78.97±6.23*	77.60±2.13*	[-0.700, 3.449]	1.319	0.191
Follow-up	78.54±6.04* **	77.08±1.69*.**	[-0.513, 3.440]	1.474	0.145
Bodily pain			·		
Before	45.38±12.11	40.50±18.39	[-2.110, 11.879]	1.391	0.168
After	79.87±8.55*	69.38±13.97*	[5.293, 15.700]	4.017	0.001
Follow-up	79.62±7.20	68.25±13.52	[6.495, 16.236]	4.647	0.000
General health			•		
Before	46.05±4.64	45.85±4.08	[-1.753, 2.156]	0.205	0.838
After	50.77±4.68*	49.13±4.13*	[-0.333, 3.622]	1.656	0.102
Follow-up	50.62±4.74	49.08±4.13	[-0.449, 3.530]	1.542	0.127
Vitality			•		
Before	64.44±3.50	63.80±4.73	[-1.231, 2.502]	0.678	0.500
After	70.00±3.52*	65.10±2.74	[3.487, 6.313]	6.905	0.000
Follow-up	69.92±3.59	65.10±2.73	[3.397, 6.250]	6.732	0.000
Social functioning					
Before	70.63±6.49	69.73±1.73	[-1.219, 3.017]	0.845	0.401
After	80.11±8.27*	75.40±4.95*	[1.668, 7.754]	3.083	0.003
Follow-up	80.88±8.18* **	75.60±5.08* **	[2.239, 8.322]	3.457	0.001
Role emotional					
Before	71.28±5.48	69.80±3.84	[-0.632, 3.596]	1.396	0.167
After	77.69±4.93*	76.03±3.39*	[-0.224, 3.558]	1.756	0.083
Follow-up	81.79±4.92* **	78.80±3.47* **	[1.090, 4.899]	3.131	0.002
Mental health					
Before	68.92±6.68	66.90±5.18	[-0.651, 4.697]	1.506	0.136
After	83.41±7.40*	80.53±6.41*	[-0.215, 5.985]	1.853	0.068
Follow-up	83.95±7.32* **	81.40±6.36* **	[-0.519, 5.617]	1.654	0.102

Table 3 Comparison of the SF-36 Score Indicators Between the Two Groups (Mean±SD)

(Continued)

SF-36 score	Study Group (n=39)	Control Group (n=40)	95% CI	t	Ρ
Health transition					
Before	72.44±22.80	64.38±25.88	[-2.874, 18.966]	1.468	0.146
After	83.33±18.44*	68.13±24.01*	[5.600, 24.817]	3.152	0.002
Follow-up	78.21±18.30* *	68.13±24.01*.**	[0.498, 19.662]	2.095	0.039
Total score					
Before	512.45±34.37	502.48±28.63	[-4.189, 24.128]	1.402	0.165
After	597.00±34.64*	568.40±25.61*	[14.983, 42.233]	4.181	0.000
Follow-up	601.37±32.31*	570.50±25.81*	[17.782, 43.952]	4.697	0.000

Table 3 (Continued).

Note: *The difference was statistically significant compared with the pre-treatment results in the same group (P<0.05), **The difference was statistically significant compared with the post-treatment results in the same group (P<0.05).

FSN therapy for CSR targets the affected muscle (Figure 5). During the therapy, the needle insertion and swaying manoeuvre creates strong mechanical stimulation on the affected and surrounding connective tissues.²¹ This traction force helps relieve inflammatory adhesions, reduce inflammation, and enhance reperfusion therapy. By repeatedly relaxing and contracting the affected muscle, as well as indwell the hose at last, FSN therapy helps engorge it, improve its ischemic and hypoxia state, and ultimately prolong stimulation for better results. Studies indicate that FSN's therapeutic mechanism is closely linked to the efficient conduction of bioelectricity within loose connective tissue.^{10,21,35,36} The swaying motion generates positive piezoelectricity, changing the liquid crystal nanostructure in the subcutaneous loose connective tissue.^{37,38} The bioelectric stimulation released by positive piezoelectricity produces a reverse piezoelectric effect when it reaches a specific lesion site via loose connective tissue. This effect modifies the local ion channel state, permeability of cell membranes, regulates cell function, alleviates muscle pain, and restores muscle function. Additionally, mechanical traction stimulates nerve endings present in the subcutaneous fascial layer, modulates pain, and improves local capillary and lymphatic circulation.^{39,40} In addition, it has also been proposed that FSN may activate the immune system's repair mechanism by stimulating it.²⁵ However, more research is still necessary to confirm this proposal.

The study reveals that the treatment plan for the study group demonstrated notable effectiveness in alleviating neck pain, as well as relieving upper limb and finger pain caused by CSR, with shorter consuming time of analgesic effect and



Figure 4 Comparison of the time indicators between the two groups.

	Study Group (n=39)	Control Group (n=40)	95% CI	t	P
Analgesic effect time	0.97±0.63	2.32±0.12	[0.870, 1.124]	-10.062	0.001
Relieve duration	II.54±0.57	12.08±0.72	[2.094, 2.560]	-0.582	0.562

Table 4 Comparison of the Time Indicators Between the Two Groups (Mean±SD)

long-lasting, non-recurrent effects in comparison to the control group. Moreover, it demonstrates a positive impact on enhancing neck and upper limb activity function, as well as daily entertainment and social activities. Nevertheless, the treatment's impact on diminishing hand numbness was moderately satisfactory, and despite demonstrating good efficacy post-treatment, it was challenging to maintain during follow-up, hinting towards patients possibly relapsing. Besides, the duration of analgesia in study group was not better than that in control group, suggesting that the treatment in study group does not have the advantage of extending the duration of analgesia, which indicated that the study group, despite exhibiting superior and faster efficacy, still maintained comparable duration of efficacy to the control group.

The overall superior efficacy of FSN therapy, as observed in this study, is potentially attributable to several factors. Firstly, despite the comparable duration of acupuncture sessions in both electroacupuncture and FSN (FSN: 3–5 treatments in each affected area, 5 minutes each; electroacupuncture: 25 minutes), the FSN therapy incorporates a 4-hour indwelling catheter post-needle extraction to consolidate and sustain the therapeutic effect. In contrast,



Figure 5 (A-D) Affected muscles.

electroacupuncture lacks this extended dwell time, resulting in more durable efficacy for patients undergoing FSN. Secondly, FSN therapy is complemented by the patient's passive resistance movements, which differ significantly from the resting state maintained during electroacupuncture sessions. These active limb movements facilitate accelerated lymphatic and blood circulation in the affected areas, thereby alleviating pain and muscle tension caused by poor local blood flow and restoring muscle balance. Additionally, the choice of needles in both treatments varies significantly. The use of a thicker, firmer, and hollow long needle $(0.60 \times 52 \text{ mm})$ for FSN, as opposed to the thinner needle $(0.30 \times 25 \text{ mm})$ or 0.30×40 mm) used in electroacupuncture, leads to a broader stimulation and therapeutic range during acupuncture manipulation. Consequently, FSN can more rapidly improve the local microcirculation affected by nerve root compression and yielding therapeutic outcomes. Therefore, Compared to traditional electroacupuncture therapy, FSN therapy has a more comprehensive treatment range and stronger, longer-lasting stimulation, which effectively improves affected muscles. Originally, the reperfusion technique can be regarded as an innovative therapy of Kinematic acupuncture. FSN combined with Kinematic acupuncture promotes recovery by accelerating blood circulation around ischemic tissues through continuous contraction and relaxation compared to a relatively stationary state of the body. While the therapeutic efficacy of FSN has been substantiated, it is imperative to acknowledge that in instances of severe nerve compression, surgical intervention remains the primary treatment option, notwithstanding the high risks, costs, and potential for recurrence typically associated with surgery. Such surgical treatments should be undertaken without delay. In these cases, FSN therapy and other conservative therapies are more appropriately reserved for patients who are not eligible for surgery or can be utilized as complementary therapies to surgical treatment.

Above all, the study still has limitations, such as a lack of more objective efficacy indicators such as serum inflammatory factor levels and imaging changes (CT, MR or X-ray), and the Kinematic acupuncture method not quantify each active movement frequency and duration. Additionally, TCM typing for the included patients was not detailed enough. Therefore, this study still requires further detailed research in the future. During the follow-up period, the reasons that caused the recurring hand numbness symptoms in the study group remained unclear. It is necessary to conduct further research on the limitations of FSN therapy or the potential errors attributed to the insufficient sample size.

Conclusion

The study's findings demonstrate that the utilization of FSN combined with Kinematic acupuncture and electroacupuncture, both of them can effectively alleviate symptoms in CSR patients, approach results in pain relief and improved numbness. Notably, FSN combined with Kinematic acupuncture produced superior therapeutic outcomes, serving as a valuable clinical reference for treating CSR. Therefore, the study results have practical application in clinical settings.

Abbreviations

FSN: Fu's Subcutaneous Needling; CSR: Cervical Spondylosis Radiculopathy; MTrP: Myofascial trigger point; VAS: The Visual analogue scale; NPQ: Northwick Park; NDI: The Neck Disability Index; TY: Tanaka Yasuhisa symptom scale, SF-36: SF-36 mental component summary.

Data Sharing Statement

All data sets and research materials associated with this study have not been archived in any repositories or websites. However, interested parties may obtain these materials from the corresponding author upon making a reasonable request.

Ethics Approval and Consent to Participate

This study has obtained informed consent from all participants to participate in the clinical trial, and its protocol was reviewed and approved by the Ethics Committee of the First Affiliated Hospital of Guangzhou University of Chinese Medicine in Sep 2022 (No. K-2022-080). Additionally, the study was registered with the Chinese Clinical Trial Registry in Feb 2023 (No. ChiCTR2300068507).

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors declare no competing interests in this work.

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