Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The Effects of Combination of Dry Needling and Kinesio Taping on Clinical Symptoms and Neurocognitive Parameters in Patients with Upper Trapezius Trigger Points

Protocol summary

Study aim

to demonstrate the effectiveness of the combination of DN and KT on clinical symptoms and neurocognitive parameters in patients with upper trapezius trigger Points (TrPs)

Design

A randomized controlled trial (RCT) with three parallel groups: dry needling (DN), kinesio taping (KT), and a combination of both (DN + KT). Participants will be randomly assigned, and outcomes will be assessed before, mid and after the intervention.

Settings and conduct

The trial will be conducted in a physiotherapy clinic. Participants will be randomly assigned to one of three groups (DN, KT, or DN + KT). Treatments will be administered by a licensed physiotherapist following standardized protocols. Outcome assessments will be performed before, mid and after the intervention. The assessor will be blinded to group allocation to minimize bias.

Participants/Inclusion and exclusion criteria

Inclusion : Age 20–50 years Unilateral upper trapezius trigger points with pain (≥3 months) Pain score ≥4 during rest or movement 1–3 trigger points on one side Normal vision and hearing Willing to participate Exclusion : History of whiplash, cervical surgery, or radiculopathy Fibromyalgia or cervicogenic headache Physical therapy in the past 6 months Needle phobia or contraindications to dry needling

Intervention groups

1. Group A - receive Dry Needling (DN) , 2. Group B- receive Kinesio Taping (KT) and 3. Group C - receive Combination (DN + KT)

Main outcome variables

Pain intensity (measured by Visual Analog Scale - VAS) Pain pressure threshold (PPT) (measured by algometry) Range of motion (assessed through photogrammetry) Neck disability (evaluated using the Neck Disability Index - NDI) Neck proprioception (measured by the neck repositioning test) Visual and auditory reaction time and anticipatory skills (assessed using the Speed Anticipation Reaction Time - SART system)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250112064358N1**
Registration date: **2025-08-28, 1404/06/06**
Registration timing: **prospective**

Last update: **2025-08-28, 1404/06/06**
Update count: **0**

Registration date

2025-08-28, 1404/06/06

Registrant information

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-23, 1404/07/01

Expected recruitment end date

2026-03-17, 1404/12/26

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effects of Combination of Dry Needling and Kinesio Taping on Clinical Symptoms and Neurocognitive Parameters in Patients with Upper Trapezius Trigger Points

Public title
Effects of Dry Needling and Kinesio Taping on Pain and Brain Function in People with Neck Muscle Pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
patients aged 20–50 years. patients with spontaneous pain or pain with movement in the neck and shoulder region related to active TrPs localized in the unilateral upper trapezius muscle patients with symptom duration of at least three months patients presenting a pain score equal to or higher than four in either rest or activity cervical spinal motion willingness to participate in the study Presence of 1 to 3 trigger points in one side. Intact vision and auditory
Exclusion criteria:
history of whiplash injury previous cervical surgery cervical radiculopathy/myelopathy fibromyalgia having undergone any physical therapy intervention in the previous 6 month fear of needles any contraindication for DN, for example, anticoagulants or psychiatric disorders. Cervicogenic headache
Age
From **20 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **54**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients will be divided at random into three groups: only DN, only KT, and combination of DN and KT . Using sealed, randomly filled envelopes with information on the intervention groups, randomization will be carried out. Three envelopes are made, and one of the three approaches is written in each one. The first person to arrive is asked to select an envelope. The third person now owns the third envelope since we also want the second person to select an envelope. For the following three people, the same cycle is repeated.
Blinding (investigator's opinion)
Double blinded
Blinding description
For this study, both the assessors and analyzer of outcomes will be unaware of the group assignments. The interventions (dry needling, kinesio taping, or combination) will be administered by separate therapists to prevent bias during outcome measurements. The statistical analysis will also be conducted without knowledge of group assignments to ensure objective analysis.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
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Tehran university of medical sciences
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Tehran
Postal code
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Approval date
2025-06-07, 1404/03/17
Ethics committee reference number
IR.TUMS.FNM.REC.1404.066

Health conditions studied

1

Description of health condition studied
The study focuses on trigger points (TrPs) in the upper trapezius muscle, which are hyperirritable spots in skeletal muscle that are associated with localized pain and discomfort. These TrPs can lead to a variety of symptoms, including muscle stiffness, restricted range of motion, and referred pain in the neck and shoulder regions. The presence of active TrPs in the upper trapezius is commonly linked to musculoskeletal disorders, particularly in individuals with poor posture, repetitive movement, or prolonged muscle tension. This study investigates the effectiveness of dry needling (DN) and kinesio taping (KT) in addressing the clinical symptoms and neurocognitive parameters in patients with upper trapezius TrPs.
ICD-10 code
M79.1 (Mus

ICD-10 code description

M79.1 (Muscle Pain)

Primary outcomes

1

Description

The primary outcome variable for this study is pain intensity, which will be assessed using the Visual Analog Scale (VAS). This variable is chosen as the primary outcome because pain is a key clinical symptom of upper trapezius trigger points (TrPs) and is expected to change as a result of the interventions. The sample size calculation is based on the effect size related to changes in pain intensity following treatment with dry needling (DN) and kinesio taping (KT). Changes in pain intensity will help evaluate the effectiveness of the combined intervention on alleviating the discomfort caused by TrPs in the upper trapezius muscle.

Timepoint

Before intervention (baseline)10 days after baseline (midpoint)3 weeks after baseline

Method of measurement

Visual analog scale (VAS) pain scale: The Visual Analog Scale (VAS) consists of a 100 mm continuous line with "no pain" at one end, representing a score of 0, and "worst possible pain" at the other end, representing a score of 100. The score is determined by measuring the distance (mm) between the two endpoints, and it is categorized as follows: no pain at 0-4 mm, mild pain at 5-44 mm, moderate pain at 45-74 mm, and severe pain at 75-100 mm

Secondary outcomes

1

Description

Pain Pressure Threshold (PPT), measured by algometry: This will assess the pressure tolerance at the trigger point area, indicating changes in muscle sensitivity following the intervention.

Timepoint

Before intervention (baseline)10 days after baseline (midpoint)3 weeks after baseline

Method of measurement

In terms of compression intensity, PPT refers to the point at which patients experience discomfort or pain rather than pressure. According to the International Association for the Study of Pain, PPT is the weakest intensity of stimulus that a subject feels as pain. A digital algometer (model SF-500, USA) will assess the PPT. The circling disk with a width of 1 cm will be placed opposite to the desired point, and pressure will increment gradually until the pain is felt and subjects indicate by saying “yes”. The normal value of three measurements will be detailed as PPT and the interval between repetitions was 30 s

2

Description

Range of Motion (ROM), measured using photogrammetry: This will evaluate the flexibility and movement capacity of the neck

Timepoint

Before intervention (baseline)10 days after baseline (midpoint)3 weeks after baseline

Method of measurement

The position of the camera will be standardized throughout the test based on the subject’s position, and the tripod will be placed accordingly on the floor. The distance between the participant's feet and the tripod will be measured using a tape to ensure consistency and prevent any changes that could influence the measurements.The subject will wear two stretchy headbands to attach head markers. The markers will be placed directly over the external acoustic meatus (ear canal) and the top of the head. Cervical flexion and extension range of motion (ROM) will be assessed in the sagittal plane. The axis of the angle between two line segments will be marked by a marker over the external acoustic meatus. The first line segment will pass through the vertex and the marker’s axis. Following a chin tuck, a second vertical line marker will be placed over the external acoustic meatus.To ensure accurate marker placement, each marker will be marked with washable ink before being adhered. The examiner will be seated behind the camera to record the process. The subject will be instructed to flex the neck, hold the position for 5 seconds, return to the neutral position, and then extend the neck, hold for 5 seconds at the end of the range, and return to neutral. The examiner will assist by guiding the subject to perform cervical flexion with a chin tuck and extension with a raised chin. This process will be repeated three times.Cervical side bending ROM will be assessed in the frontal plane. Round markers with a 1.5 cm diameter will be glued onto key bony landmarks. The participant will be asked to position their head neutrally, aligning the head's center of mass with a vertical plane passing through the atlantooccipital joints, with the nose pointing forward in line with the sternum and navel. The sternal notch will serve as the reference point where two lines intersect: one line connecting the sternal notch marker to the forehead marker, and the other vertical, intersecting the sternal notch marker.Cervical side bending movements will be performed to both the right and left. Each marker's position will be marked with washable ink before being glued. The participant will be instructed to laterally flex to the right side and hold for 5 seconds at the maximum range. They will then return to the neutral position. The process will be repeated for the left side. This will be done three times, and the average range of motion will be calculated. Cervical AROM will be measured as the angular displacement from the neutral position to the right and left sides during side bending in the frontal plane.

3

Description

Neck Disability Index (NDI), a questionnaire assessing the level of disability due to neck pain.

Timepoint

Before intervention (baseline)10 days after baseline

(midpoint)3 weeks after baseline

Method of measurement

The NDI is scored from 0–50 points (0–100%) in which higher scores correspond to greater levels of disability. Using this system, a score of 5–14 points (10– 28%) is considered to constitute mild disability, 15–24 points (30–48%) is considered to constitute moderate disability, 25–38 points (50–68%) is considered to constitute a severe disability, and scores above 34 points (68%) indicate complete disability

4

Description

Neck Proprioception, measured through a neck repositioning test to assess cervical joint position sense.

Timepoint

Before intervention (baseline)10 days after baseline (midpoint)3 weeks after baseline

Method of measurement

Cervical proprioception: Using the joint position error testing method of Revel et al., cervical joint repositioning errors will be quantified in degrees to evaluate cervical proprioception. The participants will face a target on the wall that will be 90 cm away while they will sit erect in a chair with back support. The patient will position their feet flat on the floor, their hips and knees bent to about 90 degrees, and their chest will strap to the chair to avoid thoracic rotation throughout the examination. The target, a circle with a diameter of 40 cm, will be set up so that the center of the circle will line up with the laser pointer on the subject's forehead. Participants will first need to spend a few seconds learning a neutral position as part of the protocol. Then, participants will be instructed to turn their head to the left or right, and then slowly rotate their head to line up with the center of the circular target (neutral position) while covering their eyes with a blindfold. (O') indicates the center of the circle. Centimeters will measure the distance between the center of the circle and the patient's indicated point (OC). OD indicates the distance between the patient's eyes and the target. The measured centimeter distance between the circle's center and the light point will then be converted to degrees. Using the formula (α=tan^(-1)(OC/OD)),

5

Description

Visual and Auditory Reaction Time and Anticipatory Skills, assessed using the Speed Anticipation Reaction Time (SART) system to evaluate neurocognitive aspects.

Timepoint

Before intervention (baseline)10 days after baseline (midpoint)3 weeks after baseline

Method of measurement

Speed anticipation reaction time (SART): A color LCD will be connected to a laptop to display the SART test. The SART software program consists of six neurocognitive tests that measure high inter-tester and intra-tester reliability, visual choice reaction time, visual complex choice reaction time, auditory choice reaction time, and anticipatory skill of the ball at high and low speeds. Since none of the participants had any prior experience with the SART setup and will get familiar with the testing process used in the current study, the training parameter will be the same for everyone. Each participant will take a seat on a comfortable chair during the test. The chair can be raised or lowered to ensure that all participants' feet are on the ground. The LCD monitor will be 2 meters away from the participants' seats. Every participant used the identical two-handed grip to hold the joystick throughout the task at hand. They performed each test multiple times to get the participants comfortable with the system. When the participants are familiar with all of the tests, the main tests start.1. Visual choice reaction time test: Four lamps will be illuminated on the monitor in the colors red, yellow, green, and blue to offer visual stimulation for this test. Participants must press the corresponding button on the joystick as quickly as they can when the examiner selects a button for each of the laptop's four colored bulbs. 2. Visual complex choice reaction time test: The visual choice reaction time test has an incompatible mode that can be enabled by checking the reverse key at the program's beginning. This makes it possible to measure the complexity of the choice reaction time, and participants must press the joystick's reverse button after each stimulus. 3. Auditory choice reaction time test: In this test, four separate frequencies—500 Hz, 1000 Hz, 3000 Hz, and 7000 Hz—will be used to stimulate the auditory system. The participants must press the related button on the joystick as soon as they hear the sound. 4. Auditory complex choice reaction time test: Similar to the auditory choice reaction time test, the participants must press the joystick's reverse button after each stimulus in this test. 5. The average reaction time and the number of tests where an error occurred are both shown in the reaction time test output report. The response time tests will be repeated five times for a total of ten times, with a 0.001 second measurement accuracy. 6. Anticipatory skill with high and low speed: A soccer ball will move horizontally from the right end of the screen to the left end toward the gate at a continuous high or low speed (the examiner will choose the speed at random) on the anticipatory skill test page. The soccer ball will vanish when it reaches the black curtain on the left side of the screen. Participants must push the joystick button as quickly as they can while estimating the time the ball will arrive at the gate based on its speed.The results of the anticipatory tests include the average total prediction time, total user tolerance (TUT), the number of occasions when participants failed to respond for 10 seconds before an abnormal message was sent, and the average total prediction time without an abnormal response. Positive values in the declare values indicate a sooner reaction than the actual time, whereas negative values indicate a late response. Three sets of 10 repetitions each will make up the anticipatory skill exam. This chronometer will have a 0.001 ms accuracy.

Intervention groups

1

Description
Intervention group 1: dry needling: Deep dry needling (DDN) will be used to treat the participants throughout six sessions. The patients will be told to lie down with their heads in a neutral position. They will administer DDN treatments using 50 × 0.25 mm sterile stainless-steel needles (Tony dry needling, Korea).The 0.25 mm size reduces the likelihood of pain from a needle. A mark will first be sterilized on the skin before being pinched between the physical therapist's left index finger and thumb. To reach the trigger point, the needle will be inserted vertically into the skin (the correct position will be confirmed by a re-creation of a familiar referral pain or by a visible or palpable local twitch response (LTR). With 10 continuous repeats, the needle will move quickly forward and backward or until no more LTR will be visible

Category
Rehabilitation

2

Description
Intervention group 2: Kinesio taping : Alcohol will first be used to clean the patient's skin. After handling and cutting the elastic band (Careous, Chinese tape) correctly (without touching the adhesive side), a space correction technique will be used to locate the TrP area in the upper trapezius muscle. When the upper trapezius muscle stretches to its maximum length by passively bending the head laterally to the other side, four 15-20 cm long I-shaped strips will form. The patient will be in a seated or prone position during the intervention. Each strip will be applied with a middle-third stretch of 25–50% . The elastic band's terminals won't be subject to any stretching. The tapes are adhered to one another diagonally

Category
Rehabilitation

3

Description
Intervention group 3: Combination both of DN and KT: first we will start with the DDN procedure as we mentioned above and then immediately follow by the KT procedure also as we mentioned above.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
School of Rehabilitation, Tehran University of Medical Sciences

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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Tehran University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

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Full name of responsible person
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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Individual participant data will not be shared due to privacy concerns, ethical considerations, and institutional policies that restrict data sharing beyond the research team.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Study Protocol: Title: Study Protocol for the Evaluation of the Combined Effect of Dry Needling and Kinesio Taping on Trigger Points in Upper Trapezius. Details: The study protocol will be shared after the study completion. The document will be available to researchers upon request via email or through a request form on the study's official website. It will include detailed methodology, inclusion/exclusion criteria, and treatment procedures. Statistical Analysis Plan: Title: Statistical Analysis Plan for the Study of Dry Needling and Kinesio Taping. Details: The statistical analysis plan will include the statistical methods and procedures used to analyze data. It will be available upon request after the study concludes. Interested researchers can request the plan via email or through the study’s website.
When the data will become available and for how long
Study Protocol: When it will become available: The study protocol will be available starting 6 months after study completion. Period of availability: The protocol will be available for 2 years from the date it is made accessible.
To whom data/document is available
The deidentified individual participant data (IPD) and supporting documents, including the study protocol and statistical analysis plan, will be made available to academic researchers, healthcare professionals, and individuals working in relevant fields.
Under which criteria data/document could be used
Deidentified individual participant data (IPD) and supporting documents will be shared under the following

conditions: Types of Analyses. Data will be shared for academic research, clinical studies, or systematic reviews focusing on trigger point therapy, dry needling, kinesio taping, or related interventions in musculoskeletal pain. Review Process. Mechanism of Access.

From where data/document is obtainable

- Preferred Way of Communication - Contact Information - Process for Accessing Data

What processes are involved for a request to access data/document

- Initial Request - Review of Request - Data Sharing Agreement (DSA) - Data Delivery - Post-Access Requirements

Comments