Dual-Pathway Mechanisms of Instrument-Assisted Soft Tissue Manipulation (IASTM) Dose–Response Effects in the Calf–Foot Region: Mechanical and Contextual Contributions

M. Terry Loghmani, PhD, PT, FNAP
Associate Professor
1050 Wishard Blvd., RG2124
Indianapolis, IN 46202
mloghman@iu.edu; O) 317-278-3463; C) 691-0175

Indiana University
School of Health & Human Sciences
Department of Graduate Health Professions
Doctor of Physical Therapy Program

Support Provided by:
(Investigator Initiated, Unsponsored)

Table of Contents:

Study Schema
1.0 Background & Rationale
2.0 Objective(s)
3.0 Outcome Measures
4.0 Eligibility Criteria
5.0 Study Design
6.0 Enrollment/Randomization
7.0 Study Procedures
8.0 Study Calendar
9.0 Reportable Events
10.0 Data Safety Monitoring
11.0 Study Withdrawal/Discontinuation
12.0 Statistical Considerations
13.0 Data Management
14.0 Privacy/Confidentiality Issues
15.0 Follow-up and Record Retention
16.0 References

Appendix

A.1 Quantifiable Soft Tissue Manipulation (QSTM) Calf Data Collection Sheet
A.2 Home Exercise Program (HEP) & Ice Massage (IM) Protocol

Abbreviations

AE	Adverse Event
DPTT	Dynamic Pain Threshold Testing
DSMB	Data Safety Monitoring Board
IM	Ice Massage
IRB	Institutional Review Board
LE	Lower Extremity
L	Left
NIH	National Institutes of Health
NMSK	Neuromusculoskeletal
NPRS	Numeric Pain Rating Scale
PI	Principal Investigator
QA	Quality Assurance
QSTM	Quantitative Soft Tissue Manipulation
R	Right
ROM	Range of Motion
SAE	Serious Adverse Event
SPPT	Static Pain Threshold Testing
US	United States
VAS	Visual Analogue Scale
WBLT	Weight-Bearing Lunge Test

1.0 Background & Rationale

Neuromusculoskeletal pain, injury, and disease (NMSK) are the leading cause of disability worldwide and contribute substantially to healthcare utilization, reduced mobility, and diminished quality of life. Reduced calf flexibility is associated with altered gait mechanics, increased fall risk, functional limitations, and mobility deficits and is common across musculoskeletal pain populations and neurological conditions. There is a critical need for effective, scalable, and accessible interventions that address functional impairment while remaining feasible in routine clinical practice.

Massage-based modalities, applied by hand alone or with a device, are types of manual therapy often used by clinicians to address NMSK pain and movement dysfunction. Instrument-assisted soft tissue manipulation (IASTM) is a common, non- invasive manual therapy where clinicians manually apply mechanical forces to soft tissues using rigid instruments. Through mechanotransduction processes, these forces can influence tissue properties, micro-circulation, blood flow, neuromuscular function, pain modulation, and clinical outcomes. (Fusco et al., 2025) (Brandl & Schleip, 2023). In parallel, contextual and affective touch pathways modulate autonomic and neurohormonal responses; for example, massage related touch has been associated with increased oxytocin and reduced adrenocorticotropic hormone (ACTH) (Morhenn et al., 2012). These dual pathways—mechanical and contextual—likely operate concurrently (Keter et al., 2025; Loghmani et al., 2025), yet they have not been empirically considered during IASTM. There is a need to distinguish the mechanistic and contextual pathways through which IASTM influences calf–foot tissue and function.

Evidence suggests that manual therapies—including IASTM—can reduce pain and improve physical performance and patient reported outcomes. A recent systematic review and meta-analysis confirmed that IASTM significantly reduces pain and improves function in musculoskeletal disorders (Tang et al., 2025). Earlier systematic reviews similarly support improvements in ROM, pain, and patient reported function (Seffrin et al., 2019). However, substantial heterogeneity in treatment parameters and strong contextual influences (e.g., affective response, perceived treatment intensity) complicate interpretation of underlying mechanisms (Tang et al., 2025). Critically, the specific effects of different IASTM force magnitude dose levels on biomechanical and clinical outcomes with consideration of contextual factors remain unknown, limiting the ability to optimize dosing strategies (Keter et al., 2024).

To help address this gap, quantifiable soft tissue manipulation (QSTM) device system was developed to capture force-motion data during IASTM intervention (Bhattacharjee et al., 2021 & 2023; Loghmani et al., 2022). The QSTM device system is an adaptation of stainless steel IASTM devices used clinically (Graston Technique). QSTM has similar application methods and similar treatment tips/edges for local (Q1) and dispersive (Q2) force application with embedded device sensor components that provide the clinician/examiner objective data (metrics) and graphic visualization on how much force, stroke rate, and stroke angle is being used. Visual monitoring using QSTM has been shown to improve the consistency of targeted force applications (Loghmani et al., 2026). QSTM may enable IASTM dose-response studies to be completed in humans during naturalistic application of the treating force by the clinician with minimal risk. The QSTM devices have been determined to have non-significant risk and previously used at Indiana University by this investigator in NIH-funded research studies.

This proposed study models two pathways exploring the effects of a IASTM manual therapy approach: (1) Mechanical (flexibility, tissue stiffness), and (2) Contextual/Affective (anxiety, affect valence, expectancy), integrated within a dose-controlled IASTM force magnitude applied to the human calf.

2.0 Objectives

The **purpose** of this pilot study is to explore dual-pathway mechanisms—mechanical versus contextual—potentially underlying IASTM dose–response effects applied to the calf–foot region in healthy individuals with unilateral or bilateral ankle dorsiflexion range of motion (ROM) deficits**.** Findings will inform future studies involving IASTM dose-response effects in lower leg musculoskeletal pain conditions and neuromuscular disorders.

This initial proof-of-concept study will explore the effects of different quantified IASTM dose-force levels applied to the posterior lower leg (calf) muscle groups on clinical measures, functional physical performance measures, contextual factors, and soft tissue biomechanical properties in healthy adults. The **objectives** of this study are to:

- **2.1** **Objective 1.** Determine the effect of varying IASTM dose–force levels on clinical and functional performance outcomes. **Hypothesis 1.** Higher IASTM dose–force levels as individualized to the subject will result in greater improvements in clinical and functional performance compared to lower dose–force levels.
- **2.2** **Objective 2.** Evaluate the influence of contextual factors on IASTM dose–force–response relationships **Hypothesis 2.** More favorable contextual factors (e.g., lower anxiety, positive expectations) will be associated with greater improvements in clinical and functional outcomes associated with higher dose-force levels as individualized to the subject compared to lower dose–force levels.
- **2.3** **Objective 3.** Determine the effect of varying IASTM dose–force levels on soft tissue stiffness. **Hypothesis 3.** Higher IASTM dose–force levels as individualized to the subject will decrease soft tissue stiffness more than lower dose–force levels.

3.0 Outcome Measures/Endpoints

Research assistants (examiners) will be trained in standard procedures and methods to be used at established assessment time points to ensure safety. All measurement and intervention procedures will be performed within participant tolerance. Examiners will be blinded to group assignment and dose-force levels delivered to reduce measurement bias. Measurements and timepoints are outlined in the study calendar (Section 8) and described below:

3.1. Clinical Measures.

3.1.1 Ankle Range of motion (ROM) & Passive Mobility. (Assessment Timepoint: Screening only). These measures determine the amount (degrees, °) of 1) active (AROM) and 2) passive (PROM) ankle dorsiflexion with the knee a) extended and b) flexed using an inclinometer. These measures will serve as a screening test to help distinguish gastrocnemius vs. soleus muscle flexibility (tightness). Passive dorsiflexion end-feel with knee flexed and posterior talocrural glide will help assess for ankle joint capsule tightness or intra-articular restrictions. These standard tests help indicate the extensibility (e.g. limberness) of the soft tissue (myofascial, capsular) and will be used to determine inclusion/exclusion based on criteria for subject enrollment. (Dutton, 2023; Krause et al., 2011)

3.1.2 Weight-bearing lunge test (WBLT). (All Assessment Timepoints: Screening; Session 1 (i.e., Visit 1) Baseline [i.e., before intervention], Assessment 1 [i.e., After LE Side 1 intervention], Assessment 2 [i.e., After LE Side 2 Intervention]; and Session 2 Baseline, Assessment 1, Assessment 2). The weight-bearing lunge test (WBLT) is the primary objective clinical outcome in this study. It will be used to assess ankle dorsiflexion ROM under load during screening to determine inclusion/exclusion based on criteria for

subject enrollment and all assessment timepoints. The participant stands facing a wall with the testing foot positioned closest to the wall and toes touching wall. The non-testing leg is placed behind the body in a comfortable lunge stance for balance. The participant is instructed to lunge forward and attempt to touch the knee of the testing leg to the wall while keeping the heel fully in contact with the ground. If the participant can touch the knee to the wall without heel lift as monitored by an examiner, the foot is moved incrementally backward until the point at which the knee can no longer reach the wall without the heel rising. The maximum distance at which the participant can successfully touch the knee to the wall while maintaining full heel contact is recorded. This distance is measured in centimeters from the wall to the tip of the great toe. (Chisholm et al., 2012; Powden et al., 2015; Bennell et al., 1998)

3.1.3. Numeric Pain Rating Scale (NPRS). (All Assessment Timepoints: Session 1 Baseline, Assessment 1, Assessment 2; and Session 2 Baseline, Assessment 1, Assessment 2). Self-reported pain level is the primary subjective clinical outcome in this study. It will be assessed using an 11-point Numeric Pain Rating Scale (NPRS), where 0 indicates "no pain" and 10 represents the "worst pain imaginable." Participants will be instructed to select the number that best reflects their perceived pain intensity at the time of assessment. NPRS ratings will be collected at baseline immediately prior to the intervention, at the conclusion of the intervention at each time point, and at any time during the intervention if the participant experiences discomfort/pain or a notable change in discomfort/pain intensity. Standardized instructions will be provided before each assessment to ensure consistent administration. Responses will be recorded on study data collection forms as marked by the participant and/or verbally reported by the participant and recorded by the examiner. The NPRS is a widely used, valid, and reliable measure of self-reported pain intensity and requires less than one minute to complete. (Childs et al., 2005)

3.1.4. Static Algometry. (All Assessment Timepoints: Session 1 Baseline, Assessment 1, Assessment 2; and Session 2 Baseline, Assessment 1, Assessment 2). This test helps determine a participant's mechanical pressure pain sensitivity (static pain pressure threshold, SPPT) in a single spot using a non-invasive device, i.e. algometer. SPPT is determined by the amount of force that can be applied to a person before it begins to be perceived as painful or uncomfortable. It is considered a secondary sensory (neurophysiological) outcome in this study. Pressure pain sensitivity is inversely related to the amount force tolerated, in that the less force a person can take before it is perceived as uncomfortable, the higher their pain sensitivity (i.e., the more sensitive they are to pressure pain stimuli). While the participant is lying on their stomach, a research assistant will use a standard algometer to measure the amount of force (N or kg) that can be applied slowly to one spot just medial to the mid-line of the calf until the participant says "stop" due to any beginning sensation of pain/discomfort. The average of three trials on each side will be determined. Static algometry is the gold standard for pressure pain assessment. Results of static algometry testing will be correlated to baseline Dynamic Pain Threshold Testing (DPTT) findings and to tenderness/pain level post-intervention. (Kristensen et al., 2021, Williams et al., 2020)

3.1.5. Dynamic Algometry. (Assessment Timepoints: Session 1 Baseline and Session 2 Baseline). Participants will undergo dynamic pain threshold testing (DPTT) assessment to establish an individualized IASTM force threshold over the mid-belly of each calf, just medial to mid-line, using the same QSTM broad-blade device that will be used during each intervention condition. DPTT is reliable (Farasyn & Lassat, 2016; Powell et al., 2025) and can directly inform individualized dose-force levels for IASTM intervention. With the participant positioned prone, first a trained examiner will manually palpate the tissue assessing for tender or restricted spots, then with the QSTM device. Next, the examiner to assess DPTT will apply repeated standardized strokes (parallel to muscle fiber orientation, 0.5 Hz (1 stroke every 2 seconds), ≤15 seconds per trial, up to 7 strokes, at a 45-60˚ angle of application)

while gradually increasing force (over 5-7 strokes, until the participant indicates the transition from comfortable to uncomfortable sensation (dynamic pain threshold). Two trials will be performed and averaged to determine each participant's individualized target force per calf. Two instead of three trials will be used to reduce potential discomfort. Dynamic algometry findings will be compared to static algometry measures.

3.2. Functional Physical Performance Measures. These measures will be performed before IASTM intervention at baseline and after intervention on both calves to avoid asymmetrical performance since these activities involve bilateral LE function.

3.2.1. Lower Extremity (LE) Functional Ability. (Assessment Timepoints: Session 1 Baseline, Assessment 2; and Session 2 Baseline, Assessment 2). Self-reported lower-extremity functional ability is a secondary subjective outcome in this study. It will be assessed using a 100-mm VAS. Participant instructions will be as follows: "Considering both of your calves and ankles, please indicate your overall current ability to perform daily and recreational activities such as walking, stair climbing, squatting, running, jumping, or exercise." The scale will be anchored with "Unable to perform activities requiring use of the calf muscles" (0 mm) to "Able to perform all activities without limitation" at the right end (100 mm). Participants will place a mark on the line corresponding to their current perceived level of functional ability. The distance between marks will be measured in millimeters and recorded, with higher scores indicating greater perceived function. The assessment will be administered before and following IASTM intervention at Sessions 1 and 2 to evaluate the influence of baseline function on dose-response and perceived changes in function. (Dingemans et al., 2020, Verheijde et al., 2013)

3.2.2. 10-meter Gait Speed Test. (Assessment Timepoints: Session 1 Baseline, Assessment 2; and Session 2 Baseline, Assessment 2). Gait speed over a short time/distance (velocity) (m/s) is a common measure (used for individuals between the ages of 7-85 years old) and will serve as the primary functional outcome. It has been associated in the literature with longevity, morbidity, and mortality rates. Prior to testing, a track/walking space of at least 14m [45.93 ft] will be mapped out (allowing 2m for acceleration, 10m for timed distance [32.8 ft], and 2m for deceleration). To test the participant's maximal walking speed (MWS), the research assistant will ask the participant to walk as fast as they comfortably and safely can on the track. The researcher will say, "When I say go, walk as fast as you can, safely." A stopwatch/clock will be used to time (in seconds) how long it takes the participant to walk 10 meters. There will be one practice trial and then two-timed trials that will be averaged. The research assistant will walk near-by the participant to assure safety in case the participant needs any assistance or support during the test. The gait pattern will also be observed for symmetry vs. asymmetrical timing and weight-shifting. (Adell et al., 2013, Peters et al., 2020)

3.2.3. Vertical Jump Test. (Assessment Timepoints: Session 1 Baseline, Assessment 2; and Session 2 Baseline, Assessment 2). This test is a secondary functional outcome for subjects able to participate in this activity. It is a measure of lower body power. In order for a participant to participate in this activity the participant will be able to: a) perform a controlled squat without pain, b) demonstrate stable knee and hip alignment on landing from a practice standing jump, and c) performed with good balance. A standard Vertec® device will be used to measure the vertical jump height (cm). The participant will be asked to stand, with their side toward the device, and to reach up with their hand closest to the device to determine baseline measure. Keeping their feet flat on the ground, the vane that the fingertips touch will be marked to determine their standing reach. The participant will then stand away from the Vertec and jump as high as possible (vertically), using both arms and legs to assist in the motion, while they touch the vane at the highest point of the jump. The difference in distance between the standing reach

height and the jump height (vane) is the score (cm). The best of three attempts will be recorded. A research assistant will stand by for safety in case the participant needs assistance or support during the test. (Baechle et al., 2016)

3.3. Contextual Factor Measures. These factors may influence subject response and will only be assessed at Baseline before intervention at one or both sessions as specified.

3.3.1. Expectations Assessment (Visual Analog Scale, VAS). (Assessment Timepoints: Session 1 Baseline). Treatment expectation is considered the primary contextual factor because participant beliefs regarding the effectiveness of lower- and higher-force interventions may influence symptom perception, treatment experience, and clinical outcomes independent of the mechanical dose delivered (Keter et al., 2025). Prior to intervention, participants will be informed that both lower-force and higher-force soft tissue interventions are being considered and that the relative effectiveness of each approach is currently unknown. Participants will then rate their expectations regarding the effectiveness of each force level for improving calf mobility using two separate VASs ranging from 0 ("not effective at all") to 100 ("extremely effective"). Participants will respond to the questions, "How effective do you believe a lower-force treatment will be for improving calf mobility?" and "How effective do you believe a higher-force treatment will be for improving calf mobility?" Expectation assessments will be completed at baseline in session 1 prior to intervention. Responses will be documented on the study data collection form and evaluated as potential predictors of treatment response. (Bialosky et at., 2011; Mondloch et al., 2010)

3.3.2. Affective Valence Assessment (Feeling Scale). (Assessment Timepoints: Session 1 Baseline, Assessment 2; Session 2 Baseline, Assessment 2). Affective valence will serve as a secondary contextual factor outcome. Whereas treatment expectations reflect beliefs regarding the anticipated effectiveness of the intervention, affective valence reflects the participant's immediate emotional response to the treatment experience. Participants will rate their current feeling state using the Feeling Scale (FS), a validated single-item measure of affective valence ranging from +5 ("very good") to -5 ("very bad"), with 0 representing a neutral state. Participants will be asked to select the number that best reflects how they feel at the time of assessment. Feeling Scale assessments will be completed immediately before and immediately after assessment 2, to evaluate changes in affective response associated with lower- and higher-force IASTM treatments and to explore relationships between affective responses and changes in Weight-Bearing Lunge Test (WBLT) performance, lower extremity functional mobility ratings, and other study outcomes. Responses will be documented on the study data collection form. The Feeling Scale is a widely used, validated measure of the pleasure-displeasure dimension of affect and has been widely used in exercise and rehabilitation research. (Henriques et al., 2023; Hardy et al., 1989)

3.3.3. Anxiety Assessment. (Assessment Timepoints: Session 1 Baseline, Session 2 Baseline). Anxiety will be assessed as a contextual covariate. Because anxiety, nervousness, and stress may influence pain perception, muscle tension, treatment tolerance, expectations, and mobility outcomes, participants will rate their current level of anxiety using a VAS ranging from 0 ("not at all anxious/stressed") to 100 ("extremely anxious/stressed"). Participants will indicate the point on the scale that best reflects how they feel at the time of assessment. Anxiety ratings will be collected immediately prior to the intervention at each session. Responses will be documented on the study data collection form and included as a potential covariate in statistical analyses to account for individual differences that may influence treatment response. The VAS is a simple, reliable, and sensitive method for assessing current anxiety levels. (Kindler et al., 2000; Facco et al., 2013)

3.4. Soft Tissue Biomechanical Properties (Assessment Timepoints: Session 1 Baseline, Assessment 1, Assessment 2; and Session 2 Baseline, Assessment 1, Assessment 2). Soft tissue stiffness (N/m) is the primary biomechanical soft tissue property of interest. It will be assessed at all time-points to better capture changes in soft tissue properties immediately following intervention. A standard, non-invasive device (e.g., MyotonPRO®) that can painlessly measure soft tissue biomechanical properties will be used, following the manufacturer's protocol, to help assess if IASTM affects soft tissue stiffness. While the participant lies on their stomach, a research assistant will use the measurement device to assess the stiffness of the participant's calf muscle where IASTM is applied (10 cm inferior to popliteal crease, just medial of mid-line). The average of three trials on each side will be determined. (Albin et al, 2019, Huang et al., 2018)

4.0 Eligibility Criteria

Forty healthy participants (n = 40) with baseline unilateral or bilateral ankle dorsiflexion ROM deficit due to muscle tightness, but without ankle joint limitations due to intra-articular, capsular tightness of post-fracture abnormalities, will be recruited and enrolled as eligible per the inclusion and exclusion criteria.

4.1 Inclusion Criteria

1. Male or female
2. Between the ages of 18-50 years old
3. Body Mass Index (BMI) ≥ 18.5 kg/m2 but <30 kg/m2
4. A tight calf with limited ankle dorsiflexion range of motion: < 8–9 cm on weight-bearing lunge test (WBLT) indicating restricted ankle dorsiflexion and/or side to side difference of >1.5 cm due to muscular tightness. (Baumbach, S. 2016)

4.2 Exclusion Criteria

1. Any known musculoskeletal pain conditions, such as nerve impingement (radiculopathies), rheumatoid arthritis, osteoarthritis, or inflammatory conditions that may interfere with study participation.
2. Ankle joint limitations due to intra-articular, capsular tightness, or post-fracture abnormalities.
3. Any known cardiovascular, pulmonary, metabolic disease, or other co-morbidities that could interfere with the clinician's ability to perform basic IASTM stroke patterns to the calf or subject participation.
4. Any narcotics, blood thinners, or other medications that could alter sensation, consciousness, or tendency to bruise/bleed.
5. Any recent surgeries, medical conditions, or injuries that could interfere with treatment or ability to participate.
6. Acute injuries, unhealed, acute or unstable conditions.
7. Any known contraindications to instrument-assisted soft tissue manipulation of the lower extremity, including but not limited to open wounds, active infection, unhealed fracture, deep vein thrombosis, severe vascular disorders, bleeding disorders, anticoagulant therapy associated with increased bleeding risk, or other conditions that, in the judgment of the investigator, would make study participation unsafe.
8. Current smoking or recreational/illicit drug use.
9. Individuals who answer "Yes" to any of Questions 1–7 on the Physical Activity Readiness Questionnaire (PAR-Q) will be required to obtain written clearance from their physician or other qualified healthcare provider before participating in study procedures involving physical activity

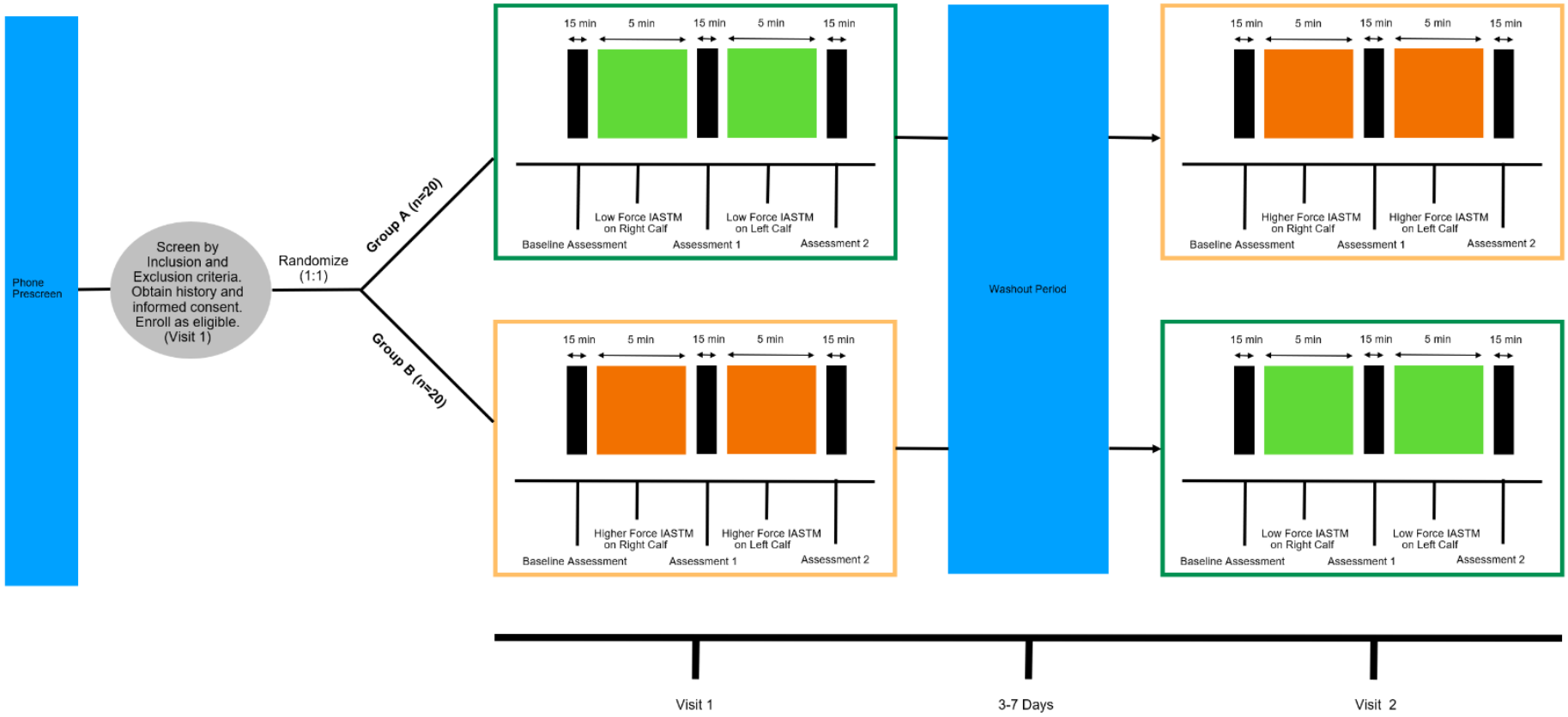
(e.g., the walking speed assessment). Individuals who do not obtain medical clearance will be excluded from study participation.

5.0 Study Design

Potential participants will be recruited through convenience sampling using approved recruitment materials distributed to students, faculty, staff, and community members. Interested individuals will complete an initial phone screening to determine eligibility based on the study's inclusion and exclusion criteria. Eligible individuals who agree to participate will provide written informed consent prior to any study procedures. Following baseline screening assessments, enrolled participants will be randomly assigned to the order of treatment conditions (higher-force followed by low-force, or low-force followed by higher-force sessions) using a computer-generated randomization schedule. A washout period of 3-7 days will separate intervention sessions to minimize potential carryover effects. The time interval for the washout period was selected to minimize potential carryover effects while reducing variability introduced by extended intervals between study visits. A minimum interval of 3 days was based on established clinical IASTM treatment protocols of at least 48 hours between treatment sessions (Graston Technique, 1998-present). The interval was extended to 72 hours in this study as a conservative measure to allow for resolution of possible post-intervention soreness or sensitivity. The maximum interval of 7 days was selected to support participant adherence while minimizing the influence of time-dependent factors unrelated to the intervention.

Due to the nature of the intervention, the treating investigator cannot be blinded to the treatment conditions. However, participants will not be informed of the specific force level being delivered during each session and will be instructed not to discuss treatment details with study examiners involved in outcome assessment. Outcome measures will be collected using standardized procedures to minimize bias. Each participant will serve as their own control in this cross-over design, reducing between-subject variability and improving the ability to detect differences between intervention conditions.

A randomized, within-participant (within-subject), two-condition crossover design will be used in which participants (subjects) will receive both intervention conditions: lower and higher IASTM treatment dose-force magnitudes, separated by a 3–7-day washout period. This approach allows controlled comparison of clinical measures, functional performance outcomes, contextual responses, biomechanical tissue changes, as described above, along with the specified assessment time-points. The Diagram below provides a schematic overview of the planned study design.


Phone Prescreen
Screen by Inclusion and Exclusion criteria. Obtain history and informed consent. Enroll as eligible. (Visit 1)
Randomize (1:1)
Group A (n=20)
Group B (n=20)
15 min
5 min
15 min
5 min
15 min
Low Force IASTM on Right Calf
Low Force IASTM on Left Calf
Higher Force IASTM on Right Calf
Higher Force IASTM on Left Calf
Baseline Assessment
Assessment 1
Assessment 2
Washout Period
Visit 1
3-7 Days
Visit 2

6.0 Enrollment/Randomization

This study utilizes a randomized crossover design in which each participant serves as their own control. Eligible participants who provide written informed consent and meet all inclusion criteria and will be enrolled in the study. Each participant will receive both intervention conditions (higher-force QSTM/IASTM and lower-force QSTM/IASTM), with treatment order determined by random assignment. A washout period of 3-7 days will separate intervention sessions to minimize potential carryover effects.

A trained research assistant will generate the randomization sequence using a computer-based random number generator and maintain the allocation schedule in a secure file separate from study data. Participants will be assigned in a 1:1 ratio to receive either the higher-force intervention first followed by the lower-force intervention or the lower-force intervention first followed by the higher-force intervention. No blocking or stratification procedures will be used.

Following completion of baseline assessments, the allocation assignment will be provided to the intervention research assistant responsible for treatment delivery. Outcome assessment research assistants will remain blinded to intervention order and force magnitude levels throughout the study. Data-entry personnel and the independent study biostatistician will work with de-identified data in which intervention order is coded. Enrollment and randomization records will be maintained separately from study outcome data to protect confidentiality and preserve study integrity.

7.0 Study Procedures

Participants who express interest in the study will complete an initial eligibility screening by telephone. Individuals meeting eligibility criteria will be scheduled for two sessions (visits) separated by a washout period of at least 72 hours. Written informed consent will be obtained and participants will have the opportunity to ask questions regarding study procedures. Prior to enrollment, participants will be screened at the first session for BMI, ankle ROM and passive mobility, and WBLT to confirm eligibility. Research assistants collecting outcome measures or intervention will follow standardized procedures.

Following enrollment at the first session, demographic information and health history will be collected to confirm eligibility based on medical contraindications. Participants will then be randomly assigned to receive either a higher-force or low-force QSTM-informed IASTM intervention. Participants will then complete baseline questionnaires and measurements will be obtained as described in Section 3, depicted in the Study Design (Section 5), and outlined in the Study Calendar (Section 8).

The IASTM intervention will be applied to the calf musculature as depicted in the Study Design figure (Section 5) and described in this section below. Separate research assistants from the outcome examiners will be trained in QSTM to administer the intervention. Individual participant's dynamic algometry values assessed at baseline during each session will be used to administer either low (10% of DPTT) or higher (35% of DPTT) relative dose–force levels, as individualized to the subject based on their dynamic pain threshold and randomized condition using the QSTM broad device. Dose-force percent levels of DPTT are based on prior work (Wade, 2025) and preliminary testing. Real-time visual monitoring of the force applied improves reliable delivery of determined force levels (Loghmani et al., 2026). An emollient will be applied to the calf to reduce skin friction. Intervention will consist of standardized sweeping (curvi-linear) strokes applied in superior and inferior directions, parallel to the

myotendinous structures in the posterior calf for 5 minutes, including a manual massage warm-up (1 min), 3 minutes at target force level (gradual build up for 1.5min; 1min at peak force with visual monitoring to assure target force application; gradual ramp-down for 0.5min), and a 1-minute manual massage wrap-up. Participant response will be continuously monitored by the examiner for feedback on pain/discomfort (e.g., muscle tensing, limb withdrawal). This approach follows standard clinical treatment protocols (Graston Technique). All force applications will be delivered within participant comfort. All force-motion parameters will be continuously captured by the QSTM system and recorded for later analysis.

Post-intervention measurements (at Assessment time points 1 & 2) will be collected using the same procedures as at baseline and outlined in Sections 3, 5, and 8.

Following IASTM Intervention.

- **Calf stretches.** Participants will be instructed in and receive a handout on simple calf stretches. These stretches should be completed for one to two days after each session.

- **Ice pack.** Participants will be given an ice pack to take with them to use for up to 10 minutes at a time. They will receive written instructions on how to apply the cold pack on their own for one to two days as needed to relieve any discomfort.

Following a washout period, participants will return for a second study session (visit). Procedures will be similar to the first visit; however, participants will receive the alternate intervention condition (higher-force or low-force) not received during the first session as randomized. Baseline and post-intervention measurements will again be collected using the same procedures and as outlined in Sections 3, 5, and 8.

Session 1 (visit 1) should require approximately 120 minutes for the participant to be consented, complete screening, measures, and intervention. Session 2 (visit 2) should require approximately 90 minutes of the participant's time to complete the measures and intervention.

Data is being collected for research purposes. Participants may experience temporary discomfort during algometry testing or soft tissue treatment similar to that encountered during routine clinical care. Participants may discontinue participation or refuse any procedure at any time without penalty.

Efforts will be taken throughout the study to minimize potential bias. Participants will be blinded to the force-dose condition administered during each session. Intervention delivery, outcome assessment, data entry and management will be conducted by separate study personnel whenever feasible. Statistical analyses will be performed by an independent biostatistician who is not involved in participant recruitment, intervention delivery, outcome assessment, or data collection.

Because the PI was involved in the development of QSTM technology and may have potential financial gain from this research, study procedures have been designed to maintain separation between intervention delivery, outcome assessment, data management, and statistical analysis roles to minimize potential investigator bias. The PI has a COI management plan on file with Indiana University.

8.0 Study Calendar

Study personnel training and QSTM calibration will begin in late September 2026. Following IRB approval, participant recruitment and pre-screening is planned to begin in late October 2026. Enrollment and data collection are expected to occur between November and December 2026, with a targeted completion prior to the end of the year 2026. Data cleaning and database verification will occur between beginning December 2026 through January 2027, followed by data analysis and interpretation starting in February 2027. Manuscript preparation and presentation dissemination activities will begin by April 2027. A description of study procedures during each study session is outlined in the Table below, including the days, time frame, and duration of the study.

STUDY PROCEDURES CALENDAR	Screening	Sessions/Treatment					
	Day 1 Screening	Day 1 Sess. 1 Baseline Before Interv.	Day 1 Sess. 1 Assess 1 After LE Side 1 Interv.	Day 1 Sess. 1 Assess 2 After LE Side 2 Interv.	Day 8 Sess. 2 Baseline Before Interv.	Day 8 Sess. 2 Assess 1 After LE Side 1 Interv.	Day 8 Sess. 2 Assess 2 After LE Side 2 Interv.
Clinical Measures							
Physical Activity Readiness Questionnaire (PAR-Q)	X	-	-	-	-	-	-
Blood Pressure (BP)	X	-	-	-	-	-	-
Height	X	-	-	-	-	-	-
Weight	X	-	-	-	-	-	-
Heart Rate (HR)	X	-	-	-	-	-	-
Ankle ROM & Passive Mobility	X	-	-	-	-	-	-
Weight-Bearing Lunge Test (WBLT)*	X	X	X	X	X	X	X
Numeric Pain Rating Scale (NPRS)	-	X	X	X	X	X	X
Static Algometry	-	X	X	X	X	X	X
Dynamic Algometry	-	X	-	-	X	-	-
Functional Physical Performance Measures							
LE Functional Ability Scale	-	X	-	X	X	-	X
10-meter Gait Speed Test*	-	X	-	X	X	-	X
Vertical Jump Test**	-	X	-	X	X	-	X
Contextual Factor Measures							
Expectations Scale* (VAS)	-	X	-	-	-	-	-
Affective Valence "Feeling Scale"	-	X	-	-	X	-	-
Anxiety Scale (VAS)	-	X	-	-	X	-	-
Soft Tissue Biomechanical Properties							
Soft Tissue Stiffness	-	X	X	X	X	X	X
LE = Lower Extremity (Calf) Side 1 and 2 (left and right randomized start) Interv. = Either low or higher IASTM force dose intervention as randomized per protocol							

STUDY PROCEDURES CALENDAR	Screening	Sessions/Treatment					
	Day 1 Screening	Day 1 Sess. 1 Baseline Before Interv.	Day 1 Sess. 1 Assess 1 After LE Side 1 Interv.	Day 1 Sess. 1 Assess 2 After LE Side 2 Interv.	Day 8 Sess. 2 Baseline Before Interv.	Day 8 Sess. 2 Assess 1 After LE Side 1 Interv.	Day 8 Sess. 2 Assess 2 After LE Side 2 Interv.
*Primary Outcome ** If eligible Assess. = Assessment X = Completed data collection for that measure - = Data collection Not completed for that measure							

9.0 Reportable Events

An adverse event (AE) is defined as any unfavorable or unintended sign, symptom, or occurrence experienced by a participant during study participation, whether or not it is considered related to study procedures. For this study, anticipated adverse events may include temporary soreness, discomfort, tenderness, skin redness, or bruising associated with measurement procedures or soft tissue manipulation. A serious adverse event (SAE) is defined as an event that results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or requires medical intervention to prevent one of these outcomes. SAEs are not anticipated with this healthy population. Any participant experiencing unexpected or concerning symptoms will be evaluated by study personnel, and participation may be discontinued if deemed necessary to protect participant safety. Any AEs will be documented and reviewed by the PI to determine severity and whether additional follow-up is warranted. Any unanticipated problems involving risks to participants or others, SEAs, protocol deviations affecting participant safety, or other reportable events will be submitted to the IU IRB in accordance with current policies and reporting requirements. The PI is responsible for ensuring timely reporting of all reportable events through the appropriate IU IRB reporting mechanisms.

10.0 Data Safety Monitoring

The PI will be responsible for monitoring participant safety and study conduct throughout the duration of the study. All study procedures will be performed by trained study personnel using standardized protocols.

Potential risks are expected to be limited to temporary soreness, mild discomfort, skin redness, or bruising associated with the assessment and treatment procedures. Participants will be monitored during all study Sessions for any AEs (SEAs), unexpected problems, or participant discomfort associated with study procedures. Any AEs (SEAs) will be documented, evaluated by the PI, and managed appropriately.

No independent Data Safety Monitoring Board (DSMB) is anticipated to be established. Data will be reviewed periodically by the PI to ensure participant safety, protocol compliance, and data integrity. Any unanticipated problems involving risks to participants or others will be reported to the IU IRB in accordance with institutional policies and applicable regulatory requirements.

11.0 Study Withdrawal/Discontinuation

Participants may discontinue participation at any time without penalty, and study procedures may be stopped if continued participation is deemed inadvisable or if the participant requests withdrawal. Any participant experiencing symptoms beyond a potential transient response will be evaluated by the PI, and appropriate action will be taken, including discontinuation from study participation if warranted.

12.0 Statistical Considerations

An independent biostatistician will perform all statistical analyses. This study uses a randomized, within-participant, two condition crossover design conducted in healthy adults. This approach allows internal comparison and control, while conserving the number of subjects needed to be enrolled. Primary outcomes are grouped by mechanistic pathway: Mechanical/contextual outcomes, e.g., WBLT, soft tissue stiffness and Contextual/Affective (Expectation VAS) outcomes.

Power calculations were based on paired samples methods appropriate for crossover designs, assuming a moderate within-participant effect size (Cohen's $d_z = 0.50$), which is commonly reported in repeated measures studies of musculoskeletal biomechanics and pain modulation responses. A minimum of 35 participants is required to achieve approximately 80% power to detect a moderate within-participant effect at a two-sided significance level of $\alpha = 0.05$ for each primary outcome. When outcomes are treated as co-primary within a pathway and a Bonferroni adjusted threshold is applied ($\alpha = 0.025$ per outcome), this sample size remains sufficient to detect moderate to moderately large within-participant changes.

Participation consists of two sessions, and loss after enrollment is expected to be minimal. To ensure that the target analyzable sample size is achieved, up to 40 participants will be enrolled to account for attrition due to potential exclusion or missed sessions, including confirmation of eligibility criteria at the initial session, participant withdrawal prior to completion of study procedures, or data that are not analyzable due to technical or measurement issues. The within-participant crossover design, in which each participant serves as their own control, further enhances statistical efficiency while minimizing participant burden and overall study risk.

Descriptive statistics will be calculated for all variables and will include means and standard deviations for continuous variables and frequencies and percentages for categorical variables. Data distributions will be assessed for normality.

The primary analysis will evaluate differences between the higher-force and lower-force QSTM-informed IASTM conditions using the randomized two-condition crossover design. Because each participant receives both interventions and serves as his or her own control, repeated-measures methods will be used to account for within-participant correlations.

For the primary mechanical outcomes (Weight-Bearing Lunge Test, 10-meter gait speed, and soft tissue stiffness), linear mixed-effects models will be used to examine the effects of treatment condition (higher-force versus lower-force), time (baseline versus post-intervention), session, and treatment sequence. Potential period and carryover effects associated with the crossover design will be evaluated and reported.

Secondary analyses will evaluate changes in pain ratings (NPRS), static algometry, lower-extremity functional ability, and vertical jump performance. Similar repeated-measures approaches will be used for these outcomes.

Expectation, anxiety, and affective valence measures will be examined as potential moderators or covariates of treatment response. Exploratory analyses will assess associations between these contextual variables and changes in primary and secondary outcomes using mixed-effects regression models.

All statistical tests will be two-sided with an alpha level of 0.05. Given the pilot nature of this study, emphasis will be placed on estimation of treatment effects and 95% confidence intervals in addition to statistical significance testing. Missing data will be evaluated and handled using maximum likelihood estimation within mixed-effects models whenever appropriate. No imputation of missing data will be performed.

13.0 Statistical Data Management

Primary data will be collected through participant screening interviews, paper self-report forms, participant questionnaires, and direct data captured from measurement instruments used during study procedures. Each participant will be assigned a unique study identification number, and all data used for analysis will be de-identified. Any document containing personal identifiers will be stored separately from study data in a secured location accessible only to approved study personnel.

Paper records will be maintained in locked filing cabinets within the PI's locked university office. Electronic data will be stored in password-protected electronic datasets (SPSS data files and Microsoft Excel spreadsheets) on secure Indiana University network servers with access restricted to authorized study personnel. Server-based data are routinely backed up by university information technology services. Statistical analyses will be conducted using IBM SPSS Statistics (current version).

Quality assurance procedures will include standardized data collection forms, training of study personnel, and review of collected data for completeness and accuracy. Data quality assurance and quality control activities will be conducted following each participant visit and prior to database lock. Quality control procedures will include verification of data entry, review of source documents for missing or inconsistent values, and data cleaning prior to statistical analysis.

14.0 Privacy/Confidentiality Issues

Every effort will be made to maintain the confidentiality of participant information; however, absolute confidentiality cannot be guaranteed. Personal information may be disclosed if required by law. Information that could directly identify participants will not be included in any presentations, publications, or reports resulting from this study.

Research records may be reviewed for quality assurance, regulatory oversight, and data analysis purposes by authorized individuals, including the Principal Investigator and approved study personnel, the Indiana University Institutional Review Board (IRB) and its designees, and other regulatory or institutional entities as required.

15.0 Follow-Up and Record Retention

The anticipated duration of the study is less than one year. Research records will be retained for a minimum of three years following study completion in accordance with institutional requirements. Paper records containing identifiable information will be destroyed by secure shredding after the

retention period. De-identified electronic data will be stored on secure Indiana University servers and may be retained indefinitely for future research, educational, or scholarly purposes consistent with applicable regulations and institutional policies.

16.0 References (Listed in Alphabetical Order)

Adell, E., Wehmhörner, S., & Rydwik, E. (2013). The Test-Retest Reliability of 10 Meters Maximal Walking Speed in Older People Living in a Residential Care Unit. Journal of Geriatric Physical Therapy, 36(2), 74–77. https://doi.org/10.1519/JPT.0b013e318264b8ed.

Albin SR, Koppenhaver SL, Bailey B, Blommel H, Fenter B, Lowrimore C, Smith AC, McPoil TG. The effect of manual therapy on gastrocnemius muscle stiffness in healthy individuals. Foot (Edinb). 2019 Mar;38:70-75. doi: 10.1016/j.foot.2019.01.006.

Baechle, T. R., Haff, G. G., & Triplett, N. T. (Eds.). (2016). Essentials of strength training and conditioning (4th ed.). Vertical Jump. Human Kinetics.

Baumbach SF, Braunstein M, Regauer M, Böcker W, Polzer H. Diagnosis of Musculus Gastrocnemius Tightness - Key Factors for the Clinical Examination. J Vis Exp. 2016 Jul 7;(113):53446. doi: 10.3791/53446.

Bennell KL, Talbot RC, Wajswelner H, Techovanich W, Kelly DH, Hall AJ. Intra-rater and inter-rater reliability of a weight-bearing lunge measure of ankle dorsiflexion. Aust J Physiother. 1998;44(3):175-180. doi: 10.1016/s0004-9514(14)60377-9.

Bhattacharjee A, Chien SYP, Anwar S, Loghmani MT. Quantifiable Soft Tissue Manipulation (QSTM™) - A novel modality to improve clinical manual therapy with objective metrics. Annu Int Conf IEEE Eng Med Biol Soc. 2021 Nov;2021:4961-4964. doi: 10.1109/EMBC46164.2021.9629616.

Bhattacharjee A, Anwar S, Chien S, Loghmani MT. A Handheld Quantifiable Soft Tissue Manipulation Device for Tracking Real-Time Dispersive Force-Motion Patterns to Characterize Manual Therapy Treatment. IEEE Trans Biomed Eng. 2023 May;70(5):1553-1564. doi: 10.1109/TBME.2022.3222124.

Bialosky JE, Bishop MD, Penza CW, et al. (2011). The Influence of Expectation on Spinal Manipulation-Induced Hypoalgesia. Journal of Pain, 12(2), 215-224.

Brandl A, Egner C, Reer R, Schmidt T, Schleip R. Immediate Effects of Myofascial Release Treatment on Lumbar Microcirculation: A Randomized, Placebo-Controlled Trial. J Clin Med. 2023 Feb 4;12(4):1248. doi: 10.3390/jcm12041248.

Childs JD, Piva SR, Fritz JM. (2005). Responsiveness of the Numeric Pain Rating Scale in Patients with Low Back Pain. Spine, 30(11), 1331-1334. https://doi.org/10.1097/01.BRS.0000164099.92112.29.

Chisholm MD, Birmingham TB, Brown J, Macdermid J, Chesworth BM. Reliability and validity of a weight-bearing measure of ankle dorsiflexion range of motion. Physiother Can. 2012 Fall;64(4):347-55. doi: 10.3138/ptc.2011-41.

Dingemans SA, Kleipool SC, Mulders MAM, Winkelhagen J, Schep NWL, Goslings JC, Schepers T. Normative data for the lower extremity functional scale (LEFS). Acta Orthop. 2017 Aug;88(4):422-426. doi: 10.1080/17453674.2017.1309886.

Dutton, M. (2023). Dutton's Orthopaedic Examination, Evaluation, and Intervention/Mark Dutton. (Sixth ed.). McGraw-Hill Education LLC. https://accessphysiotherapy.mhmedical.com/book.aspx?bookid=3216

Facco E, Stellini E, Bacci C, et al. (2013). Validation of Visual Analogue Scale for Anxiety (VAS-A) in Preanesthesia Evaluation. Minerva Anestesiologica, 79(12), 1389-1395.

Farasyn A, Lassat B. Cross friction algometry (CFA): Comparison of pressure pain thresholds between patients with chronic non-specific low back pain and healthy subjects. J Bodyw Mov Ther. 2016 Apr;20(2):224-34. doi: 10.1016/j.jbmt.2015.09.005.

Fusco A, Bonomi S, Padua L. Biological processes involved in mechanical force transmission in connective tissue: Linking bridges for new therapeutic applications in the rehabilitative field. Biocell. 2025;49(1),1-5. https://doi.org/10.32604/biocell.2024.058418.

Graston Technique Training Manual. Graston Technique. 1998-present.

Hardy CJ, Rejeski WJ. (1989). Not What, but How One Feels: The Measurement of Affect During Exercise. Journal of Sport & Exercise Psychology, 11(3), 304-317. https://doi.org/10.1123/jsep.11.3.304.

Henriques L, Teixeira DS. (2023). Assessing Affective Valence and Activation in Stretching Activities with the Feeling Scale and the Felt Arousal Scale: A Systematic Review. Perceptual and Motor Skills, 130(3), 1099-1122.

Huang J, Qin K, Tang C, Zhu Y, Klein CS, Zhang Z, Liu C. Assessment of Passive Stiffness of Medial and Lateral Heads of Gastrocnemius Muscle, Achilles Tendon, and Plantar Fascia at Different Ankle and Knee Positions Using the MyotonPRO. Med Sci Monit. 2018 Oct 23;24:7570-7576. doi: 10.12659/MSM.909550.

Keter DL, Bent JA, Bialosky JE, Courtney CA, Esteves JE, Funabashi M, Howarth SJ, Injeyan HS, Mazzieri AM, Glissmann Nim C, Cook CE. An international consensus on gaps in mechanisms of forced-based manipulation research: findings from a nominal group technique. J Man Manip Ther. 2024 Feb;32(1):111-117. doi: 10.1080/10669817.2023.2262336.

Keter DL, Esteves JE, Loghmani MT, Rossettini G, Cook CE. Context is Complex: Challenges and opportunities addressing contextual factors in manual therapy mechanisms research. Int J Osteopath Med. 2025;55:10.1016/j.ijosm.2025.100750. doi: 10.1016/j.ijosm.2025.100750.

Kindler CH, Harms C, Amsler F, Ihde-Scholl T, Scheidegger D. (2000). The Visual Analog Scale Allows Effective Measurement of Preoperative Anxiety and Detection of Patients' Anesthetic Concerns. Anesthesia & Analgesia, 90(3), 706-712.

Krause DA, Cloud BA, Forster LA, Schrank JA, Hollman JH. Measurement of ankle dorsiflexion: a comparison of active and passive techniques in multiple positions. J Sport Rehabil. 2011 Aug;20(3):333-44. doi: 10.1123/jsr.20.3.333.

Kristensen NS, Hertel E, Skadhauge CH, Kronborg SH, Petersen KK, McPhee ME (2021) Psychophysical predictors of experimental muscle pain intensity following fatiguing calf exercise. PLoS ONE 16(7): e0253945. https://doi.org/10.1371/journal.pone.0253945.

Loghmani MT, Keter DL, Bove GM, Winkelstein BA, Bulea TC, Olausson H, Pathak M, Powell R, Cook CE. A Model to Guide Force-Based Manipulation Research and Practice. PLOS One. 2025 Sep 12;20(9):e0331606. doi: 10.1371/journal.pone.0331606.

Loghmani MT, Anwar S, March K, Chein S, Al Oltaibi. Quantification of Force During Soft Tissue Massage for Research and Clinical Use. Issued US Patent # US-11,534,362, B2. December 27, 2022.

Loghmani MT, Powell R, Eckert GJ, Morgan S, Bhattacharjee A, Chien S, Anwar S. Visual monitoring in real-time improves consistency of 3D IASTM force applied to humans. Chiropr Man Therap. 2026 Jul 23;34(1):28. doi: 10.1186/s12998-026-00668-6.

Mondloch MV, Cole DC, Frank JW. (2001). Does How You Do Depend on How You Think You'll Do? A Systematic Review of the Evidence for a Relation Between Patients' Recovery Expectations and Health Outcomes. CMAJ, 165(2), 174-179.

Morhenn V, Beavin LE, Zak PJ. Massage increases oxytocin and reduces adrenocorticotropin hormone in humans. Altern Ther Health Med. 2012 Nov-Dec;18(6):11-8. PMID: 23251939.

Peters, D., Fritz, S., & Krotish, D. (2013). Assessing the Reliability and Validity of a Shorter Walk Test Compared With the 10-Meter Walk Test for Measurements of Gait Speed in Healthy, Older Adults. Journal of Geriatric Physical Therapy, 36(1), 24–30. https://doi.org/10.1519/JPT.0b013e318248e20d.

Powden CJ, Hoch JM, Hoch MC. Reliability and minimal detectable change of the weight-bearing lunge test: A systematic review. Man Ther. 2015 Aug;20(4):524-32. doi: 10.1016/j.math.2015.01.004.

Powell R, Emaus S, Noel Z, Bhattacharjee A, Loghmani MT. Dynamic pressure pain threshold assessment: reliability and impact on clinical measures. JOSPT Open. Feb 2025. https://www.jospt.org/doi/full/10.2519/josptopen.2025.AOPTCSM2. OP0190.

Riebe, D., Franklin, B. A., Thompson, P. D., Garber, C. E., Whitfield, G. P., Magal, M., & Pescatello, L. S. Updating ACSM's recommendations for exercise preparticipation health screening. Medicine & Science in Sports & Exercise. 2025;47(11), 2473-2479. https://doi.org/10.1249/MSS.0000000000000664.

Seffrin CB, Cattano NM, Reed MA, Gardiner-Shires AM. Instrument-Assisted Soft Tissue Mobilization: A Systematic Review and Effect-Size Analysis. J Athl Train. 2019 Jul;54(7):808-821. doi: 10.4085/1062-6050-481-17.

Stephanie R. Albin, Shane L. Koppenhaver, Brooke Bailey, Hilary Blommel, Brad Fenter, Chris Lowrimore, Andrew C. Smith, Thomas G. McPoil, The effect of manual therapy on gastrocnemius muscle stiffness in healthy individuals, The Foot, Volume 38, 2019, Pages 70-75, ISSN 0958-2592, https://doi.org/10.1016/j.foot.2019.01.006.

Tang S, Sheng L, Wei X, Liang M, Xia J, Chen J. The effectiveness of instrument-assisted soft tissue mobilization on pain and function in patients with musculoskeletal disorders: a systematic review and meta-analysis. BMC Musculoskelet Disord. 2025 Mar 14;26(1):257. doi: 10.1186/s12891-025-08492-4.

Verheijde, J.L., White, F., Tompkins, J., Dahl, P., Hentz, J.G., Lebec, M.T. and Cornwall, M. (2013), Reliability, Validity, and Sensitivity to Change of the Lower Extremity Functional Scale in Individuals Affected by Stroke. PM&R, 5: 1019-1025. https://doi.org/10.1016/j.pmrj.2013.07.001.

Wade L, Kinesiology Dept., University of Texas at Arlington. The effect of instrument assisted soft tissue mobilization on the passive tension properties of the lower extremities. Dissertation, Completed Aug 22, 2025. https://mavmatrix.uta.edu/kinesiology_dissertations/50/.

Williams HJ, Duncan JS, Grove-White DH, Mahen PJ, Gillespie AV. Repeatability and Feasibility of Pressure Algometry for Quantifying Mechanical Nociceptive Threshold in the Thoracic Region of Calves. Front Vet Sci. 2020 Jul 31;7:442. doi: 10.3389/fvets.2020.00442.

Appendix

The appendix includes the following documents:

A.1 QSTM Calf Data Collection Form
A.2 HEP & IM Instructions sheet

A.1 QSTM Calf Data Collection Form

Evaluation Form for Instrument-Assisted Soft Tissue Manipulation

Participant#_____
1st Session Date:_____
Assessment Point 1 (right or left LE) Assessment Point 2 (right or left LE) [circle]

2nd Session Date:_____
Assessment Point 1 (right or left LE) Assessment Point 2 (right or left LE) [circle]

Timepoints (during each session) [Order of right or left calf IASTM intervention will be randomized]:
Baseline = prior to IASTM; Assessment 1=after IASTM side 1; Assessment 2=after IASTM side 2

SUBJECTIVE HISTORY: (a-g: complete at 1st session, following informed consent, prior to enrolling to further screen for inclusion/exclusion criteria)

a. Any Primary or Secondary Complaints:

If so, Onset of Condition(s):

b. Past Medical History (including surgery)(esp. those that may influence study participation):

c. Diagnostic Tests (including imaging):

d. Medications (including vitamins/supplements):

e. Lifestyle Habits that may influence study participation: Yes or No (circle)

f. Any Prior Physical Therapeutic or Self Treatments (including orthotics; footwear):

g. Work/School History:

h. Functional Activities (for typical day and/or sport):

SYSTEMS REVIEW & SCREENING: (complete at 1st session, following informed consent, before enrolling to determine if meets inclusion/exclusion criteria)

Height _____ Weight _____ BMI _____ (Within inclusion criteria: Yes or No)

CP: HR (bpm): _____ BP (mmHg): _____

Ankle Dorsiflexion ROM (°) & Passive Mobility Testing: (screen at 1st session, after informed consent, before enrolling to determine if meets inclusion/exclusion criteria)

Active ROM (AROM)
RLE: Knee Straight: _____ Knee Bent to 90d: _____

LLE: Knee Straight: _____ Knee Bent to 90d: _____
Passive ROM (PROM)
RLE: Knee Straight: _____ Knee Bent to 90d: _____

LLE: Knee Straight: _____ Knee Bent to 90d: _____

Passive Mobility Testing. Indicate if any Ankle joint limitations detected due to intra-articular, capsular tightness, or post-fracture abnormalities. Briefly describe.

RLE: Yes or No. _____

LLE: Yes or No. _____

SUBJECTIVE (SELF-REPORTED) OUTCOME FINDINGS:

A. Pain Level [NPRS 0-10/10 scale (0=no pain; 10=worst pain imaginable]
1st Session (Baseline)
[Right (R) calf]: Now___ On Average _____At Best ____At Worst _____

[Left (L) calf]: Now___ On Average _____At Best ____At Worst _____

1st Session (Assessment 1) [circle R or L calf]: Now_____

1st Session (Assessment 2) [circle R or L calf]: Now____

2nd Session (Baseline)
[R calf]: Now___ On Average _____At Best ____At Worst ____

[L calf]: Now___ On Average _____At Best ____At Worst _____

2nd Session (Assessment 1) [circle R or L calf]: Now___

2nd Session (Assessment 2) [circle R or L calf]: Now____

B. Bilateral LE Functional Ability VAS (mm) (0%=none, 100%=full function)

1st Session (Baseline): Now_____ On Average _____At Best _____At Worst _____

1st Session (Assessment 2): Now_____

1st Session Description (optional)_____

2nd Session (Baseline): Now_____ On Average _____At Best _____At Worst _____

2nd Session (Assessment 2): Now_____

2nd Session Description (optional)_____

C. Expectation VAS (mm) (0 ="not effective at all", 100="extremely effective")
[Session 1 Baseline only]:

Higher Force Level:_____ Lower Force Level:_____

D. Affect Valence "Feeling" Scale (-5 very bad to +5 very good):

1st Session Baseline_____ Assessment 2_____

2nd Session Baseline_____Assessment 2_____

E. Anxiety VAS (mm) (0="not at all anxious/stressed", 100="extremely anxious/stressed")

1st Session Baseline_____

2nd Session Baseline_____

OBJECTIVE OUTCOMES FINDINGS:

1. Weight Bearing Lunge Test (WBLT). (Highest Attempt Score)
1st Session

Screening & Baseline (pre-IASTM)
RLE: Highest Attempt: _____cm LLE: Highest Attempt: _____cm

Assessment 1 (Right or Left) Highest Attempt: _____cm

Assessment 2 (Right or Left) Highest Attempt: _____cm

2nd Session

Baseline: RLE: Highest Attempt: _____cm LLE: Highest Attempt: _____cm

Assessment 1 (Right or Left) Highest Attempt: _____cm

Assessment 2 (Right or Left) Highest Attempt: _____cm

2. 10-Meter Gait Speed Test (m/s) (average of two trials)

1st Session: Baseline_____ Assessment 2_____

2nd Session: Baseline_____ Assessment 2 _____

3. Vertical Jump Test (as appropriate per criteria) (cm) (Best of 3 attempts)

1st Session: Baseline_____ Assessment 2_____

2nd Session: Baseline_____ Assessment 2 _____

4. Palpation Exam (Describe any soft tissue irregularities, tender spots, restrictions and specify whether detected during manual & IASTM for each calf):

1st Session:

Manual assessment:

IASTM assessment:

2nd Session:

Manual assessment:

IASTM assessment:

5. Soft Tissue Stiffness (N/m):

1st Session

Baseline: RLE: Avg. Score: _____LLE: Avg. Score: _____

Assessment Point 1 (R or L LE circle) Avg. Score: _____N

Assessment Point 2 (R or L LE circle) Avg. Score: _____N

2nd Session

Baseline: RLE: Avg. Score: _____ LLE: Avg. Score: _____

Assessment Point 1 (R or L LE circle) Avg. Score: _____N

Assessment Point 2 (R or L LE circle) Avg. Score: _____N

6. Static Pressure Pain Threshold (N)
1st Session

Baseline: RLE: Avg. Score: _____N LLE: Avg. Score: _____N

Assessment Point 1 (R or L circle)

Avg. Score: _____N

Assessment Point 2 (R or L circle)

Avg. Score: _____N

2nd Session
Baseline: RLE: Avg. Score: _____N LLE: Avg. Score: _____N

Assessment Point 1 (R or L circle)

Avg. Score: _____N

Assessment Point 2 (R or L circle)

Avg. Score: _____N

7. Dynamic Pressure pain threshold assessment (N) (at Baseline, pre-IASTM only):

(1st Session)

RLE: Avg. Score: _____N
Higher Dose (35% of avg.): _____N Lower Dose (10% of avg.):_____N

LLE: Avg. Score: _____N
Higher Dose (35% of avg.): _____N Lower Dose (10% of avg.):_____N

(2nd Session)

RLE: Avg. Score: _____N
Higher Dose (35% of avg.): _____N Lower Dose (10% of avg.):_____N

LLE: Avg. Score: _____N
Higher Dose (35% of avg.): _____N Lower Dose (10% of avg.):_____N

A.2 HEP & IM Instructions sheet

IASTM Study Stretching Exercise and Ice Instructions



Instructions: Perform the exercise and ice pack as indicated (if checked below) for 1-2 days following your study visit.

____Seated Calf Stretch

Sit in a chair with good posture and straighten one knee at a time while dorsiflexing your ankle (actively pulling your toes towards your nose). Hold 10 seconds, return to starting position, and then perform on the opposite side.

Repeat 10 reps on each leg, perform 1-2 sets. 1-2 times/day.

____Applying a Cold Pack

Place an ice pack (provided) on any sore areas for up to 10 minutes, as needed, up to twice/day.

Picture references: HEP2go.com; Movement Solutions LLC.