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The effects of trigger point dry needling dosage on functional outcomes of the lateral elbow

Submission date
25/09/2024

Recruitment status
Recruiting

Registration date
26/09/2024

Overall study status
Ongoing

Last Edited
24/06/2025

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Dry needling is a technique in physical therapy to mechanically disrupt tissue without the use of an anesthetic. It can be used to treat myofascial trigger points, which are hyper-irritable focal regions within myofascial (muscle) tissue that produce pain. The forearm extensor mass is a common trigger point that can be treated with dry needling and is commonly associated with the diagnosis of lateral epicondylalgia (tennis elbow), a condition in which the forearm muscles become damaged from overuse. One aspect of dry needling that lacks consensus is the duration of the treatment. Therefore, this study aims to determine the best treatment time to improve functional outcomes to treat impairments associated with lateral epicondylalgia.

Who can participate?
Any individual over the age of 18 years old who is experiencing lateral elbow pain (epicondylalgia)

What does the study involve?
The study involves randomly assigning participants into the control sham needling group or a dry needling intervention group (needle inserted and left in place for 2, 5 or 10 minutes). Measurements will be taken to record wrist flexion range of motion, grip strength, and pain pressure threshold.

What are the possible benefits and risks of participating?
Participants will not receive any compensation or benefits other than potentially improved pain, strength, and range of motion. Risks are minimized to bleeding, bruising, soreness, and pain at the insertion site. Rare side effects are nerve damage, fainting, infection, or worsening of symptoms.

Where is the study run from?
Franklin Pierce University (Goodyear, AZ, USA)
Impact Physical Therapy (Peoria and Scottsdale, AZ USA)

When is the study starting and how long is it expected to run for?
January 2024 to March 2025

Who is funding the study?
Franklin Pierce University (USA)

Who is the main contact?
Dr Elise Harris, harrise@franklinpierce.edu

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Optimal duration of a single session of dry needling to the common extensor mass of the forearm in adults with lateral epicondylalgia (tennis elbow) for functional outcomes of pain, muscle extensibility, and strength

Study objectives
This study aims to evaluate the optimal duration of a single session of dry needling to the common extensor mass of the forearm in those with lateral epicondylalgia (tennis elbow) for functional outcomes of pain, muscle extensibility, and strength. The hypothesis is that if the needle is inserted and left in situ for 10 minutes, then the outcome measures will show greater improvements compared to the shorter durations left in situ. There is still a lack of consensus on the optimal duration of trigger point needling application. The results obtained from this study should contribute to a better understanding of the application of duration as a dosage parameter for clinicians utilizing this intervention in clinical practice.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 15/12/2023, Franklin Pierce University Institutional Review Board (40 University Dr., Rindge, 03461, United States of America; +1 (0) 603 298 6617; irb@franklinpierce.edu), ref: TH12152023

Study design
Randomized double-blinded crossover trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Internet/virtual, Other therapist office, Telephone, University/medical school/dental school

Study type(s)
Quality of life, Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Pain, forearm extensor muscle extensibility, and strength for adult patients with lateral epicondylalgia

Interventions
Current Interventions as of 24/06/2025:
Before participants are selected, they will be screened for the exclusion criteria completed via the phone by a student physical therapist before committing to the research study. If the participant has been cleared of the exclusion criteria, they will be sent detailed information regarding the location, time, and place of the study. Each participant is required to fill out a demographics questionnaire and an informed consent form. After the forms are completed, a licensed physical therapist will perform special diagnostic tests for lateral epicondylalgia (Cozen's and Maudsley's). Only if both tests are positive, will the participant be determined eligible for the study. If the patient tests negative for at least one of the tests, the participant will not be able to participate in the study. After this, baseline measurements of pain pressure threshold, grip strength, and wrist flexion range of motion utilizing a dolorimeter, handheld grip dynamometer and goniometer respectively. These baseline measurements will be administered by the co-investigators who are physical therapist students. Each student will measure one baseline measure before and after the intervention. Each participant will undergo the 2, 5, and 10-minute intervention over 3 weeks. The dry needling intervention will be performed one week apart for all participants. Participants will be randomly assigned to groups undergoing dry needling that will last 2, 5, or 10 minutes using block randomization via computerized software for the order in which the duration of the intervention is performed. The dry needling intervention will be administered by two Doctoral Physical Therapists who are both Board-Certified Orthopedic Clinical Specialists (OCS) with dry needling certifications and eighteen-plus years of experience. The licensed physical therapists will comply with hygiene requirements by washing their hands before each patient and donning non-latex gloves beforehand. The participants' treatment area (forearm) will be sanitized via a 70% isopropanol alcohol swab first. One sterile, single-use 0.25mm X 0.40mm stainless steel acupuncture needle will be used for each subject. The participants will receive a needle placed into the deeper layer of skin and muscle targeting the trigger point in the lateral elbow which will be palpated and marked with a pen to locate the exact location. Once the needle is removed, it will immediately be discarded into a sharps container by the physical therapist. Once the participant has received their intervention, measures of pain pressure threshold, grip strength, and wrist flexion ROM will be reassessed 5 minutes and 30 minutes post-intervention.

Previous Interventions:
Before participants are selected, they will be screened for the exclusion criteria completed via the phone by a student physical therapist before committing to the research study. If the participant has been cleared of the exclusion criteria, they will be sent detailed information regarding the location, time, and place of the study. They will fill out the informed consent form and the QuickDASH outcome measure to establish a baseline of impairment within the lateral elbow. After the forms are completed, a licensed physical therapist will perform special diagnostic tests for lateral epicondylalgia (Cozen's and Maudsley's). Only if both tests are positive, will the participant be determined eligible for the study. If the patient tests negative for at least one of the tests, the participant will not be able to participate in the study.

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Each participant will undergo the 2, 5, and 10-minute intervention over 3 weeks. The dry needling intervention will be performed one week apart for all participants. Participants will be randomly assigned to groups undergoing dry needling that will last 2, 5, or 10 minutes using block randomization via computerized software for the order in which the duration of the intervention is performed. The dry needling intervention will be administered by two Doctoral Physical Therapists who are both Board-Certified Orthopedic Clinical Specialists (OCS) with dry needling certifications and eighteen-plus years of experience. The licensed physical therapists will comply with hygiene requirements by washing their hands before each patient and donning non-latex gloves beforehand. The participants' treatment area (forearm) will be sanitized via a 70% isopropanol alcohol swab first. One sterile, single-use 0.25mm X 0.40mm stainless steel acupuncture needle will be used for each subject. The participants will receive a needle placed into the deeper layer of skin and muscle targeting the trigger point in the lateral elbow which will be palpated and marked with a pen to locate the exact location. Once the needle is removed, it will immediately be discarded into a sharps container by the physical therapist. Once the participant has received their intervention, measures of pain pressure threshold, grip strength, and wrist flexion ROM will be reassessed 5 minutes and 30 minutes post-intervention.

Intervention Type
Procedure/Surgery

Primary outcome measure
The following primary outcome measures are assessed at baseline, 5 minutes, and 30 minutes post-intervention:
1. Pain measured via the pain pressure threshold using a dolorimeter
2. Grip strength measured using a handheld grip dynamometer
3. Wrist flexion passive range of motion measured using a goniometer

Secondary outcome measures
As of 24/06/2025: There are no current secondary outcome measures.

Previous secondary outcome measures:
Self-perceived disability measured using the QuickDash self-reported outcome survey before the intervention to establish a baseline level of functional impairment

Overall study start date
01/06/2023

Completion date
17/01/2027

Eligibility

Key inclusion criteria
1. Over the age of 18 years old
2. Diagnosis of lateral epicondylalgia per positive provocation using Cozen's and Maudsley's special tests

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80

Key exclusion criteria
1. Those who have received dry needling or physical therapy within the last 6 months for lateral epicondylalgia
2. Allergy to metals
3. Needle phobia
4. Blood clotting disorders
5. Recent infections
6. Diabetes
7. Peripheral neuropathy
8. Pregnant

Date of first enrolment
03/01/2024

Date of final enrolment
03/01/2027

Locations

Countries of recruitment
United States of America

Study participating centre
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14455 W. Van Buren St.
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Impact Physical Therapy
7727 W Deer Valley Rd Ste 210
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Sponsor information

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Sponsor type
University/education

Website
https://franklinpierce.edu/academics/colleges-centers/health-natural-sciences.html

ROR
https://ror.org/03e1jqq60

Funder(s)

Funder type
University/education

Funder Name
Franklin Pierce University Doctor of Physical Therapy Program

Results and Publications

Publication and dissemination plan
Planned publication in an impact factor journal

Intention to publish date
03/01/2028

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Elise Harris, harrise@franklinpierce.edu. De-identified data on the primary outcomes of pain, ROM, and strength as outlined previously at the different time points of interest outlined will be shared with the co-investigators of the study for statistical analysis. Participant consent will be obtained at the time of study enrollment.

IPD sharing plan summary
Available on request