JRSR 12 (2025) 45-52

Journal of Rehabilitation Sciences and Research

Journal Home Page: jrsr.sums.ac.ir

Original Article

The Effectiveness of Electroacupuncture on Functional Status, Symptom Severity, Pain, and Grip Strength in Patients with Carpal Tunnel Syndrome: Study Protocol for a Randomized Sham-Controlled Trial

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ARTICLE INFO

Article History:
Received: 21/11/2023
Revised: 29/01/2024
Accepted: 22/04/2024

Keywords:
Carpal Tunnel Syndrome (CTS)
Electroacupuncture (Ele-Acu)
Functional status
Grip strength
Neurodynamic technique (NDT)
Pain
Symptom severity

Please cite this article as:
Lotfi H, Pahlevan Sabagh AR, Tabatabaiee A, Kajbafvala M, Ashoori M, Yassin M. The Effectiveness of Electroacupuncture on Functional Status, Symptom Severity, Pain, and Grip Strength in Patients with Carpal Tunnel Syndrome: Study Protocol for a Randomized Sham-Controlled Trial. JRSR. 2025;12(1):45-52. doi: 10.30476/jrsr.2024.100859.1450.

ABSTRACT

Background: Carpal Tunnel Syndrome (CTS) is the most common peripheral nerve entrapment condition, impairing median nerve function at the carpal tunnel level. Previous studies indicate a strong patient preference for non-surgical treatment. While some evidence suggests electroacupuncture may promote nerve regeneration and improve functional outcomes, findings remain inconclusive. This study aims to assess the impact of electroacupuncture on symptom severity, functional status, pain, and grip strength in patients with mild to moderate CTS.
Methods: This is a protocol for a randomized, sham-controlled trial. Thirty-eight patients diagnosed with CTS will be randomly assigned to either a treatment group receiving electroacupuncture or a control group receiving sham electroacupuncture. Both groups will undergo ten sessions over five weeks (twice weekly) and receive neurodynamic techniques as standard care. Outcome measures—symptom severity, functional status, pain, and grip strength—will be evaluated at baseline, after the fifth session, 48 hours after the tenth session, and two months post-treatment. This trial is registered at https://www.irct.ir/ (IRCT20191208045652N5) as of 7/12/2022.
Results: Ultimately, the results of this study will provide evidence regarding the efficacy of Electroacupuncture combined with NDT techniques on Symptom Severity, Functional Status, Pain, and Grip strength in patients with Carpal Tunnel Syndrome.
Conclusion: This study will provide insights into the efficacy of electroacupuncture as a treatment for CTS.

Introduction

Carpal Tunnel Syndrome (CTS) is the most common peripheral nerve entrapment condition [1, 2]. A 2018 study reported a CTS prevalence of 17.53% in Iran [3, 4]. Women are more likely to experience CTS than men, with prevalence increasing up to fourfold in females with age [5]. The high prevalence of CTS results in substantial annual healthcare costs [6] and can also lead to physical, psychological, and economic consequences for both individuals and society [7]. CTS is typically classified as mild, moderate, or severe; its symptoms include tingling, pain, or numbness in the distal median nerve distribution (thumb, middle finger, and radial side of the index finger) [8, 9], along with hand dysfunction [10-13]. In severe cases, CTS can lead to atrophy of the thenar muscles [14].

CTS is a neuropathy caused by traction and compression of the median nerve at the carpal tunnel, which is bordered

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by the carpal bones and the transverse carpal ligament [15]. Observational studies have shown that increased pressure within the carpal tunnel alters the microvascular structure of the nerve, reducing endoneurial blood flow and leading to edema and hypoxia. These changes stimulate angiogenic factors, including hypoxia-inducible factor 1-alpha (HIF-1α) and vascular endothelial growth factor (VEGF), ultimately resulting in axonal degeneration and median nerve dysfunction [15].

Depending on the severity and specific symptoms of CTS, both invasive and non-invasive treatments are viable options [16]. Researchers advocate for prioritizing non-surgical treatments initially, as studies indicate that approximately 61% of patients prefer non-surgical approaches over surgical interventions [17].

Electroacupuncture (Ele-Acu) involves gentle electrical stimulation passed between two needles [18]. Research has identified several mechanisms through which Ele-Acu may relieve pain, including stimulating local inflammatory and immune responses, such as adenosine release and the increase of opioid peptide [19]. These systemic effects are linked to decreased pain and improved functional outcomes [20, 21].

Li et al. indicate that Ele-Acu may also improve electrophysiological parameters, such as distal motor latency, compound muscle action potential (CMAP) amplitude, sensory nerve conduction velocity (SNCV), and sensory nerve action potential (SNAP) amplitude [22]. Some research even suggests Ele-Acu may promote nerve regeneration and functional recovery [22]. For example, Fi et al. demonstrated enhanced facial nerve recovery in rabbits with Ele-Acu, including stimulated nerve growth, reduced apoptosis, and decreased inflammatory cytokines, ultimately restoring facial muscle function [23]. Among CTS patients, Chung et al. found improvements in symptoms, disability, dexterity, and pinch strength with Ele-Acu [18]. A 2017 randomized controlled trial further suggested long-term symptom relief, as Ele-Acu enhanced plasticity in the primary somatosensory cortex (S1) [24].

Neurodynamic Technique (NDT) is a nerve mobilization method that applies targeted forces to nerve structures through specific body positions and movements [25]. Research has shown that, in CTS, the median nerve's longitudinal and transverse excursion is often restricted [26]. By enhancing nerve gliding, NDT can help restore the dynamic balance between nerve movement and surrounding tissues, improve neurophysiological function, and alleviate symptoms in patients [27]. Due to its efficacy, NDT is considered a standard treatment approach for individuals with CTS [10].

Previous assessments of the efficacy of Ele-Acu in treating CTS have shown mixed results, likely due to varied methodologies across studies [22]. This variability has made drawing clear conclusions regarding Ele-Acu's effectiveness challenging. Nonetheless, its potential as a component of CTS treatment warrants further exploration through rigorous, randomized trials. This study is the first to evaluate Ele-Acu combined with NDT as a standard treatment compared to sham Ele-Acu.

This double-blind, randomized controlled trial with a sham intervention is designed to minimize bias. The sham Ele-Acu will be performed at therapeutic acupoints without skin penetration or electrical stimulation, a widely used approach that provides an adequate blinded comparison [28]. Both groups will receive NDT as the baseline standard treatment.

The primary objective of this study is to evaluate the effectiveness of Ele-Acu on functional status and symptom severity in patients with CTS. The secondary objective is to assess the impact of Ele-Acu on pain and grip strength in this population.

Material and Methods

Study Design

This study is a two-arm, parallel-group, double-blinded, randomized, sham-controlled superiority trial.

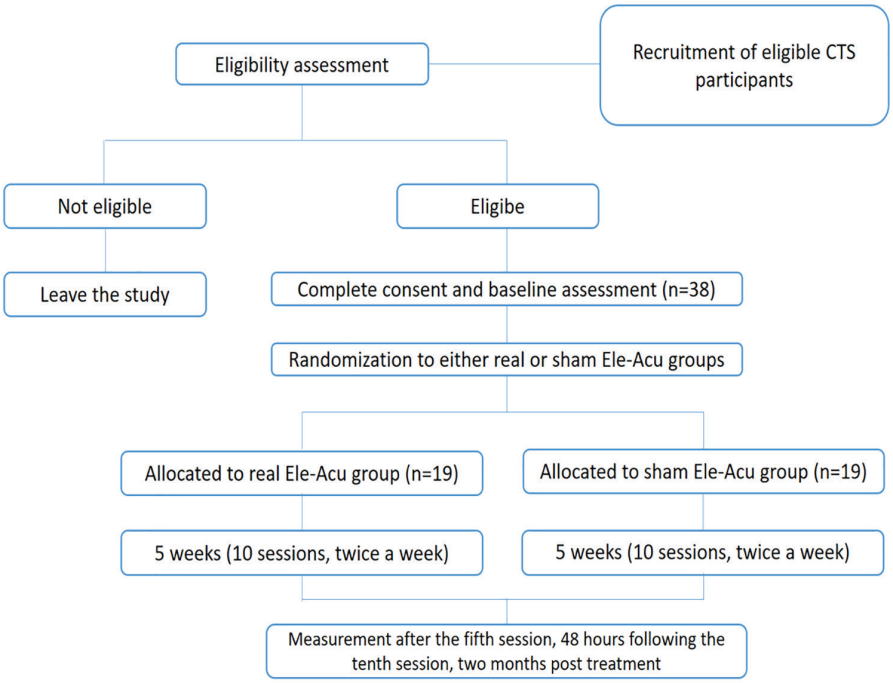

Figure 1: Trial Design

Figure 1 presents a CONSORT flow diagram, illustrating participant progression through each study stage.

Study Setting

CTS patients referred to the Orthopedic Clinic at Hazrat-e Rasool Hospital in Tehran, Iran, will be recruited for this study.

Subjects

Participants with the following criteria will be included: 1. Adults aged 18-60 diagnosed with mild or moderate CTS by a hand and peripheral nerve specialist (APS) based on electro-diagnostic findings (nerve conduction velocity <50 m/s, motor latency >4 m/s, sensory latency >3.5 m/s); [11, 18, 27, 29], 2. History of numbness and pain in the lateral aspect of the palm and the lateral three-and-a-half fingers on the anterior hand surface within the last 6 months.[27, 29], 3. Positive results in both Phalen's test and Tinel's sign [18, 27, 29].

The exclusion criteria are as follows:

1. Muscular atrophy [29-31], 2. Pregnancy [29-31], 3. Prior decompression surgery [29, 31], 4. History of wrist trauma [31], 5. Diabetes mellitus [29-31], 6. Rheumatoid diseases [31], 7. Cervical radiculopathy [29-31], 8. Any contraindication for needling, such as local infection, bleeding tendency, or a history of needling shock [32], 9. More than two absences, including two consecutive sessions, 10. Participants' unwillingness to continue the study.

Eligibility Criteria for Assessor and Therapist

The assessor for this study will be a physiotherapist with at least two years of experience assessing CTS patients. To maintain objectivity, the assessor will be blinded to participants' group allocations.

The therapist responsible for administering treatments will be the first author (HL), a physiotherapist with three years of experience in NDT and Ele-Acu, who has undergone training and supervision by a certified physician.

Group Assignment

Eligible patients will be randomly assigned to one of two parallel groups: a real Ele-Acu group or a sham Ele-Acu group. Randomization will be conducted using block-balanced randomization with 4-character blocks containing letters A and B, with an allocation ratio 1:1. Patients assigned "A" will be placed in the real Ele-Acu group. In contrast, those assigned "B" will be placed in the sham group.

Randomization and group allocation will be conducted by an individual not involved in other aspects of the trial to ensure blinding and minimize bias. A separate therapist, also not involved in the trial, will prepare sequentially numbered, sealed, and opaque envelopes containing the allocation information.

An administrative staff member not part of the research team will manage patient enrollment, assign them to groups based on the predetermined sequence, and ensure each patient is placed in the appropriate treatment group without revealing the allocation to other research team members.

Blinding

This study is designed as a double-blinded trial to minimize bias. Neither the participants nor the examiner will know the participants' group assignment throughout the study. The therapist administering the interventions is responsible for concealing the participants' allocation to maintain blinding across all sessions.

Interventions

Experimental Group

Eight specific acupoints will be targeted on the affected hand: TW-5, PC-7, HT-3, PC-3, SI-4, LI-5, LI-10, and LU-5. Patients will be positioned supine. Following skin disinfection, the therapist will insert sterile 0.25x40 mm needles into these acupoints using a guide tube. Needle insertion depth will vary from 1 to 3 cm, depending on the thickness of each patient's wrist, hand, and forearm.

After insertion, the therapist will manipulate each needle until the patient reports sensations of soreness, numbness, or heaviness at the acupoints, indicating the arrival of *Deqi*. Once *Deqi* is achieved, electrical stimulation will be applied to four pairs of acupoints: TW-5 + PC-7, SI-4 + LI-5, LI-10 + LU-5, and HT-3 + PC-3. The SDZ-II electroacupuncture device will deliver a continuous 2–4 Hz wave at a tolerable intensity to the patient. Electrical stimulation will be maintained for 20 minutes before removing the needles (Figure 2) [18].

Control Group

For the sham Ele-Acu procedure, the therapist will disinfect the skin at the designated therapeutic acupoints. However, no skin penetration or electrical stimulation will be applied to maintain the blinding for this group. After positioning needles at the surface of the skin without insertion, they will remain in place for 20 minutes and then be removed, simulating the duration and appearance of real treatment without active intervention [28, 33].

Basic standard treatment: Both groups will receive

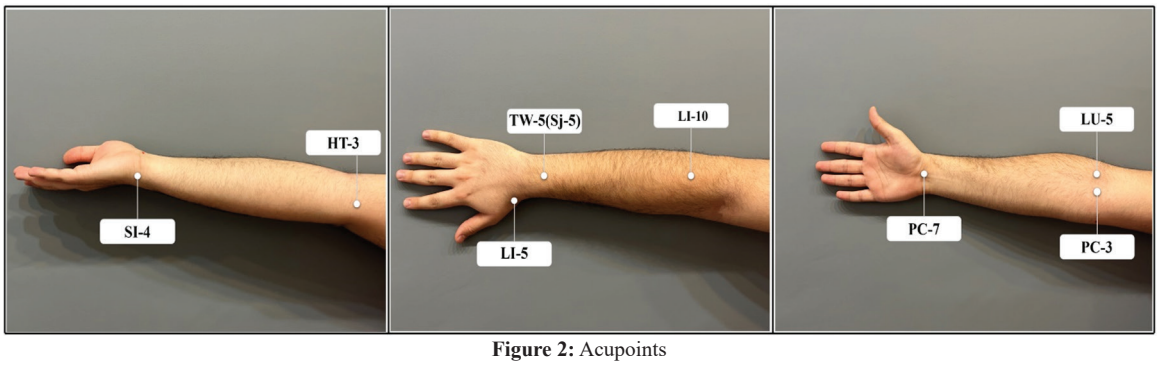

Figure 2: Acupoints

NDT as follows. Participants will lie supine with arms by their sides and head in a neutral position. The therapist will stand in stride, facing the cephalad and parallel to the patient, with the near hip close to the bed. The near foot will be positioned forward. The therapist's proximal hand will press on the bed above the patient's shoulder to prevent scapular elevation. The therapist's distal hand will hold the affected hand using a pistol grip, with the fingers wrapping around the patient's fingers distal to the metacarpophalangeal joints.

The following neurodynamic sequence will be used:

1) Glenohumeral abduction up to 90° in the frontal plane. 2) Glenohumeral external rotation to the available range. Further movement will be prevented at 90° in hypermobile participants. 3) Forearm supination. 4) Wrist and finger extension. 5) Elbow extension (Figure 3).

In this sequence, slider and tensioner techniques will be performed in proximal and distal directions as described below:

1) One-ended proximal slider mobilization: The therapist will extend the elbow in the mentioned position through mid-range with a large amplitude (Figure 4). 2) One-ended distal slider mobilization: This technique will be performed by extending the wrist with a large amplitude in mid-range (Figure 5). 3) One-ended proximal tensioner mobilization: This technique consists of a small amplitude of elbow extension at the end range (Figure 6). 4) One-ended distal tensioner mobilization: Wrist and finger extension will be performed with a small amplitude at the end range (Figure 7).

Both groups will receive these techniques as basic treatment, performing three sets of 20 repetitions each [31, 34]. These treatments will be administered twice weekly for five weeks, totaling ten sessions.

All participants will receive education on activity modification in the first session, including: 1) Reducing the duration, repetition, and force during activities of daily living (ADL). 2) Avoiding activities that require prolonged

Figure 3: Median neurodynamic techniques sequence, a) Starting position b) Arm abduction c) Arm external rotation d) Forearm supination e) Wrist and fingers extension f) Elbow extension.

Figure 4: One-ended proximal slider mobilization.

Figure 5: One-ended distal slider mobilization.

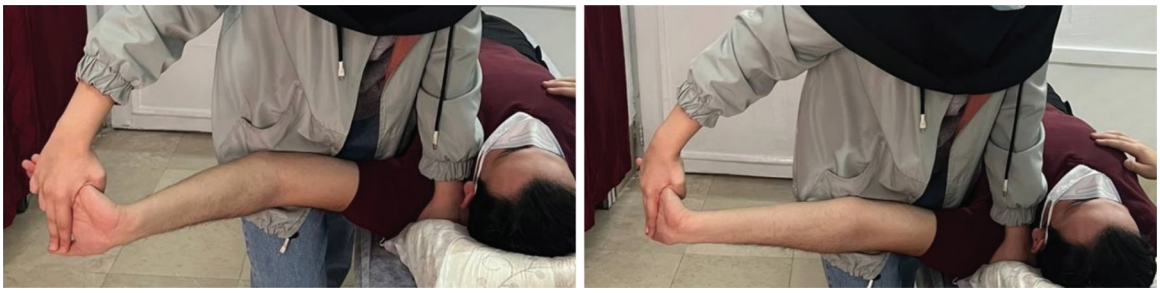

Figure 6: One-ended proximal tensioner mobilization.

Figure 7: One-ended distal tensioner mobilization.

Table 1: Participant timeline.

	Enrolment	Allocation	Study Period										Close-out
			Post-allocation										
TIMEPOINT	$-T_1$	0	t_1	t_2	t_3	t_4	t_5	t_6	t_7	t_8	t_9	t_{10}	t_{11}	T_{12}
ENROLMENT:														
Eligibility screen	X													
Informed consent	X													
Demographic questionnaire	X													
Allocation		X												
INTERVENTIONS:														
Group A (real electroacupuncture)			←									→		
Group B (sham electroacupuncture)			←									→		
ASSESSMENTS:														
Symptom Severity			X				X						X	X
Functional Status			X				X						X	X
Pain			X				X						X	X
Grip Strength			X				X						X	X

t_{11}: 48 hours following the tenth session. t_{12}: 2 months post-treatment.

and/or repetitive wrist bending. 3) Decreasing the number of activities that require repetitive pinch or grip [35].

Outcomes

Primary outcome measure: The primary outcome of this study will be the Boston Carpal Tunnel Questionaire (BCTQ), a scoring system for symptom severity and functional status of patients with CTS [36].

Secondary outcome measures: The secondary outcomes will include pain and grip strength.

Participant Timeline

Participants will be informed about the study's procedures and goals. First, the participants will sign a written informed consent form. Eligibility criteria will be assessed in the first session. Demographic information, including age, weight, height, sex, Body Mass Index (BMI), chronicity of carpal tunnel syndrome (CTS), dominant hand, and affected hand, will be recorded. The effectiveness of the treatment will be evaluated by an independent evaluator who does not know which patients

received the treatment and which did not. Assessments will be conducted at the beginning of the study, after the fifth treatment session, two days after the final session, and two months post-treatment. Following the initial evaluation, the intervention will commence and extend across ten sessions over five weeks. Each participant's involvement in the study will last approximately five weeks. A visual representation of the study's timeline is provided in Table 1.

Sample Size

The sample size was estimated using G*Power software version 3.1. The F-test and ANOVA were utilized as the family and statistical tests, respectively. According to the pilot study results, 38 participants (n=19 in each group) were needed for recruitment in the present study, considering an effect size of F=0.4, a 10% attrition rate, α=0.05, and a power of 80%.

Recruitment

CTS patients will be recruited from the Orthopedic Clinics of Hazrat-e Rasool General Hospital in Tehran, Iran.

Data Collection

Data collection will be conducted by a physiotherapist who is not part of the study and is unaware of patient allocation.

Primary Outcome

The Boston Carpal Tunnel Questionnaire (BCTQ) is divided into the Symptom Severity Scale (SSS) and the Functional Status Scale (FSS). The SSS comprises 11 questions, with responses ranging from one (mildest) to five (most severe). The overall score is determined by calculating the mean of all 11 scores. The FSS consists of eight questions that assess the difficulty of executing specific activities. The overall score for functional status is calculated as the mean of all eight questions. Consequently, a greater symptom severity or functional status score indicates worse symptoms or dysfunction [36]. This questionnaire was translated into Persian at Mashhad University of Medical Sciences. The reliability and validity of the translated version have been reported as 0.859 and 0.641 for the SSS and 0.878 and 0.701 for the FSS, respectively [37].

Secondary Outcomes

Pain will be assessed using the Numerical Pain Rating Scale (NPRS) (0=no pain, 10=maximum pain). Patients will be asked to indicate the most severe pain experienced in the previous 24 hours [38, 39].

Grip strength will be assessed using the Digital Handheld Dynamometer (CAMRY DIGITAL HAND DYNAMOMETER - 90 kg/200 lb). The dynamometer will be placed between the metacarpus and the second through fifth fingers during measurement. Participants will be asked to hold the dynamometer at their maximum strength for 10 seconds. The recorded values will be in pounds (lb). The measurement will be repeated three times, and the mean value of the three trials will be used for analysis [31].

Data Management

Each participant will complete the informed consent form and baseline demographic information form. Following the randomization process, we will print both primary and secondary outcomes on prefabricated paper forms for each participant. Participants will complete the BCTQ, and then the assessor will fill out the remaining forms related to all other outcomes. Additionally, all collected data will undergo a secondary review by a second assessor; if any unreasonable correlations are identified, a reassessment will be conducted, and any revised data will be retained. Each participant's data, including individual information, will be stored in a separate file on a personal computer. Ultimately, each participant's confidential data will be recorded in an Excel file with a unique code, which will be used for statistical analysis.

Statistical Methods

Statistical analysis will be conducted on a personal computer using STATA software for Windows, version 14.2 (StataCorp LLC), and SPSS, version 21.0 (IBM Corp). To assess the normal distribution of data, the following techniques will be employed: P-P plot analysis, comparison of mean and median, the Shapiro-Wilk test, histogram analysis, and skewness and kurtosis analysis of data distribution. If the data distribution is normal, parametric tests will be used to analyze the data before and after the intervention. In cases of non-normal distribution, the variable transformation will be the initial approach, particularly for primary outcome measurements. If data transformation is not feasible, non-parametric statistical tests will be applied.

ANOVA or ANCOVA tests will be used to assess between-group differences at each time interval. A mixed model ANOVA (repeated measures ANOVA) will be conducted to evaluate time effects, considering time as a fixed factor and groups as a random factor. Statistical tests will be conducted at a significance level of 0.05. To assess the intervention's effectiveness on each dependent variable, Cohen's d effect size will be calculated to compare the two treatment groups. Effect sizes will be interpreted as follows: 0.2=no/trivial effect, 0.2 to 0.5=small effect, 0.5 to 0.8=medium effect, 0.8 to 1.2=large effect, and 1.2 to 2=very large effect [40]. An intention-to-treat analysis will be performed to account for participants who drop out or do not follow the study plan.

Discussion

CTS is a common condition that affects median nerve function and leads to hand disability [7]. Although carpal tunnel release surgery has good long-term results for CTS treatment, it has certain disadvantages, including post-operative pain and weakness that can last for months [41]. Additionally, surgery incurs both direct and indirect costs associated with work absence post-surgery [42]. According to a previous study, 61% of patients opted for non-surgical treatment options [17]. While Ele-Acu has been suggested

as a safe and effective treatment for this population, further research is required to confirm these findings. Besides the potential effects of Ele-Acu on symptom severity, functional status, and pain, recent studies have shown that Ele-Acu may promote facial nerve regeneration in rabbits, reducing neuronal apoptosis and peripheral inflammatory responses, which in turn improves facial muscle function [23]. Therefore, this study is designed to evaluate the effectiveness of Ele-Acu combined with NDT on symptom severity, functional status, pain, and grip strength in patients with CTS.

Acknowledgment

We appreciate the patients generously dedicated their time and enthusiasm to participate in our study. We are also grateful to Sara Nazari for conducting the assessments and to Mahdi Akhgari for his assistance in preparing the figures.

Funding

The authors declare that they have no financial affiliations with any entities related to this research. The Iran University of Medical Science will support the study by providing the necessary facilities. This supervisory center will not participate in research activities, including study design, data collection, analysis, or dissemination of findings.

Conflict of Interest: None declared.

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