

The effects of thoracic manipulation for radiating leg pain

Submission date 24/09/2024	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/09/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 25/09/2024	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims
Spinal manipulation is a tactile approach frequently employed by healthcare practitioners to enhance the performance of the spine and its associated structures, including muscles and nerves. The primary objective of this study is to investigate whether this technique can influence the mobility of the nerves in the legs.

Who can participate?
Healthy adult volunteers between the ages of 18-16 years old

What does the study involve?
This study entails administering spinal manipulation to participants. After consenting to this study, participants will first complete intake paperwork and have the range of their leg motion measured. From there, they will be assigned to an intervention group a placebo group or a manipulation group with a physical therapist. The intervention consists of one 60-minute session per participant. Following the intervention the range of leg motion will be remeasured immediately and 30 minutes after the intervention. Once measurements are taken, their current status will be reviewed by a physical therapist and they will check out of the study.

What are the possible benefits and risks of participating?
Participating individuals may experience improved neural dynamics in their lower extremities as a result of the study. Following spinal manipulation, individuals may realize physical benefits, including notably elevated levels of oxytocin, neurotensin, and cortisol, as has been previously observed in other studies. Individuals undergoing spinal manipulation treatment are expected to directly benefit from changes in these physical markers.

Beyond individual benefits, this study holds potential advantages for society as well. It contributes to a greater understanding of the effectiveness of thoracic spinal manipulation in enhancing neural dynamics in the lower extremities. It also offers an alternative approach to pain management, along with addressing functionality and disability in a less complex setting. Moreover, this research will expand upon the existing body of knowledge on manipulative treatments and establish a foundational reference for thoracic manipulations geared toward enhancing lower extremity neural dynamics.

All studies are thought to have some risk. Although unlikely, the procedures or activities in this study may have unknown or unforeseeable risks. Mild effects include headaches, stiffness, and local discomfort. Severe adverse effects may include fractures or involvement of the spinal cord or vascular tissues. Rare adverse events identified in the literature concerning spinal manipulation include spinal cord or vascular tissue involvement, pneumothorax or hemothorax, fractures, esophageal rupture, aortic rupture, partial pancreatic transection, permanent neurological deficits, or fatalities. Reported most common mild adverse events following spinal manipulations, which have generally been considered benign include headaches (19.8%), stiffness (19.5%), local discomfort (15.2%), radiating discomfort (12.1%), and fatigue (12.1%), typically occurring within 4 hours of treatment, with the majority of these effects resolving within 24 hours. It is noteworthy that the thoracic manipulation, performed in the supine position – which is the same patient positioning and procedure as planned for our trial – accounted for only 3% of the cases with adverse effects. Data indicated that supine thoracic manipulation resulted in the lowest occurrence of adverse effects, in contrast to supine cervical manipulation, which accounted for 39% of the cases. Importantly, none of the identified adverse events were considered life-threatening and were primarily attributed to preexisting illnesses or conditions, such as a history of osteoporosis.

Where is the study run from?

Franklin Pierce University at the Goodyear Campus, Impact Physical Therapy in Peoria, AZ, and Impact Physical Therapy in Scottsdale, AZ

When is the study starting and how long is it expected to run for?

June 2023 to June 2027

Who is funding the study?

Franklin Pierce University

Who is the main contact?

Dr Elise Harris, harrise@franklinpierce.edu

Dr Tamara Hefferon, thefferon@impactptaz.com

Contact information

Type(s)

Scientific, Principal Investigator

Contact name

Dr Elise Harris

ORCID ID

<http://orcid.org/0009-0007-5247-8830>

Contact details

5334 West Chisum Tr

Phoenix

United States of America

85083

+1 3307306933

harrise@franklinpierce.edu

Type(s)

Public

Contact name

Dr Tamara Hefferon

ORCID ID

<http://orcid.org/0000-0001-7314-1339>

Contact details

7727 W Deer Valley Rd STE 210

Peoria

United States of America

85382

+1(0)480-298-0212

thefferon@impactptaz.com

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

The effects of thoracic manipulation for impaired lower extremity neural dynamics

Acronym

ETMILEND

Study objectives

This study aims to evaluate changes in lower extremity neural tension measures in participants with radiating leg pain before- and after the application of a high-velocity, low-amplitude (HVLA) thrust technique to the thoracic spine. The hypothesis is that measurements of neural tension in the lower extremities will improve following the application of the HVLA technique. Previous research has investigated the effectiveness of HVLA's applied to the lumbar spine in this population. There is a paucity of evidence investigating the effectiveness of this technique applied to the thoracic spine for this population.

Ethics approval required

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Ethics approval(s)

Approved 18/06/2024, Franklin Pierce University Institutional Review Board (40 University Dr., Rindge, 03461, United States of America; +1(0)6032986617; irb@franklinpierce.edu), ref: EH01312024

Study design

Multicentre interventional, single-blind, randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Medical and other records, School, University/medical school/dental school

Study type(s)

Quality of life, Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Treatment of neural tension in the lower extremities in participants with radiating leg pain.

Interventions

The intervention consists of one 60-minute session per participant. Participants will be randomly assigned to one of two intervention groups utilizing a random number generator software program. This allocation will be kept confidential from the participants by placing their assignment in a sealed envelope. The primary investigators delivering the interventions will be informed immediately before the procedure when the sealed envelope is opened by the investigator. All interventions will be delivered within a private treatment room to ensure the blinding of participants and primary investigators to each other.

A licensed physical therapist will administer either a thoracic HVLA thrust or sham thoracic HVLA as the intervention. The sham HVLA consists of setting up the technique in the same manner as the thoracic HVLA thrust, however, no thrust is delivered to the thoracic spine for the sham intervention. If a cavitation is observed upon the first application of the thoracic HVLA thrust, a second attempt will not occur. If cavitation is not observed upon the first application, the licensed physical therapist will repeat the thoracic HVLA thrust for a second attempt. A maximum of two attempts will occur in the thoracic HVLA thrust group. Participants will receive two setups of the sham thoracic HVLA.

Intervention Type

Procedure/Surgery

Primary outcome measure

Lower extremity neural tension range of motion is measured using a goniometer with the following standardized tests at baseline, immediately after the intervention, and 30 minutes

post-intervention:

1. Knee extension range of motion with the slump test
2. Hip flexion range of motion with the passive straight leg raise test

Secondary outcome measures

1. Pain measured using a Visual Analog Scale (VAS) at baseline, immediately after the intervention, and 30 minutes post-intervention
2. Level of disability measured using the Oswestry Disability Index at baseline to categorize participants on the level of severity of their condition
3. Risk classification measured using Keele STarT at baseline to categorize patients on the level of severity of their condition

Overall study start date

18/06/2023

Completion date

18/06/2027

Eligibility

Key inclusion criteria

Aged between 18-60 years old recruited from the community

Participant type(s)

Healthy volunteer, Patient, Resident

Age group

Adult

Lower age limit

18 Years

Upper age limit

60 Years

Sex

Both

Target number of participants

30

Key exclusion criteria

1. Ehler's Danlos and Marfan's Disease
2. The inability to provide verbal consent
3. Severe pain
4. Malignancy
5. Bone disease
6. Unhealed fractures or spinal fractures

- 7. Current infections
- 8. A history of deep vein thrombosis
- 9. Current pregnancy

Date of first enrolment

30/09/2024

Date of final enrolment

18/06/2027

Locations

Countries of recruitment

United States of America

Study participating centre

Franklin Pierce University

14455 W Van Buren St. #100
Goodyear
United States of America
85338

Study participating centre

Impact Physical Therapy

7727 W Deer Valley Rd Ste 210
Peoria
United States of America
85382

Study participating centre

Impact Physical Therapy

20801 N Scottsdale Rd Suite 105
Scottsdale
United States of America
85255

Sponsor information

Organisation

Franklin Pierce University

Sponsor details

Doctor of Physical Therapy Program
14455 W. Van Buren St.
Goodyear
United States of America
85338
+1 (623) 518-2386
zookl@franklinpierce.edu

Sponsor type

Research council

Website

<https://franklinpierce.edu/>

ROR

<https://ror.org/03e1jqq60>

Funder(s)**Funder type**

University/education

Funder Name

Franklin Pierce University

Results and Publications**Publication and dissemination plan**

Planned publication in an impact factor journal

Intention to publish date

18/06/2028

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Elise Harris at harrise@franklinpierce.edu. De-identified data on the the primary outcome of ROM and secondary outcomes of pain, disability, and risk as outlined previously at the different time points of interest 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