STUDY PROTOCOL

Official Title:

The Effectiveness of Conservative Treatment with Added Kinesio Taping in Decreasing Pain and Improving Hand Function and Grip Strength among Individuals with Lacertus Syndrome: A Pilot Randomized Controlled Trial

NCT Number: Pending

Version: 1.0

Date: 1 February 2026

Principal Investigator: Husam Taha

Program: PhD in Rehabilitation Sciences

Institution: Arab American University Palestine

The Effectiveness of Conservative Treatment with Added Kinesio Taping in Decreasing Pain and Improving Hand Function and Grip Strength among Individuals with Lacertus Syndrome: A Pilot Randomized Controlled Trial

A PhD Dissertation Proposal

Submitted by: Husam Taha

Program: PhD in Rehabilitation Sciences

Institution: Arab American University Palestine

1. Introduction

1.1. Problem Statement

Lacertus syndrome is also a dynamic compression of the median nerve at the lacertus fibrosus, which is becoming an increasingly recognized, but often not considered cause of forearm pain, paresthesia, and functional disability (Hagert, 2013). It has been confused with carpal tunnel syndrome or other nerve entrapment neuropathies and is uncommonly diagnosed, with up to 20% of patients having signs of median nerve involvement (Spinner & Amadio, 2003). The diagnostic issue is that this condition needs to be distinguished out of other similar syndromes and this has been facilitated recently with the introduction of more specific clinical tests including the Orthogonal Kinesiotaping Test (OKT) (Apard et al., 2025).

Surgical decompression is the current standard of care of lacertus syndrome and it has reported high levels of success (Puntillo & Bertini, 2018). Surgery is not however always a viable and desirable option especially in resource constrained healthcare systems like in Palestine. Effective, evidence-based options of conservative treatments are thus an urgent clinical and community health concern. Lacertus syndrome is currently being treated in a conservative manner that is not well defined and there is no high quality evidence to inform clinical practice. This PhD proposal is going to fill this critical gap in the literature with a promising, non-invasive, and low-cost intervention: Kinesio Taping.

1.2. Rationale for Kinesio Taping

Kinesio Taping (KT) is a treatment method which has gained prominence within the region of rehabilitation; and a growing body of evidence on the application of this method in a broad range of musculoskeletal and neurological problems continues to increase (Kase, 2003). The KT mechanism of action as postulated is multifactorial in nature and consists of cutaneous mechanoreceptor excitation, fascial decompression, proprioceptive improvement and neuromuscular re-education (Williams et al., 2012). A recent systematic review and meta-analysis demonstrated that KT can be a useful tool to alleviate pain and functional output syndrome such as

carpal tunnel syndrome that is also a median nerve entrapment neuropathy (Ahn et al., 2019; Tomás-Escolar et al., 2023). These findings indicate that concepts applied to inform the application of KT can be applied to other peripheral nerve entrapment syndromes like the lacertus syndrome.

1.3. Significance of the Research

The Palestinian healthcare system is characterized by certain special challenges, such as the shortage of resources and the lack of access to specialized surgery services (Eker & Imam, 2025). As a result, the need to develop cost-effective conservative treatment methods that may be applied in the primary care setting has become acute. Kinesio Taping is the perfect intervention in this situation because it is non-invasive, comparatively cheap and can be implemented in the patients so that they can administer it themselves. Also, the cultural background of Palestinian community, where non-surgical procedures are often preferred, suits the creation of evidence-based conservative treatment regimens quite well (Giacaman, 2018). This study can, therefore, profoundly influence clinical practice in Palestine and other health care settings with lack of an evidence-based and culturally-sensitive treatment option to lacertus syndrome.

2. Literature Review

2.1. Lacertus Syndrome: An Evolving Understanding

2.1.1. Historical Perspective and Diagnostic Evolution

The development of lacertus syndrome as an independent clinical condition has taken its time and is changing with time. It has been initially characterized as a form of pronator syndrome but it is currently perceived as a form of median nerve entrapment in the lacertus fibrosus (Johnson et al., 1979). The lacertus fibrosus or bicipital aponeurosis is a connective tissue emerging out of the tendon of the biceps brachii up to the deep fascia of the forearm which forms a potential location of the median nerve compression. The Hagert studies have also played a major role in establishing the clinical features and diagnostic criteria of lacertus syndrome that comprises forearm pain,

paresthesias of the median nerve distribution, and pain on resisted pronation and flexor-pronator loading (Puntillo & Bertini, 2018). In more recent times, the clinical tests have been developed to improve the diagnostic process. The lacertus compression test has proved to be very sensitive and specific to the condition. One of these is the Orthogonal Kinesiotaping Test (OKT) that was designed by Apard et al. (2025) and proved to be sensitive (95 percent) and specific (89 percent)(Apard et al., 2025) . The OKT is an adaptation of the lacertus antagonist test (LAT), except that the examiner places Kinesio tape that mimics the hand action of LAT and can then examine the upper limb in detail. This new diagnostic technique does not just enhance the accuracy of the diagnosis but also enhances the knowledge of the condition just as it is in the patients.

2.1.2. Current Treatment Paradigms and Their Limitations

The current standard of care for lacertus syndrome is surgical release of the lacertus fibrosus, a procedure that has consistently demonstrated positive clinical outcomes (Hagert, 2013; Puntillo & Bertini, 2018). However, surgery is not without limitations. Some patients experience persistent or incomplete symptom resolution, and the procedure requires specialized expertise that may not be available in all clinical settings—particularly those with limited resources. These challenges underscore the need for effective conservative management strategies.

Despite this need, the literature shows a significant gap: very few studies have been conducted in the area of non-surgical treatment options for lacertus syndrome (Neal & Fields, 2010). Existing conservative approaches will usually encompass activity modification, the use of anti-inflammatory medication and general physical therapy techniques. However, these interventions are not specific to the pathophysiological features of lacertus syndrome. Brutus et al. (2025) , highlight the important role of hand therapists in the management as well as diagnosis of this condition, and recommend a comprehensive intervention that includes therapist-led exercises in nerve gliding exercises, muscle stretching and ergonomic education. Corticosteroid injection (CSI) has also been tried as a conservative treatment; one trial found that 75% of patients had short-term benefit from this treatment (Frees & Ward, 2025). Nonetheless, the study also found that a third of patients initially treated with CSI eventually needed surgery as a result of the symptoms returning, suggesting that CSI may only provide temporary benefit rather than one that is definitive.

Lacertus syndrome is a very specific and relatively uncommon syndrome of dynamic compression of the median nerve at the lacertus fibrosus. Because there is a dearth of good quality research in the specific context of conservative care for the condition, the current study utilises the wider body of evidence for conservative management of other median nerve entrapment syndromes - most notably carpal tunnel syndrome (CTS). This approach makes sense given the common underlying mechanism of median nerve compression and the applicability of peripheral nerve entrapment principles of different anatomical regions (Currie et al., 2022; Del Barrio et al., 2018).

Systematic reviews of CTS management reliably advocate for a multimodal conservative approach to mild to moderate nerve entrapment before resorting to surgery (Currie et al., 2022; Del Barrio et al., 2018). Although lacertus syndrome involves the proximal forearm and not the wrist, the goals of treatment are similar: decreased mechanical compression, increased nerve mobility and relief of symptoms. Key elements of Evidence Based Conservative Management are:

Splinting: Neutral wrist splinting, especially at night, is a cornerstone of CTS care, and this reduces the pressure on the median nerve by keeping the wrist in a neutral position (Currie et al., 2022).

Nerve-Gliding Exercises (Neuromobilization): There is mounting evidence for the use of nerve-gliding techniques for optimal nerve excursion and symptom reduction in median nerve entrapment. A systematic review conducted by Ballestero-Pérez et al. (2017) showed improvements in pain and function of patients with CTS (Ballestero-Perez et al., 2017), and another clinical trial showed additional improvements when neuromobilization was used with routine physical therapy (Ijaz et al., 2022). As these exercises work on the whole of the median nerve pathway, they have direct application to the lacertus syndrome.

Activity Modification and Patient Education: Ergonomic teaching, avoidance of symptom-provoking postures (e.g. repetitive pronation especially seen in lacertus syndrome), and self-management strategies are essential components of conservative care (Del Barrio et al., 2018).

Corticosteroid Injections: Although these injections offer short-term relief, corticosteroid injections are still a known option in the treatment of median nerve entrapment (Currie et al., 2022). The recent evidence specific to lacertus syndrome is promising in terms of short-term outcomes (Frees & Ward, 2025).

Given the limited research dedicated exclusively to conservative treatment of lacertus syndrome, this study applies well-supported conservative principles established for CTS and related median nerve entrapment disorders. This evidence-based foundation provides a strong rationale for developing a standardized usual-care protocol within the proposed study, against which the additional benefit of Kinesio Taping can be systematically evaluated.

2.2. The Research Gap: A Need for Evidence-Based Conservative Treatments

It is evident that there is a critical gap in evidence base of conservative management of lacertus syndrome in existing literature. The study is extremely biased when it comes to surgical interventions, where there is a lack of quality research on non-invasive, therapist-led research. This is especially troublesome in the healthcare systems that lack resources, like in Palestine, where surgery might not be an easily available and desired procedure. This PhD proposal bridges this gap directly through the proposal of a thorough assessment of a promising conservative intervention Kinesio Taping.

3. Theoretical Framework: The International Classification of Functioning, Disability and Health (ICF) Model

Using the ICF model especially the hand core set (Kus et al., 2012, 2017), lacertus syndrome is understood not just as a nerve compression issue, but as a condition that impacts multiple levels of a person's life. The Kinesio Taping intervention is conceptualized as a facilitator within this framework, aiming to improve body functions, which in turn enhances activities and participation. Within the ICF framework, lacertus syndrome is identified as the Health Condition , representing a dynamic median nerve entrapment confirmed through clinical diagnosis using Hagert's Triad and the Orthogonal Kinesiotaping Test (OKT). This condition leads to impairments in Body Functions & Structures , which will be the primary focus of the intervention. Specifically, this study will measure impairments such as b280 Sensation of pain using the Numeric Pain Rating Scale (NRS), b730 Muscle power functions (weakness) with a hand dynamometer and pinch gauge, and b265 Touch function (paresthesia). The relevant body structure is s730 Structure of the upper extremity,

specifically the lacertus fibrosus.

The impact of these impairments on a patient's daily life is captured under the Activities & Participation domain. This study will assess limitations and restrictions in areas such as d440 Fine hand use, d445 Hand and arm use, d5 Self-care, d6 Domestic life, and d8 Major life areas (e.g., work) using the QuickDASH questionnaire.

Finally, the Environmental Factors domain includes the facilitators that are being investigated. These include the Kinesio Taping intervention itself, the standardized conservative treatment protocol (including education and exercise), and the support from health professionals (e355), which will be documented through the intervention and conservative treatment protocols.

This framework provides a comprehensive and structured approach to:

1. Holistic Assessment: It ensures that the study evaluates not just pain and strength (Body Functions), but also the real-world impact on a patient's ability to perform daily tasks (Activities and Participation), as captured by the QuickDASH.

2. Clear Intervention Target: It positions the Kinesio Taping intervention as a targeted therapy aimed at reducing impairments in Body Functions (e.g., pain, weakness) with the ultimate goal of improving Activities and Participation.

3. Standardized Language: It uses a common, internationally accepted language to describe the patient's experience and the study's outcomes, enhancing the comparability and generalizability of the findings.

By adopting the ICF and the Brief ICF Core Set for Hand Conditions, this study aligns with modern clinical research standards, ensuring that the evaluation of the Kinesio Taping intervention is comprehensive, patient-centered, and systematically structured.

4. Research Questions and Hypotheses

This pilot study is guided by primary feasibility questions and secondary effectiveness questions.

4.1. Primary Feasibility Research Questions

The primary feasibility research questions are as follows:

- What are the recruitment and retention rates for a 4-week Kinesio Taping intervention trial among adults with lacertus syndrome in the West Bank?
- What is the adherence rate to the prescribed Kinesio Taping protocol among participants in the intervention group?

4.2. Secondary Effectiveness Research Questions

- **Research Question 2a:** What is the preliminary estimate of the treatment effect of Kinesio Taping on pain intensity, as measured by the Numeric Pain Rating Scale (NRS)?
- **Research Question 2b:** What is the preliminary estimate of the treatment effect of Kinesio Taping on upper extremity function, as measured by the QuickDASH questionnaire?
- **Research Question 2c:** What is the preliminary estimate of the treatment effect of Kinesio Taping on grip strength, as measured by a hydraulic hand dynamometer?
- **Research Question 2d:** What is the preliminary estimate of the treatment effect of Kinesio Taping on pinch grip strength, as measured by a calibrated pinch gauge?

5. Methodology

5.1. Study Design

A pilot, single-blind, parallel-group randomized controlled trial (RCT) will be used in this study. It will be a 1:1 allocation ratio where a group of therapeutic Kinesio Taping (KT plus Conservative treatment) will be compared to a control group (Conservative treatment alone). It will be a single-blinded study and the outcome assessor is going to be blinded in terms of group assignment. Clinical trials registry (e.g., ClinicalTrials.gov) registration of the study protocol will take place before the recruitment starts.

5.2. Participants and Recruitment

5.2.1. Sample Size Justification

The sample size for this pilot study is set at 30 participants (15 per group). This number is consistent with established guidelines for pilot and feasibility studies, which recommend a sample size of 24 to 50 participants to reliably estimate the standard deviation for a future, larger-scale RCT (Julious, 2005; Whitehead et al., 2016). A sample size of 30 will provide sufficient data to:

- **Estimate Key Feasibility Parameters:** With 15 participants per group, we can obtain reasonably precise estimates of recruitment rates, retention rates, and adherence to the intervention.
- **Obtain Preliminary Estimates of Treatment Effect:** While this pilot study is not powered to detect statistically significant differences between the groups, it will provide preliminary estimates of the treatment effect size (Cohen, 2013) .
- **Assess the Variance of Outcome Measures:** The data collected from this pilot study will allow us to estimate the variance of the primary outcome measures (Numeric Pain Rating Scale [NRS], Quick Disabilities of the Arm, Shoulder and Hand [QuickDASH], grip strength and pinch strength), which is essential for calculating the sample size for a future, definitive RCT.

5.2.2. Inclusion and Exclusion Criteria

Participants will be eligible for inclusion if they are adults between 18 and 65 years of age with a confirmed clinical diagnosis of lacertus syndrome. This diagnosis must be established by a physician specializing in orthopedics, physical medicine, or neurology and must follow a standardized, multi-modal diagnostic protocol. Following this protocol, a comprehensive clinical examination will be administered to each of the participants and that will begin with a detailed medical history that will rule out other potential causes of forearm pain or neuropathy. The positive Hagert three criterion to be fulfilled in diagnosis will be positive palpation of lacertus fibrosus, recreation of symptoms during resisted forearm rotation, and recreation of symptoms during resisted elbow flexion. Besides these,

the participants are also required to demonstrate a positive Orthogonal Kinesiotaping Test (OKT) - a very specific diagnostic test of the lacertus syndrome - to be conducted by a certified examiner (Apard et al., 2025). A thorough neurological assessment will also be done to eliminate other forms of median nerve entrapment syndrome, including carpal tunnel syndrome. To be able to provide a greater diagnostic accuracy, electrodiagnostic analysis (electromyography [EMG]/nerve conduction study [NCS]) will be performed, which shall identify the functionality of the median nerve, the presence of nerve compression and exclude other causes of neural compromise, including cervical radiculopathy. In order to obtain a relatively homogenous sample with subacute to chronic presentations will be included only those people who have had their symptoms not less than four weeks.

Participants will be excluded from the study if they have had surgery for lacertus syndrome or any other condition that trapped the median nerve in the affected arm. Additional exclusion criteria include a known allergy to Kinesio tape or adhesive materials, the presence of any dermatological condition at the intended site of tape application, and any neurological or musculoskeletal disorder that could confound the assessment of lacertus syndrome symptoms. Pregnant individuals will also be excluded from participation.

5.2.3. Recruitment Strategy

Recruitment will take place at multiple private clinics, medical centers and hospitals from middle and north governorate in the West Bank. Potential participants will be identified by the treating clinicians and provided with information about the study. If they express interest, they will be contacted by the primary researcher (Husam Taha) to be screened for eligibility.

5.3. Randomization and Allocation Concealment

5.3.1. Randomization Procedure

Following enrollment and baseline assessment, participants will be allocated to treatment groups using a sophisticated covariate-adaptive minimization procedure designed to ensure balanced

group characteristics and minimize the risk of confounding (Lin et al., 2015). This approach represents a significant methodological advancement over simple randomization or fixed block randomization methods.

Covariate-Adaptive Minimization: The Pocock and Simon covariate-adaptive randomization method will be used in the study, which aims to dynamically balance treatment groups based on several prognostic factors over the recruitment period (Pocock & Simon, 1975). Unlike fixed block randomization, this approach does not depend on the number of participants; instead, the participant is randomized as soon as he or she joins the trial but group balance is maintained dynamically. The minimization algorithm will balance the following key prognostic variables: age (≤40 years vs. >40 years), gender (male vs. female), symptom duration (4-12 weeks vs. >12 weeks), baseline pain intensity (NRS ≤5 vs. NRS >5), and recruitment site .

Methodological Advantages: Covariate-adaptive minimization has a few advantages over conventional randomization techniques, which are relevant to this pilot study with a moderate sample size (Coart et al., 2023). Simulation studies show that minimization yields superior balanced treatment groups compared to restricted or unrestricted randomization, especially if the analysis takes several covariates into account (Scott et al., 2002). The presence of the probabilistic element in the Pocock and Simon method adds randomness while more emphasis is placed on balance, thus minimising the risk of selection bias and confounding (Zhao et al., 2015). Minimization is of particular value in trials with moderate sample sizes where chance imbalances are more likely to occur and have greater impact on validity of the study (Pandis, 2011).

5.3.2. Implementation Protocol

The minimization procedure will be implemented using validated randomization software that incorporates the Pocock and Simon algorithm with probabilistic treatment assignment (Saghaei, 2011). The system will use a biased coin probability of 0.75 for assignment to the treatment that minimizes imbalance, with 0.25 probability for the alternative treatment. This approach maintains adequate randomness while achieving superior balance compared to deterministic minimization

(Saghaei, 2011). The randomization system will operate in real-time, allowing immediate treatment allocation upon completion of baseline assessments.

5.3.3. Allocation Concealment and Blinding

The randomization sequence will be generated and maintained by an independent statistician not involved in participant recruitment or assessment. Treatment allocation will be concealed through a secure, password-protected web-based system (Schulz & Grimes, 2002). The study will employ single-blind design with the outcome assessor blinded to group allocation. To maintain assessor blinding, outcome assessments will be conducted by a research assistant not involved in treatment delivery, and participants will be instructed not to discuss their treatment with the assessor (Bang et al., 2004).

5.4. Interventions

5.4.1. Experimental Group: Therapeutic Kinesio Taping

Participants in the experimental group will receive therapeutic Kinesio Taping applied with 25–50% stretch over the lacertus fibrosus, in addition to Conservative treatment. The intervention protocol will be standardized and will include:

- **Materials:** 5 cm width elastic therapeutic tape, alcohol swabs for skin preparation, and an optional barrier film.
- **Landmarks:** Biceps tendon/lacertus fibrosus region, proximal pronator teres, and medial forearm fascia.
- **Technique:** The tape will be applied with 25–50% stretch across the symptomatic area, following standardized landmarks.
- **Training and Home Application:** The treating therapist will perform the initial application in the clinic and will provide a structured training session for the participant and/or a caregiver. This will include a hands-on demonstration and return-demonstration until competency is achieved, printed step-by-step instructions, and access to an

instructional video. Participants will be provided with a tape application log to record application and removal dates and any skin reactions. Telephone or messaging support will be available for troubleshooting.

- **Frequency/Dose:** Participants will be instructed to reapply the tape every 2-3 days for a total of 4 weeks.

5.4.2. Control Group: Standardized Conservative treatment

The control group will receive a standardized usual care protocol adapted from evidence-based conservative management for other median nerve entrapment syndromes, particularly carpal tunnel syndrome (CTS) (Ballestero-Perez et al., 2017; Del Barrio et al., 2018; Ijaz et al., 2022). This adaptation is necessary due to the lack of specific high-quality evidence for lacertus syndrome conservative care. This protocol will consist of a 4-week intervention including:

Educational Component: All participants will receive a standardized 30-minute educational session about lacertus syndrome, including anatomy and pathophysiology explanation using standardized diagrams, activity modification guidelines with specific examples, ergonomic principles for workplace and daily activities, and written educational materials in Arabic.

Standardized Exercise Program: A structured home exercise program consisting of median nerve gliding exercises (3 sets of 10 repetitions, twice daily), tendon gliding exercises for flexor tendons (3 sets of 10 repetitions, twice daily), gentle stretching exercises for forearm muscles (30-second holds, 3 repetitions, twice daily), and progressive strengthening exercises using resistance bands during weeks 3-4.

Activity Modification Guidelines: Specific, standardized recommendations including avoidance of repetitive pronation activities for more than 30 minutes continuously, use of ergonomic tools when possible, regular breaks every 30 minutes during repetitive activities, and specific workplace modifications based on occupation.

Follow-up Protocol: Standardized follow-up will include weekly telephone check-ins to monitor compliance and address questions, standardized exercise logs for tracking adherence, and

consistent messaging about expectations and timeline for improvement. This standardized usual care will be provided to both the control group and the experimental group to ensure that any observed differences can be attributed to the Kinesio Taping intervention.

5.5. Outcome Measures

Outcomes will be assessed at baseline, at the end of the 4-week intervention period.

5.5.1. Feasibility Outcomes

- **Recruitment rate:** The number of participants recruited per month.
- **Retention rate:** The proportion of participants who complete the 4-week intervention .
- **Adherence rate:** The proportion of participants who adhere to the Kinesio Taping protocol, as assessed by the tape application logs.

5.5.2. Effectiveness Outcomes

Pain Intensity - Numeric Pain Rating Scale (NRS): The NRS is an 11-point scale ranging from 0 (no pain) to 10 (worst imaginable pain). The NRS demonstrates excellent psychometric properties with strong construct validity (r = 0.86-0.95 with Visual Analog Scale [VAS]) and criterion validity (r = 0.63 with standardized pain measures) (Jensen, 2003; Nugent et al., 2021). Test-retest reliability is excellent (Intraclass Correlation Coefficient [ICC] = 0.95-0.98), and the instrument shows good responsiveness with a minimal clinically important difference (MCID) of 2 points (Modarresi et al., 2022; Young et al., 2025). The NRS is widely recommended for pain assessment in clinical trials due to its simplicity, validity, and sensitivity to change (Jt, 2001).

Upper Extremity Function - Quick Disabilities of the Arm, Shoulder and Hand (QuickDASH): The QuickDASH is an 11-item questionnaire that measures physical function and symptoms in individuals with upper extremity musculoskeletal disorders. The instrument demonstrates excellent construct validity with strong correlation to the full DASH questionnaire (r = 0.96) and good convergent validity with other upper extremity measures (Beaton et al., 2005). Internal consistency is excellent (Cronbach's α = 0.89-0.94), and test-retest reliability is excellent (ICC = 0.90-0.97) (Mintken et al., 2009). The QuickDASH shows good responsiveness to change

with effect sizes of 0.6-1.2 and an MCID of 8-16 points (Sorensen et al., 2013). The Arabic version has demonstrated excellent psychometric properties (Cronbach's α = 0.90, ICC = 0.91), making it appropriate for use in the Palestinian population(Alnahdi, 2021).

Grip Strength - Hydraulic Hand Dynamometer: Hand grip strength will be measured using a calibrated hydraulic hand dynamometer following standardized protocols established by the American Society of Hand Therapists (ASHT). Hydraulic dynamometers demonstrate excellent concurrent validity (r = 0.97-0.99 between different brands) and construct validity with overall muscle strength measures (Sartorio et al., 2025). Reliability is excellent with intra-rater reliability (ICC = 0.95-0.98), inter-rater reliability (ICC = 0.90-0.97), and within-day reliability (ICC = 0.98) (Biasini et al., 2023; Bobos et al., 2020). The standard error of measurement is 2-3 kg with a minimal detectable change of 5-6 kg (Reuter et al., 2011). Three trials will be performed for each hand with 30-second rest intervals, and the average will be recorded as recommended by standardized protocols (Fess, 1992).

Pinch Grip Strength - Pinch Gauge: Pinch grip strength will be measured using a calibrated mechanical or digital pinch gauge (e.g., B&L Engineering or Jamar). The pinch gauge is a reliable and valid instrument for measuring pinch strength, with excellent test-retest reliability (Intraclass Correlation Coefficients [ICCs] > 0.90) for all three standard pinch positions (Mathiowetz et al., 1984; MacDermid et al., 2001). The assessment will measure three standard pinch positions: tip pinch, key (lateral) pinch, and palmar (three-jaw chuck) pinch, following the standardized procedures of the ASHT. Pinch strength assessment has demonstrated good to excellent reliability (ICC > 0.80) and strong correlation with grip strength and hand function. For each pinch type, the average of three trials will be recorded for each hand, with a 30-second rest interval between trials.

5.5.3 Outcome Measures and International Classification of Functioning, Disability and Health (ICF) Alignment

This study will utilize the Brief ICF Core Set for Hand Conditions as a framework for assessing outcomes, ensuring a comprehensive and patient-centered evaluation (Kus et al., 2012, 2017). The selected outcome measures are explicitly mapped to the ICF domains as follows:

Outcome Measure	ICF Domain	ICF Code	Description

Numeric Pain Rating Scale (NRS)	Body Functions	b280	Sensation of pain
Hand Dynamometer (Grip Strength)	Body Functions	b730	Muscle power functions
Pinch Gauge (Pinch Strength)	Body Functions	b730	Muscle power functions
QuickDASH Questionnaire	Activities & Participation	d440 , d445 , d5 , d6 , d8	Fine hand use, hand and arm use, self-care, domestic life, major life areas

This alignment with the ICF framework ensures that the study evaluates not just impairments in body functions but also their impact on real-world activities and participation, consistent with modern clinical research standards.

5.6. Data Collection and Management

All data will be collected by the primary researcher. Data will be entered into a secure, password-protected database. To ensure data quality, a random 10% of the data will be double-checked for accuracy.

5.7. Data Analysis

Version 28 of the International Business Machines (IBM) Statistical Package for the Social Sciences (SPSS) will be used in data analysis. The findings of the feasibility outcomes and the nature of the participants will be summarized using descriptive statistics. In the case of the secondary effectiveness outcomes, an intention to treat (ITT) analysis will be used. The independent t-tests or Mann-Whitney U tests will be used to compare the differences in outcome

scores between baseline and 4-week time point between the two groups, as the data will prove to be distributed differently. The effect size (Cohen d) will be produced, as an approximation of the size of the treatment effect. The p-value of less than 0.05 will be considered statistically significant.

5.8. Missing Data Management

Missing Data Prevention: Primary strategies to minimize missing data include flexible scheduling for outcome assessments, multiple contact methods for follow-up reminders, compensation for time and travel expenses, and clear explanation of study importance and participant commitment.

Primary Analysis Strategy: The primary analysis will follow the intention-to-treat (ITT) principle, including all randomized participants in their originally assigned groups regardless of adherence or completion status (Armijo-Olivo et al., 2009). For missing outcome data, multiple imputation will be used as the primary method, creating 20 imputed datasets using predictive mean matching for continuous variables (Groenwold et al., 2014).

Sensitivity Analyses: Multiple sensitivity analyses will be conducted to assess the robustness of findings, including complete case analysis, per-protocol analysis, worst-case and best-case scenario imputations, and pattern mixture models to explore different missing data mechanisms(Khan et al., 2021) . All missing data will be reported according to Consolidated Standards of Reporting Trials (CONSORT) guidelines, including flow diagrams showing participant disposition and reasons for missing data by treatment group.

5.9. Safety Monitoring and Adverse Events

Skin Reaction Risk Assessment: While Kinesio Taping is generally considered safe, skin reactions can occur in 2-5% of users, particularly with prolonged application (Hofman et al., 2023). Before initial tape application, all participants will undergo skin integrity assessment, allergy

history questionnaire, and patch testing with a small piece of Kinesio tape with 24-hour observation.

Monitoring Protocol: Systematic monitoring for adverse skin reactions will include daily self-monitoring by participants using a standardized skin reaction scale, weekly clinical assessment by research staff, and immediate reporting system with 24-hour contact availability. Adverse skin reactions will be classified using a standardized four-grade scale from mild erythema to severe ulceration or systemic allergic reaction (Hamnerius et al., 2023).

Management Protocol: Standardized management procedures range from continued monitoring for mild reactions to immediate discontinuation and urgent medical evaluation for severe reactions. All adverse events will be documented according to Good Clinical Practice guidelines with detailed forms, photographic documentation when appropriate, and timely reporting to the institutional review board (Guideline, 2015).

5.10. Study Limitations

Pilot Study Limitations: It is important to recognize that this pilot study, although allowing for good feasibility information, has its own intrinsic limitations that must be taken into consideration when interpreting results. As emphasised by Leon et al. (2011), pilot studies do not give meaningful effect size estimates for planning subsequent studies due to the imprecision inherent in small sample data . The confidence intervals around effect size estimates from this 30-subject-pilot will be large and could lead to misleading results for future sample size calculations.

Effect Size Interpretation: Any treatment effects seen in this pilot study should be interpreted with extreme caution and should not be used as primary basis for sample size calculation in a future definitive trial(Sim, 2019). The primary purpose of this pilot is to evaluate feasibility parameters rather than to show efficacy. Effect size estimates will be reported with appropriate confidence intervals and clear statements about their limitations for inferential purposes. The variance estimates generated from this pilot study will enable a much more reliable estimate than the effect size estimates for planning a future definitive trial.

5.11. Ethical Considerations

This study will be performed in compliance with the ethical principles of the Declaration of Helsinki. Ethical approval will be obtained from the Institutional Review Board, ethics committee (IRB) of the Arab American University Palestine. All participants will give written, informed consent before they are included in the study. Participants will be told that they can withdraw from participation in the study at any time without consequences. All information will be anonymized to ensure confidentiality of the participants.

6. Timeline

The proposed research will be conducted over a period of 12 months. The timeline for the study is as follows:

Month	**Task**
1	Finalize proposal, obtain ethical approval, register clinical trial
2	Finalize recruitment materials, train outcome assessor
3-8	Recruitment and Intervention Period (6 months)
9	Complete data collection and begin data entry and cleaning
10	Complete data analysis and begin writing dissertation
11	Continue writing dissertation
12	Finalize and submit dissertation

7. References

Alnahdi, A. H. (2021). Validity and reliability of the Arabic quick disabilities of the arm, Shoulder and Hand (QuickDASH-Arabic). *Musculoskeletal Science and Practice*, *53*, 102372.

Apard, T., Ferembach, B., & Martinel, V. (2025). Lacertus Syndrome Diagnosis With the Orthogonal Kinesiotaping Test. *Plastic and Reconstructive Surgery - Global Open*, *13*(4), e6728. https://doi.org/10.1097/GOX.0000000000006728

Armijo-Olivo, S., Warren, S., & Magee, D. (2009). Intention to treat analysis, compliance, drop-outs and how to deal with missing data in clinical research: a review. *Physical Therapy Reviews*, *14*(1), 36–49. https://doi.org/10.1179/174328809X405928

Ballestero-Perez, R., Plaza-Manzano, G., Urraca-Gesto, A., Romo-Romo, F., de los Ángeles Atín-Arratibel, M., Pecos-Martín, D., Gallego-Izquierdo, T., & Romero-Franco, N. (2017). Effectiveness of nerve gliding exercises on carpal tunnel syndrome: a systematic review. *Journal of Manipulative and Physiological Therapeutics*, *40*(1), 50–59.

Bang, H., Ni, L., & Davis, C. E. (2004). Assessment of blinding in clinical trials. *Controlled Clinical Trials*, *25*(2), 143–156. https://doi.org/10.1016/j.cct.2003.10.016

Beaton, D. E., Wright, J. G., Katz, J. N., & Group, U. E. C. (2005). Development of the QuickDASH: comparison of three item-reduction approaches. *JBJS*, *87*(5), 1038–1046.

Biasini, N. R., Bannon, B., Pellegrino, M., Qaderi, A., Trinh, W., Switzer-McIntyre, S., Reid, W. D., & Kasawara, K. T. (2023). Reliability and validity of shoulder and handgrip strength testing. *Physiotherapy Canada*, *75*(1), 65–71.

Bobos, P., Nazari, G., Lu, Z., & MacDermid, J. C. (2020). Measurement properties of the hand grip strength assessment: a systematic review with meta-analysis. *Archives of Physical Medicine and Rehabilitation*, *101*(3), 553–565.

Coart, E., Bamps, P., Quinaux, E., Sturbois, G., Saad, E. D., Burzykowski, T., & Buyse, M. (2023). Minimization in randomized clinical trials. *Statistics in Medicine*, *42*(28), 5285–5311.

Cohen, J. (2013). *Statistical power analysis for the behavioral sciences*. routledge.

Currie, K. B., Tadisina, K. K., & Mackinnon, S. E. (2022). Common hand conditions: a review. *Jama*, *327*(24), 2434–2445.

Del Barrio, S. J., Gracia, E. B., García, C. H., de Miguel, E. E., Moreno, J. M. T., Marco, S. R., & Laita, L. C. (2018). Conservative treatment in patients with mild to moderate carpal tunnel syndrome: A systematic review. *Neurología (English Edition)*, *33*(9), 590–601.

Eker, O. Al, & Imam, A. (2025). Equity in the distribution of health resources and services in the West Bank, Palestine: a focus on hospitals and primary healthcare centers. *International Journal for Equity in Health*, *24*(1), 106.

Fess, F. E. (1992). Grip strength. *Casanova JS Clinical Assessment Recommendations*, 41–45.

Giacaman, R. (2018). The health of Palestinians. *The Lancet*, *392*(10161), 2268.

Groenwold, R. H. H., Moons, K. G. M., & Vandenbroucke, J. P. (2014). Randomized trials with missing outcome data: how to analyze and what to report. *Canadian Medical Association Journal*, *186*(15), 1153–1157. https://doi.org/10.1503/cmaj.131353

Guideline, I. C. H. H. (2015). Integrated addendum to ICH E6 (R1): guideline for good clinical practice E6 (R2). *Current Step*, *2*, 1–60.

Hagert, E. (2013). Clinical Diagnosis and Wide-Awake Surgical Treatment of Proximal Median Nerve Entrapment at the Elbow: A Prospective Study. *HAND*, *8*(1), 41–46. https://doi.org/10.1007/s11552-012-9483-4

Hamnerius, N., Dahlin, J., Bruze, M., Nilsson, K., Sukakul, T., & Svedman, C. (2023). Colophonium-related Allergic Contact Dermatitis Caused by Medical Adhesive Tape Used to Prevent Skin Lesions in Soldiers. *Acta Dermato-Venereologica*, *103*, adv18428. https://doi.org/10.2340/actadv.v103.18428

Hofman, H., Beeckman, D., Duljic, T., Al Gilani, S., Johansson, S., Kottner, J., Kinnaer, L.-M., & Eriksson, M. (2023). Patients' experiences with the application of medical adhesives to the skin: a qualitative systematic review protocol. *BMJ Open*, *13*(6), e073546. https://doi.org/10.1136/bmjopen-2023-073546

Ijaz, M. J., Karimi, H., Ahmad, A., Gillani, S. A., Anwar, N., & Chaudhary, M. A. (2022). Comparative efficacy of routine physical therapy with and without neuromobilization in the treatment of patients with mild to moderate carpal tunnel syndrome. *BioMed Research International*, *2022*(1), 2155765.

Jensen, M. P. (2003). The validity and reliability of pain measures in adults with cancer. *The Journal of Pain*, *4*(1), 2–21.

Johnson, R. K., Spinner, M., & Shrewsbury, M. M. (1979). Median nerve entrapment syndrome in the proximal forearm. *The Journal of Hand Surgery*, *4*(1), 48–51.

Jt, F. (2001). Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. *Pain*, *94*, 149–158.

Julious, S. A. (2005). Sample size of 12 per group rule of thumb for a pilot study. *Pharmaceutical Statistics: The Journal of Applied Statistics in the Pharmaceutical Industry*, *4*(4), 287–291.

Khan, N. A., Torralba, K. D., & Aslam, F. (2021). Missing data in randomised controlled trials of rheumatoid arthritis drug therapy are substantial and handled inappropriately. *RMD Open*, *7*(2), e001708. https://doi.org/10.1136/rmdopen-2021-001708

Kus, S., Dereskewitz, C., Coenen, M., Rauch, A., Rudolf, K.-D., & Hand, C. L. P. (2017). International Classification of Functioning, Disability and Health: development of an assessment set to evaluate functioning based on the Brief ICF Core Set for Hand Conditions–ICF HandA. *Journal of Hand Surgery (European Volume)*, *42*(7), 731–741.

Kus, S., Oberhauser, C., & Cieza, A. (2012). Validation of the brief International Classification of Functioning, Disability, and Health (ICF) core set for hand conditions. *Journal of Hand Therapy*, *25*(3), 274–287.

Leon, A. C., Davis, L. L., & Kraemer, H. C. (2011). The role and interpretation of pilot studies in clinical research. *Journal of Psychiatric Research*, *45*(5), 626–629. https://doi.org/10.1016/j.jpsychires.2010.10.008

Lin, Y., Zhu, M., & Su, Z. (2015). The pursuit of balance: an overview of covariate-adaptive randomization techniques in clinical trials. *Contemporary Clinical Trials*, *45*, 21–25.

Mintken, P. E., Glynn, P., & Cleland, J. A. (2009). Psychometric properties of the shortened disabilities of the Arm, Shoulder, and Hand Questionnaire (QuickDASH) and Numeric Pain Rating Scale in patients with shoulder pain. *Journal of Shoulder and Elbow Surgery*, *18*(6), 920–926.

Modarresi, S., Lukacs, M. J., Ghodrati, M., Salim, S., MacDermid, J. C., & Walton, D. M. (2022). A systematic review and synthesis of psychometric properties of the numeric pain rating scale and the visual analog scale for use in people with neck pain. *The Clinical Journal of Pain*, *38*(2), 132–148.

Nugent, S. M., Lovejoy, T. I., Shull, S., Dobscha, S. K., & Morasco, B. J. (2021). Associations of pain numeric rating scale scores collected during usual care with research administered patient reported pain outcomes. *Pain Medicine*, *22*(10), 2235–2241.

Pandis, N. (2011). Randomization. part 2: minimization. *American Journal of Orthodontics and Dentofacial Orthopedics*, *140*(6), 902–904.

Pocock, S. J., & Simon, R. (1975). Sequential treatment assignment with balancing for prognostic factors in the controlled clinical trial. *Biometrics*, 103–115.

Puntillo, F., & Bertini, L. (2018). Nerve Entrapment Syndromes. In *Ultrasound-Guided Peripheral Nerve Blocks* (pp. 85–103). Springer International Publishing. https://doi.org/10.1007/978-3-319-71020-4_4

Reuter, S. E., Massy-Westropp, N., & Evans, A. M. (2011). Reliability and validity of indices of hand-grip strength and endurance. *Australian Occupational Therapy Journal*, *58*(2), 82–87.

Saghaei, M. (2011). An overview of randomization and minimization programs for randomized clinical trials. *Journal of Medical Signals & Sensors*, *1*(1), 55–61.

Sartorio, F., Lippi, L., Vercelli, S., Gallo, F., Zanin, D., Bergesio, S., de Sire, A., & Invernizzi, M. (2025). Reliability and validity of the hand-held dynamometer “NOD”: a new instrument for assessment of isometric grip strength. *BMC Musculoskeletal Disorders*, *26*(1), 5.

Schulz, K. F., & Grimes, D. A. (2002). Allocation concealment in randomised trials: defending against deciphering. *The Lancet*, *359*(9306), 614–618. https://doi.org/10.1016/S0140-6736(02)07750-4

Scott, N. W., McPherson, G. C., Ramsay, C. R., & Campbell, M. K. (2002). The method of minimization for allocation to clinical trials: a review. *Controlled Clinical Trials*, *23*(6), 662–674.

Sim, J. (2019). Should treatment effects be estimated in pilot and feasibility studies? *Pilot and Feasibility Studies*, *5*(1), 107. https://doi.org/10.1186/s40814-019-0493-7

Sorensen, A. A., Howard, D., Tan, W. H., Ketchersid, J., & Calfee, R. P. (2013). Minimal clinically important differences of 3 patient-rated outcomes instruments. *The Journal of Hand Surgery*, *38*(4), 641–649.

Spinner, R. J., & Amadio, P. C. (2003). Compressive neuropathies of the upper extremity. *Clinics in Plastic Surgery*, *30*(2), 155–173. https://doi.org/10.1016/S0094-1298(02)00103-7

Whitehead, A. L., Julious, S. A., Cooper, C. L., & Campbell, M. J. (2016). Estimating the sample size for a pilot randomised trial to minimise the overall trial sample size for the external pilot and main trial for a continuous outcome variable. *Statistical Methods in Medical Research*, *25*(3), 1057–1073.

Young, I., Dunning, J., Escaloni, J., Maselli, F., Prall, J., Mourad, F., & Fernández-de-Las-Peñas, C. (2025). Reliability, construct validity, responsiveness and minimum clinically important difference of the numeric pain rating scale and shoulder pain and disability index in patients with subacromial pain syndrome. *Musculoskeletal Science and Practice*, 103372.

Zhao, W., Hill, M. D., & Palesch, Y. (2015). Minimal sufficient balance—a new strategy to balance baseline covariates and preserve randomness of treatment allocation. *Statistical Methods in Medical Research*, *24*(6), 989–1002.