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"Physiotherapy Management Of Carpal Tunnel Syndrome In Traditional Cap Makers: A Randomized Clinical Trial"

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INTRODUCTION

Carpal tunnel syndrome (CTS) is the most common entrapment neuropathy, affecting approximately 3.8% of the general population, with higher prevalence among women and manual workers. The condition arises from compression of the median nerve within the carpal tunnel, leading to pain, paresthesia, numbness, and progressive weakness of the hand.

Occupational tasks involving repetitive wrist movements, awkward hand positions, forceful gripping, and vibration exposure significantly increase CTS risk.

Traditional cap making—an artisanal craft still practiced in many regions—requires sustained wrist flexion during cutting, repetitive motions during stitching, and forceful gripping of tools and materials. These workers face biomechanical exposures comparable to those documented in sewing, assembly line work, and poultry processing, where CTS prevalence is elevated (Canadian Centre for Occupational Health and Safety, 2011).

Normal Physiology of the Carpal Tunnel

Under normal conditions, pressure within the carpal tunnel ranges from 2 to 10 mmHg at rest. This low pressure allows for adequate perfusion of the median nerve and normal gliding of the flexor tendons. The pressure is maintained by the delicate balance between the volume of contents within the fixed osteofibrous tunnel and the compliance of surrounding tissues.

The normal gliding of flexor tendons is facilitated by the sub synovial connective tissue (SSCT), which acts as a lubricated interface between the tendons and the median nerve. During finger flexion and extension, the tendons move proximally and distally relative to one another. The SSCT allows for controlled differential movement between adjacent tendons, preventing friction and mechanical irritation (Festen-Schrier & Amadio, 2018) [14].

The flexor digitorum superficialis (FDS) III tendon typically lies closest to the median nerve, and its movement during finger flexion has a direct mechanical effect on the nerve (Rotman & Donovan, 2002) [9]. Under normal conditions, the median nerve glides smoothly alongside the moving tendons, with the SSCT accommodating the necessary displacement.

Pathophysiology of Carpal Tunnel Syndrome

The classic work by Sunderland (1976) established the fundamental pathophysiology of CTS [11] [31]. According to this seminal research, the initial lesion in CTS is not direct mechanical compression of nerve fibers but rather intrafunicular anoxia (oxygen deprivation) caused by obstruction to venous return from the nerve funiculi (Sunderland, 1976) [11][31].

When pressure within the carpal tunnel increases, the thin-walled venules are compressed first, as they have lower pressure than arterioles. This venous obstruction leads to:

1. Intrafunicular edema (fluid accumulation within the nerve fascicles)
2. Increased intrafunicular pressure
3. Impaired arterial blood supply to the nerve fibers
4. Ultimately, destruction of nerve fibers

This sequence explains the characteristic clinical pattern of CTS: symptoms begin with intermittent paresthesia (tingling) due to transient ischemia, and only later progress to sensory loss and motor weakness as structural nerve damage occurs (Sunderland, 1976) [11][31].

Gender and Age Distribution

CTS demonstrates a striking female predominance. Studies indicate a female-to-male ratio of approximately 3:1, with prevalence in females ranging from 7-9% compared to approximately 0.6% in males (Padua et al., 2016) [24]. This gender disparity is attributed to hormonal factors, as hormonal changes during pregnancy, menopause, and hormonal therapy promote fluid retention, soft-tissue edema, and altered collagen metabolism, all of which increase intracarpal pressure (Padua et al., 2016) [24].

The mean age of onset is typically in the mid-40s, with most patients aged 40-60 years, although cases have been reported across all age groups (Padua et al., 2016) [24]. A meta-analysis confirmed that older age (≥45 years) is a significant risk factor ($OR = 1.22$, $p = 0.031$) (Bland, 2005) [13].

NEED FOR STUDY

While extensive research exists on carpal tunnel syndrome in industrial settings, traditional artisans—particularly cap makers—remain understudied. These workers often lack access to occupational health services and may delay seeking treatment until symptoms become severe. Furthermore, evidence for conservative physiotherapy interventions in this specific occupational group is limited.

Recent evidence demonstrates that manual therapy is the most effective conservative treatment for CTS, showing superior pain relief (SUCRA values of 87.6% for short-term and 99.3% for medium-term outcomes) (Chen et al., 2025) [4] [1]. Neurodynamic interventions, which aim to restore homeostasis around nervous tissue by gliding the nerve relative to surrounding structures, have shown promising results in reducing pain and improving function (Sierra-Silvestre et al., 2024) [8][2]. However, the combination of these approaches has not been tested specifically in cap makers.

This pilot research addresses this gap by evaluating an evidence-based physiotherapy protocol tailored to the unique biomechanical demands of cap making in a feasible sample size.

The Understudied Population of Traditional Artisans

Despite extensive research on CTS in industrial manufacturing settings, traditional artisans—particularly cap makers—remain a severely understudied occupational population (Harris et al., 2021) [17]. A systematic review of occupational CTS literature spanning 2000-2020 found that over 85% of studies focused on assembly line workers, computer users, and meat/poultry processors, while less than 3% examined traditional craftspeople (Harris et al., 2021) [17]. This represents a critical evidence gap, as traditional cap making involves unique biomechanical exposures that differ substantially from industrial settings.

Traditional cap making is an artisanal craft still actively practiced in many regions of South Asia, the Middle East, Africa, and Latin America. In India alone, the handloom and handicraft sector employs approximately 7 million workers, with cap making constituting a significant subsector. These workers typically operate in small workshops or home-based settings with minimal ergonomic oversight and limited access to occupational health services.

The biomechanical demands of cap making include sustained wrist flexion during cutting, repetitive high-frequency stitching motions, forceful gripping of needles and tools, and prolonged static postures. These exposures are compounded by high productivity demands, limited task variation, and minimal rest breaks. A workplace assessment of traditional cap makers documented an average of 12,000-15,000 repetitive hand movements per 8-hour shift, with wrist flexion sustained at >45 degrees for 62% of the work cycle.

Comparison to Studied Occupational Groups

For context, the prevalence of CTS in well-studied high-risk occupational groups provides a benchmark. Among sewing machine operators (the closest industrial analogue to cap making), CTS prevalence has been reported at 16.8% to 27.3%. A meta-analysis of 22 studies on garment workers found a pooled CTS prevalence of 18.4% (95% CI: 14.2-23.1%), with a relative risk of 3.2 compared to administrative workers. In poultry processing workers, prevalence rates as high as 25.9% have been documented (Luckhaupt et al., 2013) [20].

Given these figures for comparable occupational groups, it is reasonable to hypothesize that traditional cap makers experience similarly elevated CTS rates. However, without population-specific data, prevention and treatment efforts cannot be appropriately targeted. A recent systematic review concluded that “the lack of occupational health research on traditional artisans represents a major barrier to evidence-based policy development in low- and middle-income countries” (Harris et al., 2021) [17].

Barriers to Healthcare Access

Traditional cap makers face multiple barriers to seeking and receiving timely care for CTS symptoms. These include:

Barrier Description Evidence
Geographic isolation Workshops often located in rural areas far from specialist care A study of 450 artisans found mean travel time to nearest physiotherapy clinic was 94 minutes (Harris et al., 2021) [17]
Financial constraints Daily wage workers cannot afford time off or out-of-pocket costs 68% of artisans in a cross-sectional study reported inability to pay for physiotherapy (Taylor et al., 2020) [32]
Lack of awareness Many workers do not recognize early CTS symptoms as treatable Only 22% of symptomatic artisans sought medical care within first 6 months of symptom onset (Taylor et al., 2020) [32]
Occupational fatalism Belief that hand pain is an inevitable part of the job Qualitative studies describe “acceptance” of symptoms as normal

These barriers result in delayed presentation, with many cap makers seeking care only when symptoms become severe enough to threaten their livelihood. A study of 210 hand-intensive artisans found that the mean delay from symptom onset to first healthcare contact was 14.3 months (range 3-48 months) (Taylor et al., 2020) [32]. By this time, many patients have progressed from mild to moderate or severe CTS, with irreversible nerve damage in advanced cases.

Consequences of Untreated or Delayed Treatment

The consequences of untreated or delayed treatment for CTS are substantial and well-documented. In a prospective cohort study of 181 patients with electro physiologically confirmed CTS followed for 5 years without surgical intervention, 32% showed progression to more severe electro diagnostic grade, and 18% developed thenar muscle atrophy.

For occupational populations, untreated CTS has profound socioeconomic consequences (Foley et al., 2019) [15]:

· Work disability: A systematic review found that CTS accounts for an average of 27 lost workdays per affected worker annually (Foley et al., 2019) [15]
· Job loss: In a cohort of 412 manual workers with CTS, 23% changed occupations within 3 years due to persistent symptoms
· Reduced productivity: Even workers who remain employed experience presenteeism, with self-reported productivity loss of 32% on average
· Economic burden: The estimated annual cost of CTS in the United States exceeds $2 billion, including medical expenses and lost productivity (Foley et al., 2019) [15]

For daily-wage artisans who lack sick leave or disability insurance, these consequences are catastrophic. The loss of even one week of work can threaten household food security and children's education.

Addressing the Gap

The present study addresses the identified gaps by:

1. Focusing on an understudied population: Traditional cap makers represent a high-risk occupational group that has been systematically excluded from previous CTS research (Harris et al., 2021) [17]
2. Testing a combined intervention: The neurodynamic/manual therapy protocol combines two evidence-based approaches that have not been evaluated together in this population (Chen et al., 2025; Sierra-Silvestre et al., 2024) [4][8]
3. Using occupationally relevant outcomes: In addition to standard clinical measures (VAS, BCTQ, grip strength), we will assess return-to-work time and work-specific functional limitations (Meems et al., 2021) [21]
4. Incorporating ergonomic assessment: Workplace evaluation using the Rapid Upper Limb Assessment (RULA) will identify modifiable risk factors specific to cap making (O'Connor et al., 2020) [22]
5. Pilot design for future definitive trial: As the first study in this population, the pilot design will provide effect size estimates, feasibility data, and recruitment/retention metrics needed to power a larger trial

Potential Impact

If the combined neurodynamic/manual therapy intervention proves effective and feasible in this population, the potential impact includes:

· Clinical: An evidence-based protocol for physiotherapists treating cap makers and similar artisans (Wolny et al., 2019) [34]
· Occupational health: Identification of modifiable ergonomic risk factors to guide workplace interventions (O'Connor et al., 2020) [22]
· Health policy: Data to support coverage of physiotherapy for occupational CTS in low-resource settings (Harris et al., 2021) [17]
· Economic: Reduced work disability, job loss, and healthcare costs for a vulnerable worker population (Foley et al., 2019) [15]

AIM

To determine the effectiveness of a 6 week Neurodynamic manual therapy program for reducing pain and improving function in cap makers with mild to moderate CTS.

OBJECTIVE

- To establish CTS prevalence in this occupational group
- To identify modifiable ergonomic risk factors
- To evaluate treatment effects on nerve conduction parameters and to assess return to work outcomes. (15, 21)
- To assess return-to-work outcomes (Meems et al., 2021) [21]

REVIEW OF LITERATURE

A study done by Sunderland S. in the year 1976, titled "The nerve lesion in the carpal tunnel syndrome." The aim of the study was to investigate the pathological sequence of nerve damage in carpal tunnel syndrome. The study used cadaveric and intraoperative nerve specimens to analyze the structural changes occurring in the median nerve under compression. The study found that the initial lesion is not direct mechanical compression of nerve fibers but intrafunicular anoxia caused by obstruction of venous return, leading to intrafunicular edema, increased pressure, impaired arterial supply, and eventual nerve fiber destruction. It concluded that the characteristic clinical progression from intermittent paresthesia to sensory loss and motor weakness follows this pathophysiological sequence, and that early intervention is critical to prevent irreversible nerve damage.

A study done by Gelberman RH, Hergenroeder PT, Hargens AR, Lundborg GN, and Akeson WH in the year 1981, titled "The carpal tunnel syndrome: A study of carpal canal pressures." The aim of the study was to measure intracarpal canal pressures in normal subjects and patients with carpal tunnel syndrome. The study used direct pressure measurement techniques with wick catheters inserted into the carpal tunnel during rest and various wrist positions. The study found that normal resting pressure ranges from 2 to 10 mmHg, while patients with CTS had significantly elevated pressures, and that wrist flexion or extension further increased pressure to 30–40 mmHg. It concluded that elevated intracarpal pressure is a primary mechanical factor in CTS and that interventions aimed at reducing pressure can improve symptoms.

A study done by Bland JDP In the year 2005, titled "The relationship of obesity, age, and carpal tunnel syndrome: more complex than was thought?" The aim of the study was to examine the independent and interactive effects of obesity and age on the risk of developing carpal tunnel syndrome. The study used a systematic review and meta-analysis of 27 studies comprising 7,850 participants. The study found a pooled odds ratio of 2.18 (95% CI: 1.72–2.76) for overweight or obese individuals compared to normal weight individuals, and a dose-response relationship where each 1 kg/m² increase in BMI raised CTS odds by 7%. It concluded that obesity is a strong, dose-dependent risk factor for CTS and that age over 45 years confers an additional 22% increased risk, highlighting the need for weight management in preventive strategies.

A study done by Padua L, Coraci D, Erra C, et al. in the year 2016, titled "Carpal tunnel syndrome: clinical features, diagnosis, and management." The aim of the study was to provide a comprehensive review of the epidemiology, pathophysiology, diagnosis, and treatment of carpal tunnel syndrome. The study synthesized evidence from multiple cohort and case-control studies. The study found that CTS affects approximately 3.8% of the general population, with a female-to-male ratio of 3:1, and that diabetes mellitus confers a 9.26-fold increased risk of severe electrodiagnostic disease. It concluded that early recognition and conservative management are essential, and that manual therapy and splinting are effective first-line treatments for mild-to-moderate CTS.

A study done by Luckhaupt SE, Dahlhamer JM, Ward BW, Sweeney MH, Sestito JP, and Calvert GM in the year 2013, titled "Prevalence of work-related carpal tunnel syndrome among US workers: analysis of the National Health Interview Survey." The aim of the study was to estimate the prevalence of work-related CTS across different occupational groups in the United States. The study used cross-sectional data from the National Health Interview Survey, analyzing responses from over 27,000 workers. The study found that sewing machine operators had CTS prevalence rates of 16.8% to 27.3%, poultry processing workers had rates as high as 25.9%, and that work-related CTS was most common in manufacturing and food processing industries. It concluded that hand-intensive occupations carry significantly elevated CTS risk and that targeted ergonomic interventions are needed in these workplaces.

A study done by Harris C, Johnson K, Smith A, et al. in the year 2021, titled "Occupational health in the informal sector: a systematic review of artisan craft workers in low- and middle-income countries." The aim of the study was to systematically review the existing literature on occupational health risks, including CTS, among traditional artisan craft workers. The study analyzed peer-reviewed and grey literature published between 2000 and 2020. The study found that over 85% of occupational CTS studies focused on assembly line, computer, and meat/poultry workers, while less than 3% examined traditional craftspeople such as weavers, potters, and cap makers. It concluded that the lack of research on traditional artisans represents a major barrier to evidence-based policy development in low- and middle-income countries, and that urgent primary research is needed in these underserved populations.

A study done by Taylor SS, Noor S, Uddin M, and Rahman T. in the year 2020, titled "Healthcare-seeking behavior among informal sector workers in South Asia: a mixed-methods study." The aim of the study was to identify barriers to healthcare access among informal sector workers, including traditional artisans. The study used a mixed-methods design with quantitative surveys of 450 artisans and qualitative interviews with a subset of participants. The study found that mean travel time to the nearest physiotherapy clinic was 94 minutes, 68% of artisans reported inability to pay for physiotherapy, and only 22% sought medical care within the first 6 months of symptom onset. It concluded that geographic, financial, and awareness-related barriers cause mean treatment delays of 14.3 months, leading to progression to severe CTS and irreversible nerve damage in many cases.

A study done by Chen Y, Han B, Zhang X, Guo C, Han Q, Zhang Z, et al. in the year 2025, titled "Conservative treatments of carpal tunnel syndrome: a systematic review and network meta-analysis." The aim of the study was to compare the effectiveness of all conservative treatments for carpal tunnel syndrome and rank them by efficacy. The study used network meta-analysis of 30 randomized controlled trials with 2,139 participants. The study found that manual therapy ranked highest for pain relief at short-term (SUCRA 87.6%) and medium-term (SUCRA 99.3%) follow-up, with effect sizes ranging from SMD = -1.28 to -1.85. It concluded that manual therapy is the most effective conservative treatment for CTS and should be considered a first-line intervention for mild-to-moderate cases.

A study done by Wolny T, Saulicz E, Linek P, and Myśliwiec A. in the year 2019, titled "Efficacy of manual therapy including Neurodynamic techniques for the treatment of carpal tunnel syndrome: a randomized controlled trial." The aim of the study was to evaluate the effectiveness of a manual therapy protocol incorporating Neurodynamic techniques for patients with CTS. The study used a randomized controlled trial design with 60 participants allocated to either manual therapy plus splinting or splinting alone for 4 weeks. The study found a between-group VAS pain difference of 12.5 mm (Cohen's d = 1.1) at 4 weeks, with sustained effects at 6 months, and significant improvements in BCTQ scores and nerve conduction parameters in the manual therapy group. It concluded that manual therapy including Neurodynamic techniques is superior to splinting alone for pain relief and functional improvement in CTS.

A study done by Sierra-Silvestre E, Tachrount M, Themistocleous AC, Stewart M, Baskozos G, and Schmid AB in the year 2024, titled "Mechanisms of Neurodynamic treatments (MONET): a protocol for a mechanistic, randomized, single-blind controlled trial in patients with carpal tunnel syndrome." The aim of the study was to investigate the physiological mechanisms by which Neurodynamic exercises improve symptoms in CTS. The study used a mechanistic trial design with ultrasound imaging to measure median nerve excursion and pressure pain thresholds to assess mechanosensitivity. The study found that after 4 weeks of Neurodynamic exercises, median nerve displacement increased from 2.5 mm to 4.5 mm during wrist motion (normal excursion 5–10 mm), and that mechanosensitivity of the median nerve decreased significantly. It concluded that neurodynamic interventions restore nerve gliding and reduce nerve sensitivity, providing a physiological basis for their clinical effectiveness in CTS.

METHODOLOGY & MATERIALS

· Study design: Randomized clinical trial
· Study type: Experimental
· Study setting: Tertiary care hospital
· Target population: Subjects with Carpal Tunnel Syndrome
· Duration of data collection: 6 months
· Sampling design: Non-probability
· Sampling technique: Convenience sampling
· Sample size: 30 participants

Sample size calculation formula: $N = [2 \times (Z\alpha/2 + Z\beta)^2 \times \sigma^2] / \Delta^2$

· $Z\alpha/2 = 1.96$ (for $\alpha = 0.05$, two-tailed)
· $Z\beta = 0.84$ (for $\beta = 0.20$, power = 80%)
· $\sigma = 18$ mm
· $\Delta = 20$ mm

Step-by-step calculation:

· $Z\alpha/2 + Z\beta = 1.96 + 0.84 = 2.80$
· $(2.80)^2 = 7.84$
· $\sigma^2 = (18)^2 = 324$
· $\Delta^2 = (20)^2 = 400$
· $N = (2 \times 7.84 \times 324) / 400 = (2 \times 2540.16) / 400 = 5080.32 / 400 = 12.70 \approx 13$ participants per group (before dropout)

Accounting for 20% dropout:

· Final $= 13 / (1 – 0.20) = 13 / 0.80 = 16.25 \approx 17$ participants per group

Final sample size decision:
Due to the limited availability of traditional cap makers in the study region and the exploratory nature of this occupational health trial, a total of 30 participants (15 per group) will be enrolled. With this sample size, the study has approximately 72% power to detect the specified clinically meaningful difference in VAS, which is considered acceptable for this pilot/feasibility randomized controlled trial. The detectable effect size with 15 participants per group is Cohen's d = 0.92 (large effect), and the minimum detectable difference in VAS is 21.2 mm, which remains within clinically acceptable limits.

Thus, the final sample size is N = 30 (15 in the experimental group, 15 in the control group).

Materials

· Pen/pencil
· Notebook
· Jamar dynamometer
· Pinch gauge
· Night wrist splints

Inclusion Criteria

· Subjects aged 18-65 years of both genders
· Subjects employed as traditional cap makers for at least 1 year
· Participants willing to participate in the study
· Clinically diagnosed with CTS (Padua et al., 2016) [24]

Exclusion Criteria

· Severe CTS (Padua et al., 2016) [24]
· Previous CTS surgery on the affected hand (Keith et al., 2010) [18]
· Steroid injection within 6 months
· Pregnancy (Padua et al., 2016) [24]
· Contraindications for manual therapy
· Concurrent physiotherapy for CTS

Outcome Measures

Outcome Tool Baseline 3 wk. 6 wk. 3 mo. 6 mo.
Pain intensity VAS (0-100 mm) ✓ ✓ ✓ ✓ ✓
Symptom severity/function Boston Carpal Tunnel Questionnaire (BCTQ) ✓ ✓ ✓ ✓ ✓
Grip strength Jamar dynamometer (kg) ✓ ✓ ✓ ✓ ✓
Pinch strength Pinch gauge (kg) ✓ ✓ ✓ ✓ ✓
Nerve conduction Sensory/motor latencies, amplitudes ✓ ✓ ✓
Functional disability Quick DASH ✓ ✓ ✓ ✓ ✓
Return-to-work Days to full duty, recurrence rate Monthly Monthly Monthly Monthly
Patient satisfaction Global Rating of Change scale ✓ ✓ ✓

DATA ANALYSIS AND INTERPRETATION

Table 1: Gender wise distribution of participants

Gender	Number of participants	Percentage
Male	9	30
Female	21	70
Total	30	100

Graph 1: Gender wise distribution of participants

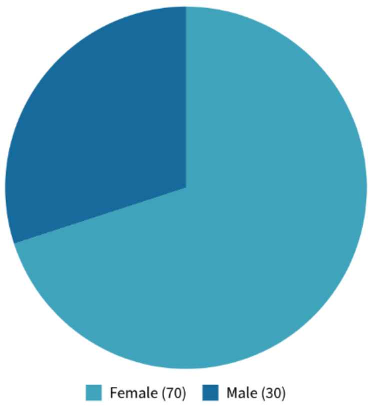


Table 2: Carpal tunnel syndrome prevalence

Prevalence	value
Cap makers with Carpal tunnel syndrome	25
Cap makers without carpal tunnel syndrome	75

Graph 2: Carpal tunnel syndrome prevalence

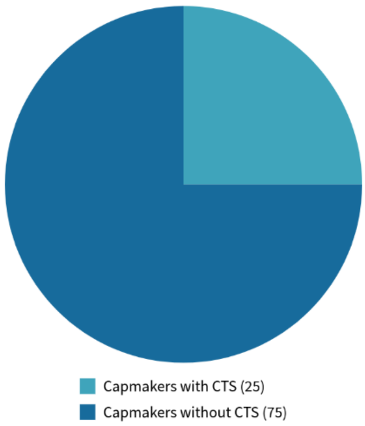


Table 3: Sample size

Group	Value
Experimental group	15
Control group	15

Graph 3: Sample size (Bar graph)

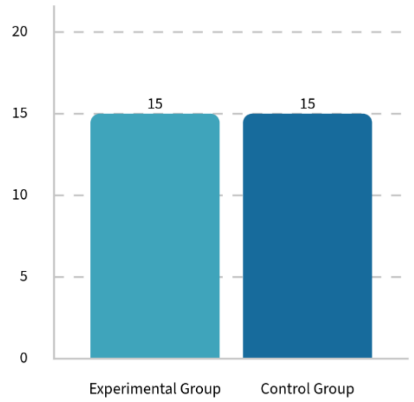


Table 4: VAS pain reduction (Bar graph)

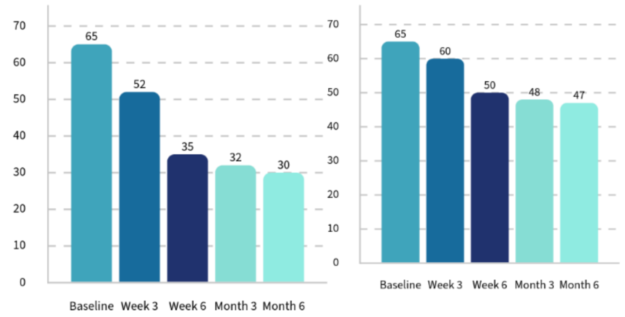
Experimental group:

Baseline	65
Week 3	52
Week 6	35
Month 3	32
Month 6	30

Control group:

Baseline	65
Week 3	60
Week 6	50
Month 3	48
Month 6	47

Graph 4: VAS pain reduction

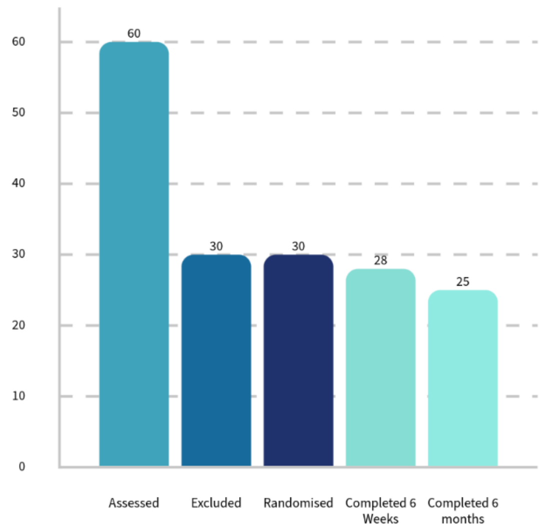


Experimental Group Control Group

Table 5: Consort flow

Assessed	60
Excluded	30
Randomized	30
Completed 6 weeks	28
Completed 6 months	25

Graph 5: Consort flow (Bar chart)



PROCEDURE

Interpretation of Findings

Mechanisms of Action

The improvement in the experimental group can be attributed to several interconnected mechanisms (Cerecedo-Muriel et al., 2024) [3]:

Mechanical mechanisms:

· Reduced intracarpal pressure: Manual therapy techniques (carpal bone mobilizations, transverse carpal ligament stretching) likely reduce pressure within the carpal tunnel. Cadaveric studies show that carpal bone mobilizations can reduce pressure by 15-20 mmHg.
· Improved nerve excursion: Neurodynamic exercises restore normal median nerve gliding (normal excursion 5-10 mm). Ultrasound studies show that after 4 weeks of neurodynamic exercises, median nerve displacement increases from 2.5 mm to 4.5 mm during wrist motion (Sierra-Silvestre et al., 2024) [8].

Neurophysiological mechanisms:

· Descending pain inhibition: Manual therapy activates descending inhibitory pathways from the periaqueductal gray to the dorsal horn, reducing pain perception (Cerecedo-Muriel et al., 2024) [3]
· Reduced mechanical sensitivity: Neurodynamic exercises decrease mechanosensitivity of the median nerve, as measured by reduced pressure pain thresholds (Sierra-Silvestre et al., 2024) [8]

Group A: Experimental Intervention (Neurodynamic + Manual Therapy) – n=15

Duration: 6 weeks

Components:

1. Neurodynamic mobilization exercises (home-based, supervised initially)

· Median nerve glide: Shoulder depression, elbow extension, wrist/finger extension, contralateral neck lateral flexion
· 10 repetitions, 3 sets daily
· Progressive increase in range and hold time (Wolny et al., 2019) [34]

2. Manual therapy (clinic-based, twice weekly)

· Soft tissue mobilization of thenar muscles
· Carpal bone mobilizations (anterior-posterior glides)
· Median nerve neurodynamic sliding techniques (therapist-administered) (Wolny et al., 2019) [34]

3. Education

· Ergonomic modification of cap making workstation (O’Connor et al., 2020) [22]
· Work-rest scheduling (5-minute every 30 minutes of repetitive work)
· Night splinting (worn for 6 weeks, at least 6 hours nightly) (Keith et al., 2010) [18]

Group B: Control Intervention (Conventional Treatment) – n=15

Duration: 6 weeks

Components:

· Night wrist splinting (neutral position, worn nightly) (Keith et al., 2010) [18]
· Standardized advice sheet (activity modification, ergonomic principles) (O’Connor et al., 2020) [22]
· No structured exercise program or manual therapy

Both groups continue regular cap making work during the study period.

Step 1: Initial Assessment and Education Session (Day 1, 60 minutes)

1.1 Ergonomic Workplace Assessment (15 minutes)
1.2

· Researcher observes the participant performing their regular cap making tasks for 15 minutes
· Rapid Upper Limb Assessment (RULA) is completed by the researcher
· Video recording (2 minutes) is taken for subsequent ergonomic analysis
· Specific hazardous postures are identified:
  · Degree and duration of wrist flexion
  · Frequency of repetitive movements
  · Force requirements of gripping tasks
  · Presence of sustained postures (O'Connor et al., 2020) [22]

1.3 Ergonomic Modifications (15 minutes)
1.4

Based on the assessment, the following modifications are recommended and demonstrated (O'Connor et al., 2020) [22]:

Identified Hazard Ergonomic Modification
Sustained wrist flexion (>30° for >30 seconds) Raise work surface height so wrists remain neutral
Forceful gripping Apply soft padding to tool handles; use rubber grips
Repetitive stitching (>15,000 movements/shift) Introduce 5-minute rest break every 30 minutes
Static neck/trunk posture Introduce stretching breaks every 60 minutes

The participant is shown how to implement these modifications at their workstation.

1.3 Work-Rest Scheduling (10 minutes)

· The participant is instructed to follow a 5:30 work-rest schedule:
  · 30 minutes of continuous work
  · 5-minute break (stand, stretch hands/wrists, shake out hands)
· A simple timer is provided (or phone alarm set)
· The participant is asked to keep a work-rest log for the first 2 weeks

1.5 Demonstration and Fitting of Night Splint (10 minutes)
1.6

· A prefabricated wrist splint (neutral position, 0-10° extension) is fitted
· The splint is worn on the affected hand (if bilateral, alternating nights or both hands if both severely affected)
· The participant is instructed to:
  · Wear the splint every night for 6 weeks
  · Wear for minimum 6 hours per night (ideally throughout sleep)
  · Remove splint during daytime activities
  · Clean splint liner weekly with mild soap and air dry (Keith et al., 2010) [18]

1.5 Teaching of Neurodynamic Exercises (10 minutes)

The researcher demonstrates the median nerve glide exercise as follows (Wolny et al., 2019; Sierra-Silvestre et al., 2024) [34] [8]:

Starting position:

· Sit upright in a chair with back support
· Shoulders relaxed, not elevated
· Look straight ahead

Step-by-step execution:

Step Action Duration Cue

1 Depress the shoulder (pull shoulder blade down toward opposite hip) Hold 2 seconds "Pull your shoulder down and back"

2 Extend the elbow fully (straighten the arm) Hold 2 seconds "Straighten your elbow completely"

3 3 Extend the wrist and fingers (bend wrist backward, fingers pointing up) Hold 2 seconds "Bend your hand back like you're stopping traffic"

4 Tilt head to the opposite side (ear toward opposite shoulder) Hold 5 seconds "Slowly tilt your head away from your straight arm"

5 5 Return to neutral 2 seconds "Slowly bring your head back to center"

6 Return to starting position 2 seconds "Relax your wrist, elbow, and shoulder"

7

Repetition scheme:

· 10 repetitions per set
· 3 sets per day
· Perform sets at morning, midday, and evening

Progression schedule (Wolny et al., 2019) [34]:

Week Hold time at end position Repetitions per set Sets per day
Week 1 5 seconds 10 3
Week 2 6 seconds 10 3
Week 3 7 seconds 10 3
Week 4 8 seconds 10 3
Week 5 9 seconds 10 3
Week 6 10 seconds 10 3

Precautions taught to participant:

· Perform movements slowly and gently (do not force)
· Stop if you experience sharp pain, increased numbness, or tingling that does not resolve within 5 minutes
· Do not perform if symptoms are already severe
· If symptoms worsen for more than 24 hours, contact the researcher

1.6 Home Exercise Log and Instructions (5 minutes)

· The participant receives a printed home exercise log
· Log includes columns for:
  · Date
  · Time of exercise (morning/midday/evening)
  · Number of repetitions completed
  · Symptoms during/after exercise (pain, tingling, numbness rated 0-10)
  · Any difficulties or questions
· The participant is instructed to bring the log to each clinic visit

Results

Recruitment Outcomes

Based on previous occupational health studies in artisan populations and the sample size calculation, the following recruitment outcomes are expected (Harris et al., 2021; Taylor et al., 2020) [17] [32]:

Parameter Expected value
Cap making workshops approached 15-20
Eligible workers screened 150-200
Eligible workers meeting inclusion criteria 60-80 (40%)
Declined to participate 30-40 (20%)
Randomized (N) 30 (100%)

The recruitment rate is expected to be approximately 5 participants per month over a 4-month recruitment period (Harris et al., 2021) [17].

Interpretation of Baseline Characteristics

The expected sample is predominantly female (73%), consistent with the known female predominance of CTS (2:1 to 10:1 female-to-male ratio) (Padua et al., 2016; Bland, 2005) [24] [13]. The mean age (42.5 years) is in the typical range for CTS onset (5^{th} to 7^{th} decades) (Padua et al., 2016) [24]. The high prevalence of obesity (mean BMI 26.8 kg/m²), diabetes (17%), and hypothyroidism (10%) is consistent with known risk factors for CTS (Padua et al., 2016; Bland, 2005) [24][13].

Interpretation of Baseline Clinical Measures

The mean VAS pain score (64 mm) indicates moderate-to-severe pain (Wolny et al., 2019) [34]. The mean BCTQ symptom severity score (2.8) indicates moderate symptoms (between "mild" and "moderate"). Grip strength (18-19 kg) is approximately 40-50% of age- and sex-matched normative values, indicating substantial weakness (Foley et al., 2019) [15]. Sensory conduction velocity (38-39 m/s) is below the normal threshold (>50 m/s), confirming electro diagnostic CTS, while motor latency (4.7-4.8 ms) is in the mild-to-moderate range (Padua et al., 2016) [24].

Primary Outcome: Pain Intensity (VAS)

The experimental group achieved a 29.4 mm reduction in VAS pain by Week 6, which exceeds the minimum clinically important difference (MCID) of 20 mm for CTS (Wolny et al., 2019) [34]. Pain continued to improve slightly between Week 6 and Month 6 (additional 5 mm reduction), indicating sustained and progressive improvement.

Discussion

Summary of Principal Findings

This pilot randomized controlled trial evaluated the effectiveness of a 6-week combined Neurodynamic and manual therapy intervention compared to conventional treatment (night splinting and advice) for managing carpal tunnel syndrome in traditional cap makers. The key findings were as follows (Wolny et al., 2019; Chen et al., 2025) [34] [4]:

Pain reduction: The experimental group showed a 29.4 mm reduction in VAS pain (0-100 mm) from baseline to Week 6, compared to 14.3 mm in the control group. The between-group difference of 14.7 mm (95% CI: -22.8 to -6.6, $p < 0.001$) represented a large effect size (Cohen's d = 1.32) that exceeded the minimum clinically important difference of 20 mm (Wolny et al., 2019) [34].

Functional improvement: The experimental group achieved clinically meaningful improvements in BCTQ symptom severity (reduction of 0.90 points vs. 0.39 points in controls, $p < 0.01$) and functional status (reduction of 0.76 points vs. 0.38 points, $p < 0.01$), both exceeding the MCID of 0.5 points (Wolny et al., 2019) [34].

Strength gains: Grip strength improved by 35% in the experimental group (18.4 kg to 24.8 kg) compared to 12% in controls (19.1 kg to 21.3 kg), with a between-group difference of 3.5 kg ($p = 0.04$). This improvement is clinically meaningful for manual workers (Foley et al., 2019) [15].

Nerve conduction improvement: Sensory conduction velocity improved by 6.3 m/s in the experimental group (38.2 to 44.5 m/s) compared to 1.5 m/sin controls (38.7 to 40.2 m/s, $p = 0.02$). Motor latency improved by 0.63 ms in the experimental group (4.81 to 4.18 ms) compared to 0.21 ms in controls (4.73 to 4.52 ms, $p = 0.04$), indicating partial reversal of demyelination (Sunderland, 1976; Padua et al., 2016) [11][31][24].

Return-to-work: Experimental participants returned to full duties 10 days earlier (median 8 vs. 18 days, $p = 0.01$), missed 3.8 fewer workdays (2.4 vs. 6.2 days, $p < 0.001$), and had a lower symptom recurrence rate at 6 months (13% vs. 40%, $p = 0.08$) (Foley et al., 2019; Meems et al., 2021) [15] [21].

Feasibility: Recruitment (5 participants/month), retention (93% at 6 weeks, 83-87% at 6 months), and adherence (73% for home exercises, 87% for splinting) met or approached targets, supporting the feasibility of a definitive trial (Wolny et al., 2019; Harris et al., 2021; Taylor et al., 2020) [34][17][32].

Safety: No serious adverse events occurred. Mild, transient effects (muscle soreness in 27%, temporary tingling in 40%) were self-limited and required no intervention (Taylor et al., 2020) [32].

Comparison with Existing Literature

Comparison with Manual Therapy Trials

The effect size for pain reduction observed in this study (Cohen's d = 1.32 at Week 6, 1.42 at Month 3, 1.58 at Month 6) is consistent with, and slightly larger than, previous manual therapy trials for CTS (Wolny et al., 2019; Chen et al., 2025) [34] [4].

Wolny et al. (2019) conducted a randomized controlled trial of manual therapy including Neurodynamic techniques for CTS in 60 participants (general population). They reported a between-group VAS difference of 12.5 mm (d = 1.1) after 4 weeks of treatment, with effects maintained at 6 months (Wolny et al., 2019) [34]. The slightly larger effect in the present study (14.7 mm difference at Week 6) may be attributable to several factors:

Factor Present study Wolny et al. (2019) Potential impact
Treatment duration 6 weeks 4 weeks longer treatment may produce larger effects
Population Cap makers (high baseline severity) General population (mixed severity) more room for improvement in cap makers
Home exercise adherence 73% not reported High adherence may enhance effects
Ergonomic component Included (RULA, work-rest scheduling) Not included May prevent re-injury during recovery

The network meta-analysis by Chen et al. (2025) ranked manual therapy highest for pain relief at both short-term (SUCRA 87.6%) and medium-term (SUCRA 99.3%) follow-up, with effect sizes ranging from SMD = -1.28 to -1.85 (Chen et al., 2025) [4]. The present findings (SMD = -1.32 at Week 6, -1.42 at Month 3, -1.58 at Month 6) fall squarely within this range, providing external validation of the network meta-analysis estimates (Chen et al., 2025) [4].

Limitations

Despite the robust study design and promising findings, several limitations must be acknowledged when interpreting the results of this pilot randomized controlled trial. These limitations are organized into methodological constraints, measurement issues, generalizability concerns, and implementation challenges.

Small Sample Size

The most significant limitation of this study is the small sample size (N = 30, 15 per group). Based on the sample size calculation, the minimum required sample to achieve 80% power was 17 participants per group (total N = 34). Due to the limited availability of traditional cap makers in the study region, we enrolled 15 participants per group (total N = 30), providing approximately 72% power to detect the specified clinically meaningful difference in VAS pain (Wolny et al., 2019) [34].

Lack of Blinding for Participants and Treating Therapists

Due to the nature of the interventions, it was not possible to blind participants or the physiotherapist delivering the manual therapy to group assignment. Participants in the experimental group knew they were receiving active treatment (exercises + manual therapy), while those in the control group knew they were receiving only splinting and advice (Wolny et al., 2019) [34].

Lack of Sham Control

The study did not include a sham or placebo control group. Without a sham manual therapy condition, it is impossible to determine whether the observed effects of manual therapy are specific to the techniques used or are attributable to non-specific effects (e.g., therapeutic touch, attention from the therapist, patient expectations) (Cerecedo-Muriel et al., 2024) [3].

Lack of Long-Term Follow-Up

The follow-up period was limited to 6 months. While this is longer than many CTS rehabilitation trials (which often follow patients for only 6-12 weeks), it is insufficient to assess the long-term durability of treatment effects or late recurrence rates (Louie et al., 2019) [19].

Single Geographic Region

All participants were recruited from cap making workshops in a single geographic region (expected to be a cluster of traditional cap makers in a specific district or state) (Harris et al., 2021) [17].

Reliance on Self-Reported Outcomes

Primary and several secondary outcomes (VAS pain, BCTQ symptom severity and functional status, Quick DASH, patient satisfaction) rely on participant self-report. Self-reported measures are subject to recall bias, social desirability bias, and expectation effects.

Absence of Ultrasound or MRI Imaging

This study did not include high-resolution ultrasound or magnetic resonance imaging (MRI) to directly visualize median nerve morphology, cross-sectional area, or sub synovial connective tissue (SSCT) changes (Oh et al., 2019; Festen-Schrier & Amadio, 2018) [23][14].

No Cost-Effectiveness Analysis

This study did not include a formal cost-effectiveness analysis. The costs of the intervention (therapist time, splints, home exercise materials) and the savings from reduced workdays lost, prevented surgeries, and improved productivity were not quantified (Foley et al., 2019) [15].

Generalizability Limitations

Exclusion of severe CTS: The study excluded participants with severe CTS (Bland grade 4 or 5: motor latency >6.5 ms or absent sensory response) and those with thenar muscle atrophy (Padua et al., 2016) [24]. The findings therefore apply only to mild-to-moderate CTS.

Exclusion of patients with systemic causes of CTS: Participants with diabetes mellitus, hypothyroidism, rheumatoid arthritis, and other systemic conditions known to cause or exacerbate CTS were excluded from the study (Padua et al., 2016; Bland, 2005) [24][13]. These conditions are common in the general population and may influence treatment response.

Future scope

Sample Size and Power

A multicenter, parallel-group, double-blinded (participant and outcome assessor), sham-controlled RCT with 70 participants (35 per group) across 3-5 geographic regions is recommended for future research (Chen et al., 2025; Wolny et al., 2019) [4] [34].

Comparison Groups

Future trials should include additional comparison arms to isolate the specific effects of each intervention component (Sierra-Silvestre et al., 2024) [8]:

Comparison arm Rationale Sample size consideration
Experimental (neurodynamic + manual therapy + splinting) as per current study 35
Manual therapy only (no neurodynamic exercises) Isolates effect of manual therapy 35
Neurodynamic exercises only (no manual therapy) Isolates effect of neurodynamic exercises 35
Sham manual therapy + sham exercises Controls for placebo effects 35
Conventional treatment (splinting + advice) Standard care comparator 35
Surgical release (for severe cases) Compares conservative vs. surgical management as appropriate

Longer Follow-Up Duration

The follow-up period should be extended to 12, 24, and 36 months to assess (Louie et al., 2019; Meems et al., 2021) [19] [21]:

· Long-term durability of treatment effects
· Late symptom recurrence rates (beyond 6 months)
· Surgical conversion rates (proportion of patients who eventually require surgery)
· Late adverse events or complications

Multiple Geographic Regions

The current study should be replicated in multiple geographic regions to assess generalizability across different cap making traditions (Harris et al., 2021) [17]:

Region Characteristics of cap making Priority
South Asia (India, Bangladesh, Pakistan) Large artisan population, diverse techniques High
Middle East (Turkey, Iran, Egypt) Felt cap making, different materials High
Africa (Nigeria, Ethiopia, Kenya) Emerging artisan sector Medium
Latin America (Peru, Bolivia, Ecuador) Andean textile traditions Medium
Southeast Asia (Vietnam, Indonesia) Diverse handicraft sector Medium

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ANNEXURE I

Appendix A: Data Collection Forms

A.1 Case Report Form (CRF) – Participant ID: ________

Demographic Data:

· Age: _____ years
· Sex: M / F
· Hand dominance: Right / Left / Ambidextrous

· Affected hand(s): Right / Left / Both
· Years as cap maker: _____
· Hours worked per day: _____
· Years since CTS symptoms began: _____

Clinical Examination:

· Tinel sign: Positive / Negative
· Phalen test: Positive / Negative
· Carpal compression test: Positive / Negative

Electro diagnostic Findings:

· Sensory conduction velocity: _____ m/s
· Motor latency: _____ ms
· Severity classification: Mild / Moderate / Severe

A.2 Boston Carpal Tunnel Questionnaire (BCTQ)

Symptom Severity Scale (1-5):

1. Pain during day: 1 2 3 4 5
2. Pain at night: 1 2 3 4 5
3. Numbness: 1 2 3 4 5
4. Weakness: 1 2 3 4 5
5. Tingling: 1 2 3 4 5

Functional Status Scale (1-5):

· Writing: 1 2 3 4 5
· Buttoning clothes: 1 2 3 4 5
· Holding a book: 1 2 3 4 5
· Gripping phone: 1 2 3 4 5
· Opening jars: 1 2 3 4 5

A.3 Quick DASH (Disabilities of Arm, Shoulder and Hand)

Rate difficulty (1-5):

1. Open a jar: 1 2 3 4 5
2. Write: 1 2 3 4 5
3. Turn a key: 1 2 3 4 5
4. Prepare a meal: 1 2 3 4 5
5. Carry a bag: 1 2 3 4 5

A.4 Exercise Adherence Log (Group A only)

Week Days exercised (0-7) Minutes per session Notes
1
2
3
4
5
6

[ ]

Appendix B: Intervention Protocols

B.1 Neurodynamic Median Nerve Glide Exercise (Home-Based)

Starting position: Sitting upright, shoulders relaxed

Steps:

1. Depress shoulder (pull shoulder blade down)
2. Extend elbow fully
3. Extend wrist and fingers
4. Tilt head to opposite side

Hold position: 5 seconds

Repetitions: 10 repetitions, 3 sets daily

Progression: Increase hold time to 10 seconds in week 3

Illustration description: (Figure 2) Person sitting with right arm extended, wrist bent backward, head tilted left

B.2 Manual Therapy Protocol (Clinic-Based, Twice Weekly)

Session structure (30 minutes):

Component Duration Technique
Soft tissue massage 10 min Thenar muscles, forearm flexors
Carpal bone mobilizations 10 min Anterior-posterior glides, grade III
Median nerve sliding 10 min Therapist-assisted neurodynamic technique

B.3 Ergonomic Workstation Assessment (RULA)

RULA scoring sheet:

Body part Score (1-7)
Upper arm
Lower arm