Effects of Cervical Manual Therapy Versus Conventional Physical Therapy on Clinical Outcomes in People With Carpal Tunnel Syndrome: A Study Protocol for a Randomized Controlled Trial

Milad Zarrin
Ahvaz Jundishapur University of Medical Sciences: Ahvaz Jondishapour University of Medical Sciences
maryam saadat (saadat.phd@gmail.com)
Ahvaz Jundishapur University of Medical Sciences: Ahvaz Jondishapour University of Medical Sciences
https://orcid.org/0000-0002-8337-0976
Mohammad Jafar Shaterzadeh
Ahvaz Jundishapur University of Medical Sciences: Ahvaz Jondishapour University of Medical Sciences
Davood Shalil Ahmadi
Ahvaz Jundishapur University of Medical Sciences: Ahvaz Jondishapour University of Medical Sciences

Study protocol

Keywords: Carpal tunnel syndrome, Cervical, Manual therapy, Physical therapy

Posted Date: June 7th, 2021

DOI: https://doi.org/10.21203/rs.3.rs-220385/v1

Abstract

Background

Carpal tunnel syndrome (CTS) is the most common entrapment neuropathy. A recent systematic review described limited or no evidence about the conservative interventions. Literature has expressed that more proximal area such as the cervical spine is involved in CTS. Therefore, the aim of this study is to examine the effects of combination cervical manual therapy and conventional physical therapy on pain, self-reported function, and electrophysiological findings in the management these patients.

Methods

This study will be a double-blind, parallel-group, randomized, controlled trial (RCT) in which carpal tunnel syndrome subjects randomize to either conventional or combined exercise groups. The conventional group take routine physical therapy treatments, while patients in combine exercise group receive cervical manual therapy plus routine physical therapy treatments. All patients receive 10 sessions of supervised intervention. The outcome measures included visual analogue scale (VAS), Boston Carpal Tunnel and DASH questionnaire, motor distal latencies and sensory nerve conduction velocity of median nerve. They obtain pre- and post-intervention.

Discussion

The findings of this study will provide knowledge about the comparison effectiveness of conventional physical therapy with and without cervical manual therapy on symptom severity, functional status, disability, velocity and latency median nerve in patients with CTS.

Trial registration

Iranian Registry of Clinical Trials, IRCT20201201049565N1. Registered on 15 December 2020.

Background

Carpal tunnel syndrome (CTS) is the most common compression neuropathy in the upper limb, which is caused by increased pressure on the median nerve at the wrist (1). The syndrome is characterized by pain, numbness, and tingling in the distribution median nerve (2). The prevalence of this syndrome is estimated at 2.7 to 14.4% in the general population and women are affected often twice more than men (3). Lost workdays, marked decline in performance due to this syndrome lead to high costs on society and the health care systems; Therefore, it is important to investigate effective methods in treating these patients.

American College of Surgeons Clinical Practice Guideline recommended conservative treatments, including physiotherapy for patients with mild to moderate symptoms (4). Previous studies have reported a variety of physiotherapy interventions in the management of these patients such as thermotherapy,

electrical stimulation, low power laser, magnet, ultrasound, manual therapy, and exercise therapy (5-9). A recent systematic review (2018), reported moderate evidence for them in short term but no improvements in symptom severity in long term (10). Besides, limited or low-quality evidence was found on the effectiveness of some of these interventions (5,11). This may be the reason that this conventional approach emphasis on localized treatments mainly focused on the hand.

There is evidence that the symptoms of people with carpal tunnel syndrome, especially mild to moderate, are not limited to the wrist area (12). More proximal areas such as the peripheral nerve at the pronator teres or intervertebral foramen are involved (13). An estimated 45% of people with CTS reported pain in the upper extremities (forearm, elbow, arm, or shoulder) and 14% pain in the neck (14,15). An association between the occurrence of carpal tunnel syndrome and trigger points in the upper trapezius and infraspinatus muscle has been found (16,17). Rincón et al demonstrated the cervical range of motion especially in the opposite direction to the symptomatic side were significantly reduced in women with CTS (17).

At present, a comprehensive form of management for such patients entails an approach combining proximal therapeutic interventions in the neck with distal conventional treatments that may need to be conducted. Little evidence has supported the effectiveness of this approach in decreased symptoms and improving pinch grip force in CTS condition (18). However, to the best of our knowledge, no study has assessed the efficacy of adding cervical manual therapy in comparison with conventional treatments that target only the carpal tunnel.

Hypothesis and aim:

Therefore, the purpose of this study to compare the effectiveness of conventional physical therapy with and without cervical manual therapy on median motor latency, sensory nerve conduction velocity, pain, and disability in people with carpal tunnel syndrome. The research hypothesized that cervical manual therapy would be more effective than conventional physical therapy treatment on improving the electrophysiological finding, pain, and disability in individuals with carpal tunnel syndrome.

Methods

Study design and setting:

The proposed trial is a double-blind, parallel-group, randomized control. This trial is reported according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 Statement. This trial will be conducted in the physical therapy clinic at Golestan Hospital, affiliated with Ahvaz Jundishapur University of Medical Science, Iran. The experimental design of this study is shown in Figs 1 and 2.

Participants:

Inclusion criteria will be aged range between 18 to 60, history of pain greater than twelve weeks, tingling, numbness, burning or pain in at least 2 of digits 1, 2, or 3, positive Phalen or Tinnel test or Carpal compression test, pain intensity at least a 4/10 on a Visual Analog Scale over the past 24 hours. A neurologist diagnoses carpal tunnel syndrome based on a nerve conduction study. Participants with mild to moderate damage to the median nerve include (mild: sensory nerve conduction velocity in the third digit-wrist segment <44 meters/second(m/s) and distal motor latency ≤4 milliseconds. moderate: sensory nerve conduction velocity in the third digit-wrist segment <44 m/s and distal motor latency >4 ms) (19).

Participants will be excluded if they have any sensory or motor deficit in either the ulnar or radial nerve, history of surgery, or injection in the wrist area. Presence of systemic diseases such as rheumatoid arthritis, fibromyalgia, diabetes mellitus, hyperthyroidism, or hypothyroidism. Also, the presence of conditions that might cause numbness in the hand, including cervical radiculopathy, cervical ribs, plexopathy, polyneuropathy, pregnancy. And history of neck, shoulder, or upper extremity trauma.

Ethical considerations and trial registration

This study was approved by the Ethics Committee of the Jundishapur University of Medical Science, Ahvaz, Iran (Approval number IR.AJUMS.REC.1399.727). This study was also registered at the Iranian Registry of Clinical Trials (registration number: IRCT20201201049565N1) on 15 December 2020. All participants that agree to attend this study will provide written informed consent.

Interventions

Participants in both group receive a conventional exercise program for two weeks, five times a week. It consist wrist splints(neoprene wrist splint tebosanat 31190), TENS (Novin, model 733x, Iran) to the wrist region for 20 min (20), phonophoresis of betamethasone valerate 0.1% ointment (using ultrasound Novin, model 215P, Iran. 3MHz, 5-cm probe, 1.5 W/cm, pulse 1:4, 10 min/ each session((21), and wrist joint mobilization (20).

Experimental group:

Patients in this group will receive cervical manual therapies. The interventions apply to the neck include manual cervical distraction, lateral glides, and poster- anterior pressure applied to the mid-cervical spine. Besides, patients in this group will be instructed to complete an exercise program for stretching neck muscles (the upper fibers of the trapezius muscle, upper fibers of the scalene muscles, and levator scapulae muscle) (see Appendix for details). All treatments were applied by a skilled and experienced physiotherapist in manual therapy approaches.

Outcome measures:

Outcomes will be assessed in random order at baseline before treatment and after completion of treatment sessions. Outcomes will be median nerve motor distal latency (mMDL) and median sensory

nerve conduction velocity (mSNCV) that measure by a neurologist. Other outcome measures were pain intensity, the Boston Carpal Tunnel Questionnaire, and the DASH questionnaire will assess by the physical therapist that will be blind to the group allocation.

Electrophysiological study of the median nerve:

The neurophysiological studies will be performed using a Tru trace 4 EMG system DEYMED electromyography device. At first, we will prepare the patients' hands by asking them to rest for 10 minutes at room temperature, 22-24 ° C. To record the mSNCV, an antidromic technique is used; Ring electrodes (4 cm apart) placed on the distal metacarpophalangeal and interphalangeal joints of the index finger at a standard distance of 14 cm from the active electrode. It is stimulated with supramaximal stimulation. To record the mMDL, the ground electrode will be placed on the dorsal of the wrist at the distance between the stimulating and active electrodes. After cleaning the skin to reduce resistance, the bipolar surface electrode at a distance of 8 cm is placed on the extensor pollicis brevis muscle so that the active electrode is on the muscle motor endplate and the reference electrode is on the metacarpophalangeal joint. It is stimulated to supramaximal stimulation (30% more than maximal stimulation) (22).

Pain:

Pain assessment was done using the visual analog scale. The person is asked to determine the average amount of pain that they felt in the previous week on line 100 mm long. The left end of this line (score zero) indicates the absence of pain and the right end (score 100) indicates the most severe pain imaginable (23).

Boston Carpal Tunnel questionnaire:

The Persian version of Boston Carpal Tunnel Questionnaire will be filled by every patient. This questionnaire consists of two parts: symptom severity scale (SSS) and the functional status scale (FSS). SSS section has 11 questions about the severity and frequency of symptoms and FSS contains 8 questions about usual hand-related tasks. Each item has 5 options and each option has a score from 1 to 5, with a score of 1 indicating the absence of symptoms and 5 indicating the presence of the most severe symptoms. To calculate the severity of symptoms and functional status, the average score in each section is calculated. Higher means show worse functional status and greater symptom severity. The Persian version of Boston scale is a valid and reliable tool for Iranian patients (24).

DASH questionnaire:

This questionnaire contains 30 questions about the symptoms and function of the upper limb. Each question has 5 options, the range of which from 1 means no difficulty and symptoms to 5 means the inability to perform the activity and the most severe symptoms. The final score is the sum of the scores in terms of 100, the increase of which is a sign of more involvement (score 100 means severe disability) and the decrease is a sign of less involvement (score 0 means no disability) of the upper limb. In addition

to 30 questions, there are two series of questions with 4 items that are optional to answer:1. sport/music component 2. work component. The validity and reliability of DASH has been evaluated in Iran, and the results showed that this questionnaire has high validity and reliability among the Iranian population (25).

Sample size:

The sample size was determined based on the primary outcome measure (changes in the Numeric Rating Pain Scale) in the study by Wolny 2019. Assuming a type, I error of 0.05, power of 80%, 21 patients require for each group. Considering attrition of 10%, we will include at least 24 patients for each group in this study. The length of the trial may need to be extended for achieving adequate participant enrolment to reach target sample size.

Assignment of interventions: allocation

Individuals who met the inclusion criteria will randomly be allocated to Group A (conventional physiotherapy) or Group B (a combination of conventional physiotherapy treatments with cervical manual therapy) using a computerized random allocation sequence with different block sizes. An independent statistician with no clinical involvement in the trial prepare it. The allocation will be concealed in an opaque, sealed envelope.

Implementation:

All eligible patients will guide to the baseline assessment. First, demographic characterizes of each patient are collected, then a research assistant opens the envelopes to reveal group allocation before starting the intervention for that patient. After that, each patient will be directed for treatment in the control group or experimental group. Outcomes measure pre and post intervention.

Blinding:

Participants and the outcome assessor will be unaware of assigning individuals to groups. The physiotherapist that will deliver the intervention, not be blinded to group allocation.

Data collection and management:

Data will be entered by one of research team members. They recheck by a different research member, Database available only for investigators. Personal information all patients protect during and after the trail. One independent professors (physical therapist) is responsible for reviewing of informed consents, the interests and safety of the trial subjects and monitoring the progress of the study. Any deviation from the protocol and adverse effect will reported to the Medical Ethics Committee of Ahvaz Jundishapur University of Medical Sciences.

Statistical methods:

Data will be analyzed using SPSS version 23.0. The normal distribution the data are determine by the Shapiro-Wilk test. Student's t-test will be used for comparison of baseline clinical characteristics of the two groups. One-way between-group analysis of covariance (ANCOVA) and Paired t-test or Wilcoxon rank-sum test will be conducted to examine within and between group difference per and post intervention. Scores on the baseline (mMDL, mSNCV, pain, DASH and BOSTON score) are as the covariate that adjust in this analysis. Effect size will be calculated using Cohen's d coefficient for effectiveness of two interventions. An intention-to-treat analysis will be conducted in this trail **to handle non-adherence subjects.**

Plans for communicating important protocol amendments to relevant parties:

Agreement for protocol modifications and amendments will be taken for from the ethical committees at the Ahvaz Jundishapur University of Medical Sciences and reported to it. All changes will be entered in the study registration

Dissemination plan

The results of this study will be disseminated at international physical therapy congress. A full study report will be submitted for publication in a physical therapy journal.

Discussion

The findings of this project will be used in the management of people with mild to moderate CTS. It could show whether distal symptoms decrease with proximal treatment in CTS and whether or not regarding cervical component to the CTS is necessary. This study compares the positive outcomes of these multimodal conservative therapies with treatments that target only the carpal tunnel. Finally, if improvement of proximal spinal conditions optimizes outcomes, it can prevent the progression of this disorder or need to surgery in these patients. Results and recommendations based on the findings of this study will be presented to scientific conferences and announce by paper in peer-review journals.

Trial status

This trial was approved in December 2020. The first patient was enrolled in 25 December 2020 and we expect to complete recruitment by July 2021

Declarations

Acknowledgement:

Not applicable now.

Authors' contributions:

MZ, MS, MJS, and DS contributed to the design of this trail. MZ, MS, and MJS contribute to data extraction. DS is responsible for data collection of electrophysiological outcomes. MS and MZ prepare the manuscript. All authors read and approved the final manuscript. The authors finally acknowledge co-workers that might be involved in the data analysis.

Funding

This study will be supported by Ahvaz Jundishapur University of Medical Sciences (Grant number: PHT-9933). The funder played no part in the study design; the collection, management, analysis, or interpretation of the data; the writing of the report; or the decision to submit the report for publication.

Availability of data and materials

The datasets generated and analyzed during the current study are not publicly available to study completion and publication of the results but are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

This study was approved by the Ethics Committee of the Jundishapur University of Medical Science, Ahvaz, Iran (Approval number IR.AJUMS.REC.1399.727). Each subject will sign the informed consent form before to participate in the study.

Consent for publication:

Not applicable.

Competing interests:

The author submitted this trail declared that are no conflicts of interest.

References

1. Olney RK. Carpal tunnel syndrome: complex issues with a “simple” condition. AAN Enterprises; 2001.
2. Werner RA, Andary M. Carpal tunnel syndrome: pathophysiology and clinical neurophysiology. Clinical Neurophysiology. 2002;113(9):1373-81.
3. Atroshi I, Gummesson C, Johnsson R, Ornstein E, Ranstam J, Rosen I. Prevalence of carpal tunnel syndrome in a general population. Jama. 1999;282(2):153-8.
4. Graham B, Peljovich AE, Afra R, Cho MS, Gray R, Stephenson J, Gurman A, MacDermid J, Mlady G, Patel AT, Rempel D. The American Academy of Orthopaedic Surgeons evidence-based clinical practice guideline on: management of carpal tunnel syndrome. JBJS. 201;98(20):1750-4.
5. 5. Erickson M, Lawrence M, Jansen CWS, Coker D, Amadio P, Cleary C, et al. Hand Pain and Sensory Deficits: Carpal Tunnel Syndrome: Clinical Practice Guidelines Linked to the International

Classification of Functioning, Disability and Health From the Academy of Hand and Upper Extremity Physical Therapy and the Academy of Orthopaedic Physical Therapy of the American Physical Therapy Association. Journal of Orthopaedic & Sports Physical Therapy. 2019;49(5):CPG1-CPG85.

6. Kim S-D. Efficacy of tendon and nerve gliding exercises for carpal tunnel syndrome: a systematic review of randomized controlled trials. Journal of physical therapy science. 2015;27(8):2645-8.
7. 7. Gibson W, Wand BM, O'Connell NE. Transcutaneous electrical nerve stimulation (TENS) for neuropathic pain in adults. Cochrane Database of Systematic Reviews. 2017(9).
8. Kakihata C, Malanotte J, Portolez J, Sample L. Low-level laser therapy in carpal tunnel syndrome–systematic review. Int Phys Med Rehab J. 2019;4(3):106-10.
9. 9. Page MJ, O'Connor D, Pitt V, Massy-Westropp N. Therapeutic ultrasound for carpal tunnel syndrome. Cochrane Database of Systematic Reviews. 2013(3).
10. Huisstede BM, Hoogvliet P, Franke TP, Randsdorp MS, Koes BW. Carpal tunnel syndrome: effectiveness of physical therapy and electrophysical modalities. An updated systematic review of randomized controlled trials. Archives of physical medicine and rehabilitation. 2018;99(8):1623-34.
11. Rankin IA, Sargeant H, Rehman H, Gurusamy KS. Low-level laser therapy for carpal tunnel syndrome. Cochrane Database of Systematic Reviews. 2017(8).
12. Zanette G, Marani S, Tamburin S. Extra-median spread of sensory symptoms in carpal tunnel syndrome suggests the presence of pain-related mechanisms. Pain. 2006;122(3):264-70.
13. Pierre-Jerome C, Bekkelund SI, Pierre-Jerome C, Bekkelund SI. Magnetic resonance assessment of the double-crush phenomenon in patients with carpal tunnel syndrome: a bilateral quantitative study. Scandinavian journal of plastic and reconstructive surgery and hand surgery. 2003;37(1):46-53.
14. Zanette G, Marani S, Tamburin S. Proximal pain in patients with carpal tunnel syndrome: a clinical-neurophysiological study. Journal of the Peripheral Nervous System. 2007;12(2):91-7.
15. Chow C, Hung L, Chiu C, Lai K, Lam L, Ng M, et al. Is symptomatology useful in distinguishing between carpal tunnel syndrome and cervical spondylosis? Hand Surgery. 2005;10(01):1-5.
16. Azadeh H, Dehghani M, Zarezadeh A. Incidence of trapezius myofascial trigger points in patients with the possible carpal tunnel syndrome. Journal of Research in Medical Sciences: The Official Journal of Isfahan University of Medical Sciences. 2010;15(5):250.
17. Qerama E, Kasch H, Fuglsang-Frederiksen A. Occurrence of myofascial pain in patients with possible carpal tunnel syndrome–A single-blinded study. European Journal of Pain. 2009;13(6):588-91.
18. Fernandez-De-Las-Penas C, Cleland J, Palacios-Ceña M, Fuensalida-Novo S, Pareja JA, Alonso-Blanco C. The effectiveness of manual therapy versus surgery on self-reported function, cervical range of motion, and pinch grip force in carpal tunnel syndrome: a randomized clinical trial. journal of orthopaedic & sports physical therapy. 2017;47(3):151-61.
19. DeLisa JA. Manual of nerve conduction velocity and clinical neurophysiology: Lippincott Williams & Wilkins; 1994.

20. Hertling D, Kessler RM, Shimandle SA. Management of Common Musculoskeletal Disorders, Physical Therapy Principles and Methods. Dimensions of Critical Care Nursing. 1990;9(5):279.
21. CİNEVRE SOYUPEK F, KUTLUHAN S, Uslusoy G, Ilgun E, Eris S, Askin A. The efficacy of phonophoresis on electrophysiological studies of the patients with carpal tunnel syndrome. 2012.
22. Kaymak B, Özçakar L, Çetin A, Çetin MC, Akıncı A, Hasçelik Z. A comparison of the benefits of sonography and electrophysiologic measurements as predictors of symptom severity and functional status in patients with carpal tunnel syndrome. Archives of physical medicine and rehabilitation. 2008;89(4):743-8.
23. Price DD, McGrath PA, Rafii A, Buckingham B. The validation of visual analogue scales as ratio scale measures for chronic and experimental pain. Pain. 1983;17(1):45-56.
24. Hassankhani GG, Moradi A, Birjandinejad A, Vahedi E, Kachooei AR, Ebrahimzadeh MH. Translation and validation of the Persian version the Boston carpal tunnel syndrome questionnaire. Archives of Bone and Joint Surgery. 2018;6(1):71.
25. Mousavi SJ, Parnianpour M, Abedi M, Askary-Ashtiani A, Karimi A, Khorsandi A, et al. Cultural adaptation and validation of the Persian version of the Disabilities of the Arm, Shoulder and Hand (DASH) outcome measure. Clinical rehabilitation. 2008;22(8):749-57.

Figures

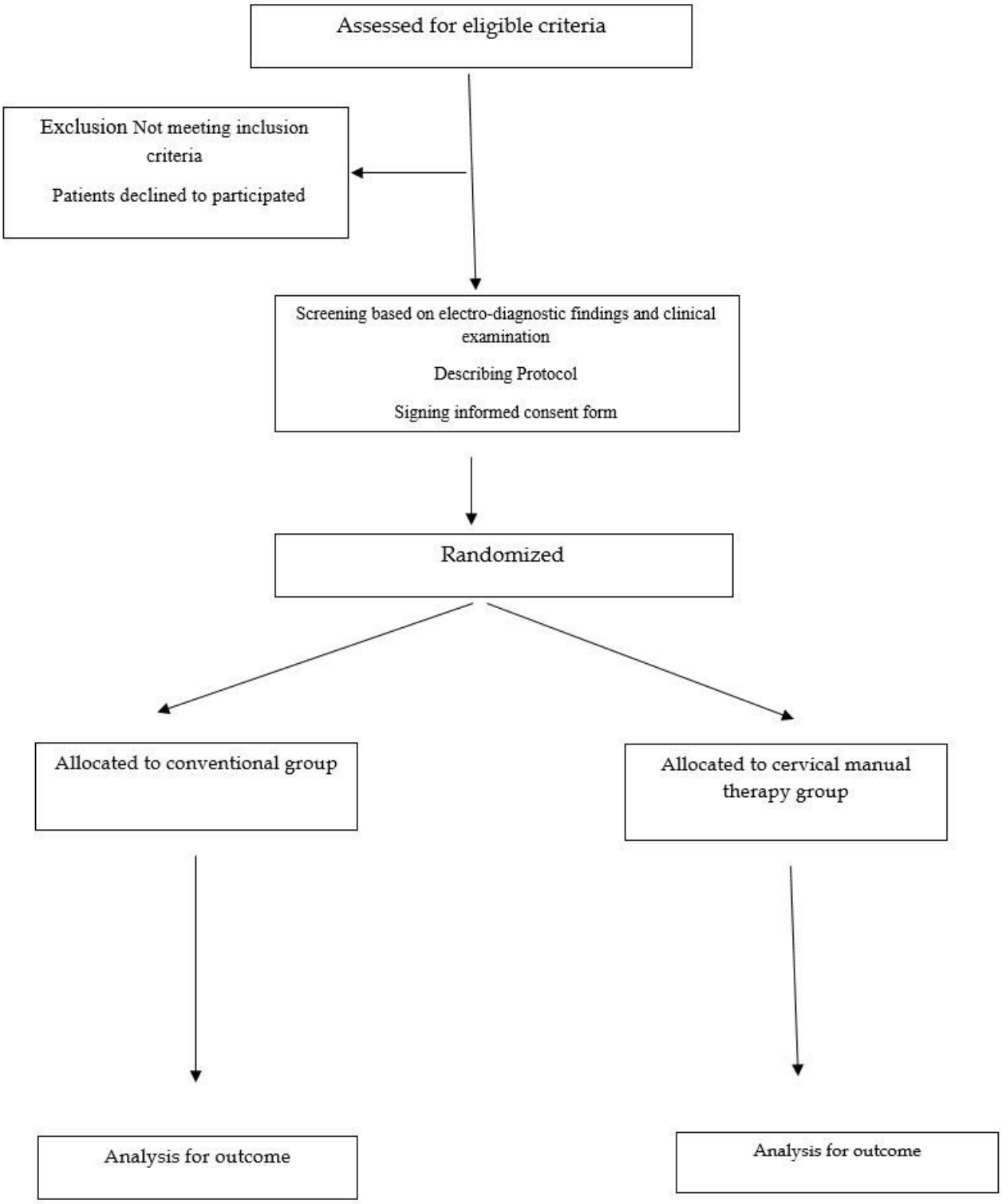

Figure 1

Flowchart diagram of study.

	STUDY PERIOD				
	Enrolment	Allocation	Post-allocation		Follow up
TIMEPOINT**	**-week**	**Baseline (week 0)**	**Baseline (week 0)**	**2 weeks**	**-**
ENROLMENT:					
Eligibility screen	X				
Informed consent	X				
Allocation		X			
INTERVENTIONS:					
Study group (conventional physiotherapy with cervical manual therapy)			◆—	—◆	
Control group (conventional physiotherapy)			◆—	—◆	
ASSESSMENTS:					
Demographic characteristics	X				
mMDL& mSNCV			X	X	
Pain intensity (VAS)			X	X	
Boston Carpal Tunnel Questionnaire			X	X	
DASH Questionnaire			X	X	

Figure 2

Schedule of enrolment, interventions, and assessments, according to SPIRIT guidelines

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Appendix.docx