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The effects of thoracic manipulation for radiating leg pain

Submission date	Recruitment status	[X] Prospectively registered
24/09/2024	Recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
26/09/2024	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
25/09/2024	Musculoskeletal Diseases	[ ] 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
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Contact information

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Additional identifiers

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
Ethics approval required

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

Primary study design
Interventional

Study design
Multicentre interventional, single-blind, randomized controlled trial

Study type(s)
Quality of life, Treatment

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(s)
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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
All

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

ROR
https://ror.org/03e1jqq60

Funder(s)

Funder type
University/education

Funder Name
Franklin Pierce University

Results and Publications

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