PINPOINT Study

Pain **I**ntervention with **N**eedling: **P**ilot Of **I**ntegrated **N**euromodulation **T**echniques

Exploration of Dry Needling as a Treatment of Chronic Low Back Pain

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PROTOCOL GUIDANCE

1. Introduction and Purpose

Chronic low back pain (cLBP) is a disabling condition that affected approximately 619 million people worldwide in 2020.[1] While this area has been a focus of research due to its high cost to the individual and medical system, interventions that are successful in reducing pain and improving quality of life are limited. The World Health Organization recommends physical activity and rehabilitation for those with cLBP.[1] Rehabilitation techniques have shown to be helpful but also continue to lack specificity in their approach. Dry needling is a technique which allows the provider to target the desired tissue and directly provide a therapeutic intervention. This project is proposed to assess the acceptability and feasibility of dry needling techniques in those with cLBP.

Dry needling is a technique that involves inserting a solid, monofilament needle into dysfunctional tissue to promote blood flow, enhance neurological connection, and improve muscle function. This procedure can be performed by trained healthcare providers, such as physical therapists, and is part of the recommended practices for treating individuals with acute low back pain, though evidence supporting its use in those with cLBP is limited. A 2021 revision of clinical practice guidelines[2] indicated that dry needling can be beneficial for those with cLBP in the short term, but it acknowledged the need for further research to understand optimal parameters and long-term effects.

Due to the limited research on optimal parameters for the use of dry needling, this pilot study aims to explore the acceptability and feasibility of procedures and techniques relevant to future research. These procedures and techniques are intended to enhance our mechanistic understanding of dry needling and the combination of dry needling with percutaneous electrical nerve stimulation (PENS). The primary endpoint will assess the feasibility of the study by examining components such as participant retention, session costs, scheduling, and more. In addition, this pilot study will gauge the acceptability of the procedures through interviews and surveys conducted with the participants. A secondary endpoint will involve analyzing preliminary data to identify optimal outcome measures for future research.

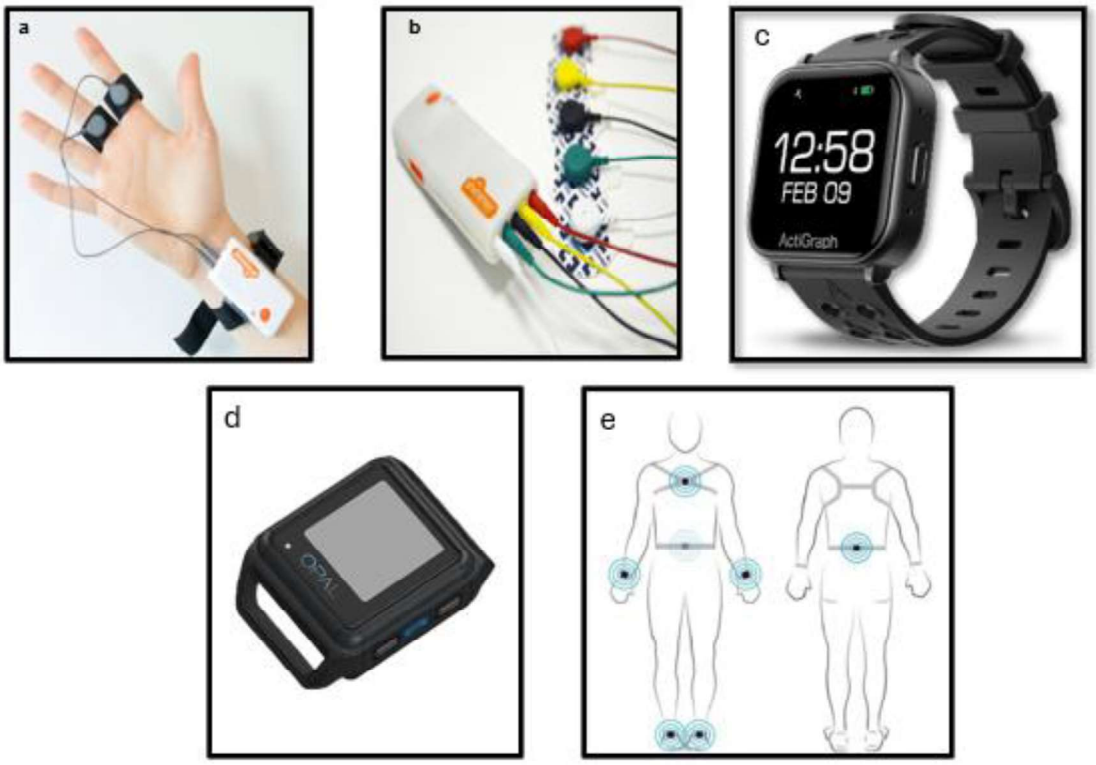
In a previous study, Impact of Dry Needling on Lumbar Muscle Activation in Healthy Adults: A Pilot Study, 24-0116, the PI explored the feasibility of a protocol to explore how different interventions impacted the lumbar muscle activation. These interventions included exercise only, exercise plus dry needling, or exercise plus dry needling and electrical stimulation. From this, the PI observed that dry needling and dry needling with PENS were both acceptable to the participants without any adverse events and the protocol was achievable. The PI was able to recruit the appropriate number of individuals for this study. This study used ultrasound imaging to assess the impacts on the lumbar multifidus. Integrating this tool into the protocol was beneficial to gather images of the musculature; however, combining the images with exercises unfortunately made the images difficult to interpret and would need additional revision to procedures to enhance the quality of future data collected. Additional secondary outcomes analysis are currently being explored.

To identify optimal outcomes, this study aims to collect patient-reported outcome measures (PROMs), physical assessments, quantitative sensory testing (QST), and activity monitoring through wearable sensors. As noted in section 3, the chosen PROMs have a specific rationale for inclusion. These are chosen to collect a wide range of data from the patient's perception of their condition to ensure the study's success beyond scientific measurements. Likewise, physical assessments will be gathered to help understand how this intervention may impact the participant's ability to interact with their daily tasks and environments. For this reason, the participants will be asked to wear activity monitors to help understand if the influence of dry needling translates beyond the intervention session. Finally, QST allows researchers to have a better mechanistic understanding of how the intervention impacts the participant physiologically.

Through activity monitors and wearable sensors, this proposed study aims to collect physiological measures, such as heart rate and skin galvanometry. These measures may serve as indirect

indicators of the autonomic nervous system's function. The measurements will provide insight into how and if dry needling techniques influence this system. For instance, pain has been shown to affect the function of the autonomic nervous system by impacting overall nervous system function, sleep patterns, and immune system performance. In future studies, these wearable sensors will be utilized to gain insight into whether dry needling techniques may impact the participants' physiological responses. The primary purpose of including sensors into this study is to assess the feasibility of use and to collect preliminary data for future funding. Figure 1 displays a visual of the wearable sensors that will be worn during sessions. A Shimmer3 GSR (a) sensor records galvanic skin response. Electrocardiogram data is captured with a Shimmer3 ECG (b) or a Bitalino (Plux Wireless Biosignals, Arruda dos Vinhos, Portugal) data acquisition board, which features a 3-cable ECG extension for collecting a single lead heart rhythm signal. The ActiGraph LEAP (c), is a consumer wearable which collects data based on a person's physical activity, sleep periods, and functional mobility along with physiological measures not collected by the Shimmer3. The Opal V2R® (d) system allows for collection of precise movement data that will be used to determine quality of movement. Image e shows the placement of the Opal system which would be worn during physical activity screening.

Figure 1. Biometric Sensor



Biometric sensors such as galvanometers (a), and ECG (b) quantify physiological responses to the VR environment. ActiGraph LEAP (c) quantifies physical function and community involvement. Opal V2C (d-e) allows for precise movement data which can be assessed to determine quality of movement changes.

The generalizable benefits of including wearable sensors include a better understanding of the impact of dry needling on the neuromuscular system, which may influence therapeutic interventions used commonly in physical therapy practice. The information from this pilot study will provide preliminary data to inform the design of future larger studies which may explore a variety of pain conditions. Secondarily, this information will assist in understanding optimal outcome measures which may also be used in larger studies and in other pain conditions.

QST encompasses a set of standardized, non-invasive tests designed to assess somatosensory function by quantifying responses to calibrated sensory stimuli. These tests systematically evaluate both small and large nerve fiber function by measuring detection and pain thresholds for various stimuli including mechanical, thermal, electrical, and chemical sensations. QST provides objective measurements of both peripheral and central pain processing mechanisms, offering insights into the underlying pathophysiology of pain conditions.

QST is particularly valuable in cLBP research for several key reasons. It helps differentiate between peripheral and central pain mechanisms contributing to cLBP, allowing for more targeted interventions. cLBP is heterogeneous in nature; QST enables classification of patients based on their sensory profiles, facilitating personalized treatment approaches. QST parameters can serve as biomarkers to predict response to specific interventions, including dry needling. It provides objective measures of treatment efficacy beyond subjective pain ratings. Additionally, QST can identify central sensitization, a key factor in many chronic pain conditions including cLBP.

QST procedures have been extensively validated in research settings and demonstrate excellent safety profiles when conducted by trained personnel. The tests are non-invasive, well-tolerated by patients, standardized with normative data available, reversible with no lasting effects, and suitable for repeated measurements. Numerous studies have successfully employed QST in cLBP populations without adverse effects, establishing its safety profile for research applications.

Temporal summation measures the increased pain perception in response to repetitive noxious stimuli at constant intensity, reflecting wind-up phenomenon and central sensitization. Enhanced temporal summation is associated with central sensitization in cLBP patients and predicts response to centrally acting treatments. Studies have shown that cLBP patients often exhibit facilitated temporal summation compared to healthy controls. The stimulus intensity is controlled and calibrated to the individual's threshold, ensuring discomfort remains within tolerable limits.

Conditioned Pain Modulation (CPM) assesses endogenous pain inhibitory systems by measuring how pain perception to a test stimulus is reduced by a concurrent conditioning painful stimulus applied to a remote body site. Impaired CPM has been documented in cLBP patients, indicating dysfunction in descending pain inhibitory pathways. This dysfunction may contribute to pain persistence and chronicity. The test involves controlled painful stimuli that are temporary and calibrated to the individual's tolerance, with immediate cessation upon request.

Pressure Pain Algometry quantifies pressure pain thresholds (PPT) using a handheld pressure algometer applied perpendicular to the skin with gradually increasing pressure. cLBP patients typically show lower PPTs both locally (lumbar region) and at remote sites, suggesting both peripheral and central sensitization. Algometry has been used to evaluate treatment effectiveness, including manual therapies similar to dry needling. Pressure is applied gradually with clear participant feedback mechanisms, and is stopped immediately upon pain threshold indication.

Two-Point Discrimination measures the minimum distance at which two points applied simultaneously to the skin can be perceived as distinct. cLBP is associated with impaired tactile acuity in the affected region, reflecting cortical reorganization. Improvement in two-point discrimination correlates with pain reduction following interventions. This test applies only light touch and poses no risk beyond minimal discomfort.

Von Frey Filaments are calibrated monofilaments that bend at specific forces to assess mechanical detection thresholds. Von Frey testing can identify mechanical hyperalgesia or hypoesthesia, providing information about both peripheral and central sensitization in CLBP populations. The filaments are designed to exert precise, limited force and cannot cause tissue damage.

The Michigan Visual Stress Test consists of a display of varying light, color, and display intensities. This test can identify more directly involvement and sensitivity of the central nervous system. The test only applies visual images and poses no risk beyond minimal sensory discomfort.

QST is particularly relevant to dry needling research for several reasons. It can help identify whether patients' pain is predominantly driven by peripheral nociception, central sensitization, or impaired descending inhibition—all potentially modifiable by dry needling. Through QST, it is possible to detect and differentiate between issues involving the A-beta, A-delta, and C-fibers. By identifying specific pain processing abnormalities, QST can help determine which patients might benefit most from dry needling. QST can be used to elucidate the neurophysiological mechanisms through which dry needling exerts its effects, by measuring changes in local and remote pressure pain thresholds, temporal summation, and conditioned pain modulation. Beyond subjective pain reports, QST provides objective markers of treatment efficacy.

Multiple studies have successfully implemented QST protocols in cLBP research. Goubert et al. (2017) used pressure algometry, temporal summation, and CPM to identify sensory phenotypes in cLBP patients.[3] Marcuzzi et al. (2018) employed a comprehensive QST battery to track sensory processing changes following cLBP interventions.[4] Rabey et al. (2015) utilized QST to subgroup CLBP patients, demonstrating differing treatment responses based on sensory profiles.[5] Starkweather et al. (2016) incorporated QST in evaluating the neurophysiological effects of manual therapy interventions, showing normalization of enhanced temporal summation following treatment.[7] These studies confirm both the feasibility and utility of QST in cLBP intervention research, with no reported adverse events related to the sensory testing procedures.

QST provides valuable, objective measurements of somatosensory function that can significantly enhance research into dry needling for cLBP. These procedures offer mechanistic insights into both the pathophysiology of cLBP and the therapeutic effects of interventions. The tests have established safety profiles and have been successfully implemented in numerous cLBP research projects. The use of QST in this study will allow for more precise identification of pain mechanisms, potentially leading to better patient selection and more targeted application of dry needling interventions.

The risks for this study are comparable to the dry needling interventions performed in routine clinical practice and may include pain with needle insertion, bruising, soreness, and potential bleeding, which are minimal for dry needling. Additionally, as there the participants skin will be pierced, there is a chance of infection, however, this risk is extremely low and mitigated through proper cleaning and use of sterile needles. The techniques and procedures being studied are commonly used in physical therapy practice and have been found to have minimal to no adverse effects. The potential benefits of this line of study in relation to risk are high when considering the significant impacts which low back pain and dysfunction has for the individual and society.

This research is being conducted as pilot work for future research by the primary investigator (PI). As faculty with University of Texas Medical Branch (UTMB), the Department of Physical Therapy and Rehabilitation Sciences has granted the PI support to work on this study through time and use of resources. Resources include physical space and supplies to conduct the research study. The study will be conducted on the UTMB Galveston campus with a potential for expansion to the Clear Lake and League City campuses. Funding support for the project is also available through external grant funding

This study will be considered a pilot study exploring the feasibility and acceptability of using the previously mentioned processes and overall protocol. Additionally, the study will aim to explore the mechanistic impact of dry needling on the neuromuscular system and is thus not a clinical trial. While human subjects are being used, based on the National Institute of Health’s definition of a clinical trial, this study will not aim to evaluate the effectiveness of an intervention on health-related biomedical or behavioral outcomes. Due to this, the study would qualify as a basic experimental study involving humans.

Research Question and Study Aims

The overarching research question is as follows: Do dry needling techniques decrease pain and improve quality of life in adult patients experiencing chronic low back pain? To begin exploring this question, the following specific aims will be assessed.

SPECIFIC AIM 1 (Phase 1): Conduct preliminary protocol testing in *healthy adults* at the Center for Health Promotion, Performance, and Rehabilitation Research (CHPPRR) within UTMB.

Primary Outcome: Assess the acceptability and feasibility of the protocol
Secondary Outcome: Assess the various outcome measures used for improvements in nervous system functioning, quality of life, and physical function.

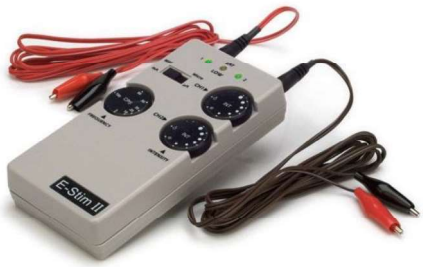
SPECIFIC AIM 2 (Phase 2): Refine and conduct preliminary protocol testing in *adults with chronic low back pain*.

Primary Outcome: Assess the acceptability and feasibility of the protocol
Secondary Outcome: Assess the various outcome measures used for improvements in nervous system functioning, quality of life, and physical function.

2. Background

This project aims to assess the acceptability and feasibility of dry needling and dry needling with electrical stimulation in the treatment of cLBP. The target tissues that will be treated by dry needling are the lower back muscles, including the multifidus, erector spinae, quadratus lumborum, and gluteal musculature. Previous studies have demonstrated the effectiveness of exercise to improve the function of the lumbar musculature;[7-9] however, these studies also note that participants have difficulty achieving the necessary specificity of exercise to improve multifidus function.[10,11]

Percutaneous electrical nerve stimulation (PENS) applies low-intensity electrical stimulation to a needle inserted into the tissue. Electrical stimulation may be added to improve the benefits of dry needling and to reduce pain to a greater extent. This procedure is considered safe and is common practice in physical therapy clinics. Electrical stimulation is provided through a device using a 9-volt battery or equivalent energy source approved for use with dry needling. The use of PENS has been shown to be a more effective treatment for improving pain, disability, pressure pain threshold, and strength compared to dry needling alone.[2] An example of this device is shown below.



Currently, physical therapy consists of exercise prescription along with adjunct therapies.[2] These therapies may include the use of manual work, such as joint mobilization and manipulation, but also modalities such as dry needling and dry needling with PENS. While mainstream practice, there is not a current best practice for the standardization of dry needling or a complete understanding of the mechanisms of action. The lack of understanding results in variable clinical approaches to the utilization of dry needling as either the primary or adjunct intervention when caring for individuals with low back pain. As a result, the care for patients varies, which may negatively impact outcomes and

increase the cost of care. This study would help to understand better the impact which dry needling and dry needling with PENS may have on the function of the lumbar musculature and descending pain pathways which are key issues for people with cLBP. The lumbar multifidi and other musculature play a critical role in the stabilization of lumbar vertebrae during all activities, especially those involving rotational components.[12.13] This is important to understand because it is well documented that the lumbar musculature is impaired when there is a history of or current episode of low back pain.[2,13] This study would be pilot work to lay the groundwork for future research which will further utilize conventional dry needling practices to restore or improve the functioning of the lumbar musculature and descending pain pathways in order to decrease pain and improve quality of life of patients with chronic pain.

The use of dry needling practices in physical therapy is common. Due to this, there are no additional concerns around dry needling use beyond the standard concerns regarding its use as standard of care which are referenced in "risks" below. Due to the limited literature on standard practices of dry needling or the use of dry needling when treating chronic low back pain, this study would be pioneering a branch of research to improve pain and quality of life in those with cLBP through mechanistic assessments and understandings.[2] Additionally, electrical stimulation (e-stim) is also a common practice in physical therapy. E-stim is often used to assist those with muscle weakness and pain conditions.[15,16] This modality can be administered using FDA-approved devices either over the skin with electrode pads or in specific soft tissues using dry needling. Due to the specificity needed, this project will aim to utilize e-stim with dry needling techniques. Currently, dry needling is recommended when treating those with acute low back pain.

The research team consists of faculty and staff within UTMB. Drs. Brusola and Pontiff are trained in research methods through their PhD training and are both dry-needling certified. Drs. Tucker and Morrow are experienced researchers who will assist with the study procedures and oversight. Ms. Durgens is a nurse practitioner trained in research procedures and study recruitment. Dr. Brightwell has training in research protocols and is experienced in baseline assessments which will be included in this study. The research team will also consist of doctor of physical therapy students who will be participating in data collection

3. Concise Summary of Project

This project will be conducted in two phases to determine the acceptability and feasibility of the outlined procedures

Phase 1: Specific Aim 1

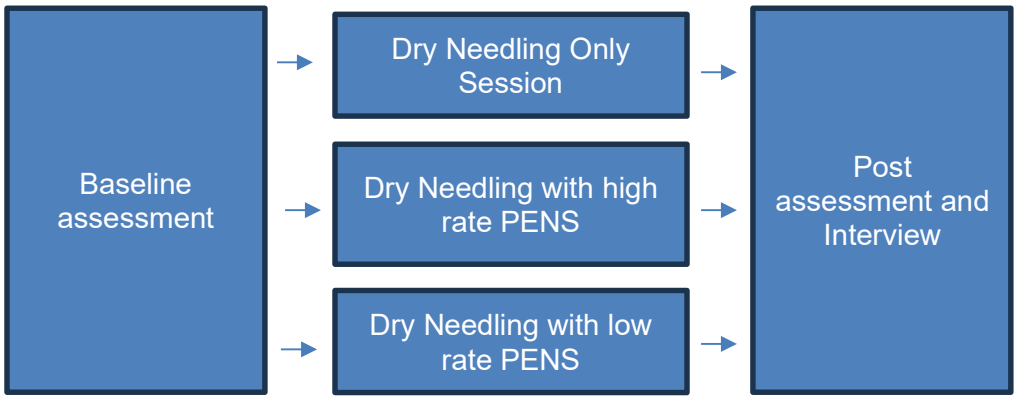
Phase 1 of the pilot project will explore the acceptability and feasibility of procedures in healthy adults. This phase will recruit up to 12 healthy individuals. Individuals will undergo a baseline assessment followed by a one-time intervention and a post-assessment. This phase will assess the protocol for areas that could improve procedures and reduce participant risk in the future population of interest. Participants will be block-randomized into either a dry needling or dry needling with a PENS group. The aim will be to have 4 participants in each group.

An amendment will be filed with the IRB for any significant alterations to the protocol. Significant alterations will be considered for changes that would reduce risk or improve the safety of the study. At the conclusion of this phase, all procedures will be reevaluated to assess successful events and areas for improvement which will be implemented in Phase 2. Similarly, each participant will be asked to provide feedback about the acceptability of the procedures and study via written feedback and one-on-one interviews.

Subjects will participate in 3 visits. The first visit will be a baselining assessment. The second will involve either dry needling only, dry needling with high-rate PENS, or dry needling with low rate PENS

and the 3rd will be a repeat of baseline assessments and a one-on-one interview. These visits are outlined further in section 3. See Figure 2 for the flow of the participant involvement. A research member will aim to schedule the next session with at least one day (24 hours) between sessions.

Figure 2. Flow of Participation



Baseline Assessment – Visit 1

Baseline assessment procedures will include consenting the participant and gathering sociodemographic information, quantitative sensory testing (QST), patient-reported outcome measures, and physical assessments.

Healthy participants (n=12) will complete a sociodemographic questionnaire electronically via the REDCap system which will request the following information:

- Age
- Sex/Gender
- Race/ethnicity
- Occupation
- Education level
- Comorbidities
- Past medical history and contraindications review

REDCap is a secure web application with electronic data capture tools for building and managing online surveys and databases. The REDCap system allows for audit trails for tracking data manipulation and exporting procedures

QST will include visual and tactile components to assess the nervous system's sensitivity. Each participant will be tested at 2 sites: the low back and an area that is distal and perceived to be 'normal' such as the hands or feet. The tester will aim to ask participants if the dominant hand is perceived as "normal and pain-free." If no, the team member will progress to the nondominated hand, dominant foot, and non-dominant foot until a normal and pain-free limb is identified. The various QST measures will be assessed via the following.

- **Visual sensitivity** will be assessed by using the M-VAST (Michigan Visual Aversion Stress Test) which will provide a visual stimulus to the participant, followed by a rating screen. Participants will be shown a black screen, followed by a visual cue, followed by an aversive visual stimulus and a rest time prior to the rating screen. Participants will be able to rate the sensory and unpleasantness of the stimulus. The stimulus is a flashing annular checkerboard pattern with varying illuminations.
- **Two-point discrimination** will be used to assess the mechanical somatosensory sensitivity by assessing the tactile acuity for non-painful mechanical sensation. The 2-point discrimination

tools will be used in the lumbar region and in a distal “normal” area. The mid-extensor belly of the dominant arm will be the primary target unless painful or perceived as normal. We will use the non-dominate arm as an alternative location, followed by the mid-dominant calf, and then the mid-dominant calf if needed. Participants will complete a series of ascending (in which the 2 points of the aesthesiometer are initially adjacent) and descending (in which the 2 points of the aesthesiometer are initially far apart) trials in which they indicate whether they “feel one or two points” when the stimulus is applied. The distance between the points is increased or decreased until the experimenter locates the minimum distance at which the participant perceives 2 points instead of one. The results of ascending and descending trials are averaged to calculate the two-point discrimination threshold.

- **Mechanical detection threshold (MDT)** will be measured using von Frey hairs that exert 0.25 to 512 mN of force. Five tests will be performed with the filaments. A mid-ranged filament will be chosen, followed by an ascending or descending stimulus until the detection threshold is identified. The average of the five tests will be calculated to determine MDT.
- **Mechanical Pain sensitivity (MPS)** will use weighted pinprick stimulus weighted at 256 and 512 mN. Participants will be provided a single stimulus 5 times and asked to rate the sensation on a 0-100 scale with 0 indicating “no pain” and 100 indicating “the worst pain imaginable” for each. Following the single stimulus, 10 repetitive pinprick stimuli will be applied for 5 sets. This will assess the wind-up ratio, which will be calculated as the mean rating of the five series divided by the mean rating of the five single stimuli.
- **Pressure pain threshold (PPT)** will use a pressure gauge device on the participant's lumbar and a distal site such as the participant's mid-forearm extensor belly. Slowly, ascending pressure will be provided until the participant first perceives pain. This will be performed three times and averaged. Measurements will be conducted 3x/site (separated by 60-s rest intervals) with means used for analysis. Probe placement will be varied slightly trial to trial to prevent tissue sensitization from repeated testing of the same site.
- **Conditioned pain modulation (CPM)** is used to induce the endogenous analgesic response. This is done by immersing the participants hand in 10-degree Celsius cold-water bath to 10 cm above the wrist. The hand is immersed for 60 seconds or to the participant's tolerance. Perceived pain will be rated at 30 seconds and at 60 seconds. Participants will be asked to rate their pain on a scale off 0-100 with 100 being the worst pain imaginable. This will be combined with the pain-pressure threshold procedures at a distal site. This will assess the adequacy of the conditioning pain of the endogenous system.

Patient-reported outcome measures (PROMs) will assess the participants' perceptions of pain and its impact on their quality of life. All PROMs will be provided to the participants electronically for them to complete through the REDCap system.

Physical assessments will assess the subjects' ability to interact with their environment.

Lastly, a subset of the participants will be asked to wear an activity monitor, ActiGraph LEAP (ActiGraph LLC, Pensacola FL), while participating in the study. Up to 2 participants from each group, for a total of 6 participants, may be asked to wear activity and health monitors to collect pilot data to inform future related studies. These sensors will gather information about activity levels during sedentary and movement times. This data will help in answering the question of if dry needling impacts a person’s quality of life through increased activity. Those asked to wear the ActiGraph will be asked to wear the device for the duration of their participation in the study. Activity monitors will be collected following the post-intervention visit. Participants will be explained how to return the devices if they are unable or unwilling to continue participation in the study.

Additionally, during the assessment and intervention visits, participants will be asked to wear the Shimmer3 GSR+ and ECG units to gather information such as heart rate variability and skin response, which is an indirect measurement of the autonomic nervous system function of the intervention. The Opal V2C® system will be used during the data collection of physical assessment outcomes. Participants will be instructed on the proper use and wearing of the activity monitors.

All activity monitors can be worn comfortably under or over clothing. Activity monitors are attached with Velcro straps or on the trunk (with an elastic chest harness, or hypoallergenic medical-grade skin adhesive), on the wrist (with a watch band or elastic strap). The activity monitors are worn during the participants' waking hours, but will not be worn while bathing or swimming

The following table outlines the outcome measures which will be collected.

	Outcome measure	Approx. time to set up and complete in minutes	Rationale
Wearable sensor for physiological data	ActiGraph LLC	5	Physical activity assessment in the community by assessing both sedentary and physical activity behaviors
	Shimmer3 GSR+ Unit	5	Galvanic skin response
	Shimmer3 ECG Unit	10	aimed to measure and record the electrical activity of the heart, including electrocardiogram, respiration rate, and electromyography
	Opal Unit	5	To measure accelerometry and gait information
QST	Michigan Visual Stress Test (M-VAST)	10	Visual Sensitivity
	Pressure Pain Threshold	5	Pressure sensitivity
	2-point discrimination	5	Assesses tactile spatial acuity
	Von Frey Filaments	10	Mechanical pressure sensitivity
	Temporal Summation	10	Repeated stimuli sensitivity
	Conditioned pain modulation	10	Assess the involvement of the central nervous system
Physical Assessments	Range of motion measurements	5	To determine functional mobility
	Timed up and go	3	Assesses mobility, function, active balance
	6-minute walk test	7	Assessing functional capacity
Self-Report Outcomes	Numeric Pain Rating Scale	2	Assessed participants' perceived pain
	PROMIS-29+2	5-10	assesses various aspects of health, including physical function, anxiety, depression, fatigue, sleep disturbance, social roles, and pain interference (HEAL common data element)
	Roland-Morris Disability Questionaire	5	assesses the impact of low back pain on various aspects of daily living, including physical

			functioning, personal care, lifting, walking, sitting, standing, sleeping, sex life (if applicable), social life, and traveling
	Patient-Specific Functional Scale	4	Assesses functional activities which the participant finds to be important
	Complex Medical Symptoms Inventory	15	Assesses nervous system sensitivity to internal and external stimulus
	WHOQOL	3	Quality of life (HEAL common data element)
	TAPS	2	Substance use screener (HEAL common data element)
	PGIC	3	Global satisfaction with treatment (HEAL common data element)
	Generalized anxiety disorder	1	Anxiety screening (HEAL common data element)
	Patient Health Questionnaire	2	Depression screening (HEAL common data element)
	Pain Catastrophizing Scale	3	Pain catastrophizing (HEAL common data element)
	Sleep Disturbance	2	Sleep (HEAL common data element)
	Pain, Enjoyment of Life, and General Activity (PEG)	2	Pain intensity and pain interference (HEAL common data element)
	Sensory Processing Sensitivity Questionnaire (SPSQ)	2	To determine increased sensitivity to environmental stimulation
	Chronic Pain Acceptance Questionnaire – Revised (CPAQ-R)	2	To determine how accepting a person is of their pain, they are.
	University of Washington Concerns About Pain (UW-CAP) – 8	2	Identify patients' concerns and self-efficacy about pain

Phase 1 Consent forms will be provided for the participant to read and will be reviewed verbally by a member of the research team. The consent form will include information about the study, risks, purpose, procedures, contraindications, and other pertinent information.

Healthy participants (n=12) will complete a sociodemographic questionnaire which will request the following information:

- Age
- Sex/Gender
- Race/ethnicity
- Occupation
- Education level
- Comorbidities
- Past medical history and contraindications review

<u>Intervention phase - Visit 2</u>

Subjects will be randomized into and participate in one session of 3 groups: dry needling only, dry needling with high-rate PENS, or dry needling with low-rate PENS. For the intervention groups, study equipment will include dry needles. Solid monofilament needles ("dry" needles) will be used for the procedures. The needles are made from stainless steel with a thin, flexible shaft and plastic handle. Each needle is housed in sterile packaging with a provided tube to prevent contamination of the needle shaft. The tube is used to guide the needle to the appropriate placement on the skin and is made of 100% PVC-free polypropylene. The appropriate needle length for this study will range between 40 and 100 mm in length, depending on the tissue density of the individual. The tips of the needles are silicone-coated to allow for an easier and more painless transition into the target tissues. Both groups will utilize techniques that will target musculature in the lumbar region.

Dry Needling Only Group
This group will receive dry needling only.

Dry Needling Plus high-rate PENS
This grouping will receive dry needling plus high-rate PENS.

Dry Needling Plus low-rate PENS
This grouping will receive dry needling plus low-rate PENS.

Procedures for this section are outlined in the following section.

Sensor Data Collection: For the subset of participants using the sensors, they will be asked to don the Shimmer3 units prior to the intervention and will be removed after the session. A rest period of 5 minutes will be used prior to intervention to create a physiological baseline.

Post-intervention phase – Visit 3
This visit will include the baseline assessments and a short feedback form and a one-on-one interview. This interview will aim to gather the participant's perceptions and feedback on the procedures, techniques, and any hardships which they may have experienced. The interview will use an interview guide to allow for a semi-structured experience. Interviews will be audio only recorded so that they may be analyzed. Audio recordings will be conducted using the Zoom platform with the camera turned off. Audio recording will be stored on the secure cloud platform. The guide has been uploaded for review. The PI will collect the take-home wearable activity monitors at the end of this session.

Once phase 1 has been completed, the PI will review all procedures and participant interviews to assess the acceptability and feasibility of the various protocol components. The PI will assess the protocol for ease of procedures, participant burden, time requirements, retention, intervention delivery, data collection, and data analysis. This review will inform the protocol used in phase 2.

Phase 2: Specific Aim 2

Phase 2 of this study will explore the protocol's acceptability and feasibility in those with cLBP. This phase will aim to recruit 30 individuals with cLBP. This phase will aim to assess the feasibility and acceptance of the interventions for those with cLBP. The assessment of the protocol and data will aim to generate a protocol and battery of outcomes ideal for a larger study regarding this population of interest. In this phase, participants will be block-randomized into one of three groups: dry needling only, dry needling with high-rate PENS, or dry needling with low-rate PENS.
Figure 3 demonstrates the timeline for phase 2. Participants will undergo baseline testing prior to being randomized into the interventions. In order to help support patients with pain, once consented, participants will be allowed to complete survey questions either at home or in the research lab. The intervention phase of Phase 2 will involve the same processes as Phase 1. However, the participants will be asked to attend six (6) intervention sessions which represents how this intervention may be

utilized in clinical practice. Following the post-intervention (2nd) assessment, all participants will undergo a wash out period of at least 2 weeks before being asked to return for a 3rd assessment. The final (3rd) assessment will involve a repeat of the baseline assessment and a one-on-one interview to assess the participant's opinions and the benefits of the treatment.

Additionally, participants will be sent once daily ecological momentary assessments (EMAs) during the time period between the first and third assessment points. EMAs are a valuable tool for capturing real-time data on participants' experiences and behaviors in their natural environments. To facilitate this data collection, we will utilize the MyDataHelps platform, which allows for the efficient delivery of EMAs and collection of participant responses. These assessments will be used to determine 1) the impact of dry needling on the participant's symptoms, 2) to determine the participant's perception of their need for any pain medications they may be taking, and 3) if taking medications other than those prescribed, has the participant adjusted their medication habits. Participants will be prompted to complete these assessments at the end of each day after 7 pm. The data collected will be used to assess how the intervention may impact the participant's quality of life.

The first question will ask the participant to rate their symptoms on a 0-10 scale with 0 being "no symptoms" and 10 being "worst symptoms imaginable." Question 2 will ask the participant if they perceive the current medication quantity to be what they need to take for their current symptoms, and if no, should it be increased or decreased? The final question will be if the participant regularly takes any non-prescription substances for their symptoms and, if yes, if they have increased or decreased the use of the substances since the start of the study.

MyDataHelps will be used to collect and store participant responses. The platform ensures that data is encrypted and stored securely in compliance with relevant data protection standards. All data collected will be encrypted and stored on secure servers. Access to the data will be limited to authorized study personnel. Only authorized study team members will have access to the data for the purposes of data management and analysis. Data will be de-identified for analysis and sharing, as applicable.

A subset of participants from the interventions may be asked to wear the health monitors, ActiGraph, Opal, and Shimmer3 units, as in Phase 1. Up to 5 participants from each group, a total of 15, will be asked to utilize the wearable devices. Participants will be instructed on proper use and wearing of the activity monitors and charging requirements. The devices do not require the participant to interact with the devices other than charging which reduces the participant burden.

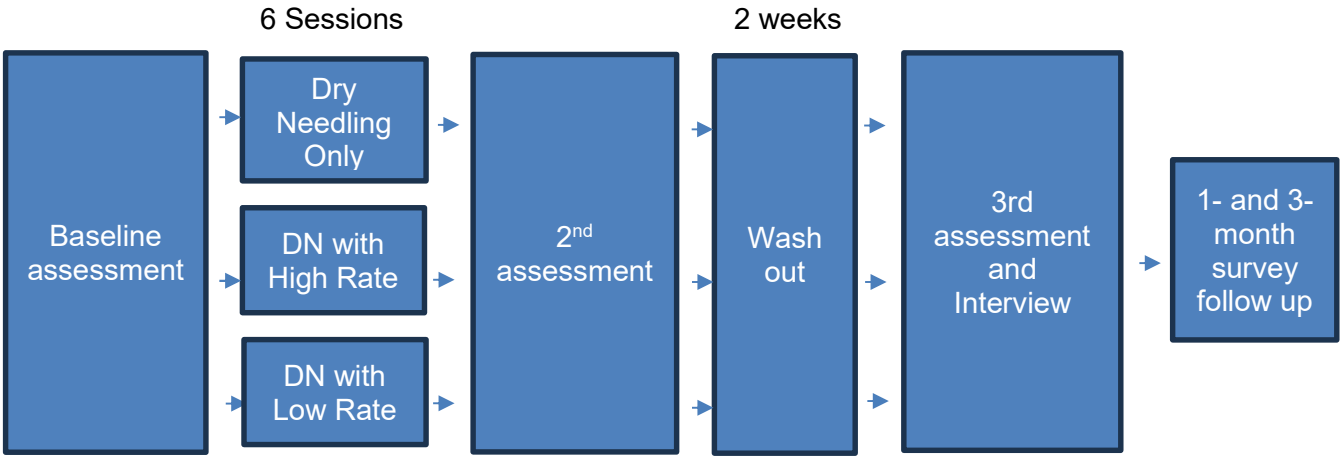
Unless an assessment is modified after Phase 1, participants will follow the same procedures for assessments. Any large modifications impacting protocol procedures for assessments will be submitted to the IRB between phases for approval.

Following the final assessment, participants will be asked to complete an online survey 1 and 3 months after final assessment. Survey items for the 1 and 3-month follow-up will include participant-reported outcome measures that focus on pain perception and function.

Participants will be compensated for their participation in the study. Participants will be compensated for the visits that require them to be present at the Center for Health Promotion, Performance & Rehabilitation Research (CHPPRR). These visits include all assessments and the dry needling sessions. The cost of parking will be covered if needed. Participants will receive remuneration at a flat rate for each visit . A baseline assessment and 2nd assessment are anticipated to take up to 2 hours, intervention sessions up to 1 hour, and final assessment and interview up to 2.5 hours. Follow-up surveys will be reimbursed at a rate of $15 each. A potential total time of 5.5 hours for Phase 1 and 12.5 for Phase 2 is anticipated. Remuneration for Phase 1 may be up to $165 and Phase 2 up to $405 plus any parking costs. Remuneration will be provided based on number of visits completed regardless of full study completion.

Participants will be allowed to withdraw from the study at any point without question. Additionally, participants may be withdrawn, or the session may be stopped at the research team's discretion if any major adverse events take place, such as fainting, cardiac events, or heightened anxiety related to the use of needles. To mitigate these risks, the participants will be screened through a self-report survey to determine any history of major events or fear of needles. If the individual expresses a fear of needles, which they feel they cannot overcome, they will not be allowed to continue. Common risks for dry needling include discomfort with needle insertion and soreness after the session. Rare risks include bruising and minor bleeding at the needle site. To mitigate these risks, participants will be made aware of potential needle discomfort and advised that they may apply ice to ease any discomfort if any delayed soreness or bruising occurs.

Figure 3. Flow of participants for Phase 2



Resources: The resources necessary to conduct this research are being provided by CHPPRR and the NINDS within the NIH through the HEAL initiative. This is a funded K12 study.

4. Study Procedures

A timeline of the study procedures is detailed in Figure 4.

Figure 4. Project Timeline.

Activity	Month																
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17+
Form submission																	
Aim 1 – Participant recruitment																	
Aim 1 – Data collection																	
Aim 1 – Procedure and data analysis																	
Aim 1 → 2 – Revision of study tasks																	
Aim 1 – Manuscript development																	
Aim 2 – Participant recruitment																	
Aim 2 – Data collection																	
Aim 2 – Data analysis																	

Aim 2 – Manuscript & Grant development																	

Phase 1: Specific Aim 1
Once IRB approval is granted, the research team will initiate participant recruitment for Phase 1. This phase aims to recruit participants over a period of 4 months or until 12 participants are enrolled. Participants will be asked to wear comfortable clothing that allows them to move easily and allows access to the lumbar region.

Participants will be expected to participate in 3 sessions. Session 1 will last up to 120 minutes (2 hours), session 2 is expected to last up to 1 hour, and session 3 up to 120 minutes (2 hours). Depending on scheduling availability, participants can be expected to be a part of the study for 1 to 2 weeks. Each session will be at least 1 day apart (24 hours) to allow for their health systems to return to baseline.

Upon completion of data collection, the study team will aim to develop a protocol for publication and disseminate other relevant findings.

Phase 2: Specific Aim 2
Recruitment for Phase 2 will begin once the recruitment procedures for Phase 1 are reviewed with a goal of recruiting 30 participants, 10 in each group. Prior to beginning the study, participants will complete the informed consent for phase 2.

Participants will be block-randomized into one of three intervention groups. Participants in the intervention groups will be expected to participate in a baseline assessment, 6 intervention visits, a 2nd assessment, at least 2 weeks of wash out, a post-intervention assessment with a one-on-one interview, and a one- and three-month survey follow-up. Figure 2 outlines the flow of participation. Participants will be asked to wear comfortable clothing that allows them to move easily and allows access to the lumbar region.

Assessments and interventions are anticipated to be completed within 2 months. When including the follow-up surveys, the total time for participants in this phase to be in the study is anticipated to be 4 to 5 months. The proposed work for study 2 is anticipated to be completed in approximately 1 year with an additional 6 months for manuscript development.

Data Collection

Phase 1: Specific Aim 1

<u>Baseline Assessment – First Visit</u>
Study assessment procedures and sessions will be conducted in UTMB's School of Health Profession's Center for Health Promotion, Performance & Rehabilitation Research (CHPPRR) labs. At the initial visit, the research team will explain and clarify all procedures to the potential participants and review screening questions for accuracy and to ensure no changes have occurred. The potential participants will be given sufficient opportunities to ask questions during the consenting process and will be asked to sign the informed consent form if the participant agrees to continue and qualifies. If desired, a copy of the informed consent will be available to the participant if desired. The informed consent has been uploaded for review. A research team member will review forms for completion.

Once consented, a research team member will set up the take-home activity monitor for the subgroup of participants who will be using the sensors. The subject will be asked to wear the sensor until it is collected at the end of the study.

The participants will participate in the following procedures:

- A sociodemographic form

- Self-report measures
- Physical assessments
- QST testing

After the completion of the self-report measures, the subgroup of participants using the wearable sensors will don the Shimmer3 units and the Opal devices. These will be worn during the physical assessments. The Opal devices will be removed after the physical assessments, but the Shimmer will continue to be worn during the QST testing.

Procedures will follow this order to ensure that the self-reports are reflected upon in the context of the participant's general lived experiences and not their perception of the physical and QST testing. Participants will be allowed a break between self-report measures to reduce survey fatigue. Trained members of the study team will distribute all forms and perform assessments.

Additionally, for up to 4 participants prior to the end of the assessment, a study team member will assist the participant with downloading the MyDataHelps app and ensure the participant is enrolled on their personal devices. The team member will ensure the participant understands how to operate the app and answer any questions the participant may have. Participants will be selected at random.

Intervention - Second visit

Prior to the session, all tables and equipment to be used will be thoroughly disinfected before and after use to reduce the risk of infection using Super Sani-Cloth Germicidal Wipes or a similar hospital-grade disinfectant. A research team member will prepare and apply the in-session Shimmer3 sensors.

Trained individuals will perform all dry-needling techniques to ensure accurate data collection and the safety of techniques.

Participants will be placed in a prone position on an electronic hi-low mat with a clean single pillow layer under the lower abdomen to place the spine in a neutral position. These hi-low mats can be raised and lowered to allow for optimal body mechanics of the provider and ease of getting on and off the table for the participant. Participant clothing will be positioned to expose the lumbar region. The skin will be sanitized with isopropyl alcohol prior to the use of dry needles. The trained research team member will don gloves and disinfect the gloves with ethyl or isopropyl alcohol. All needles are arranged in a sterile package.

Musculature that will be the target of needling will include the bilateral quadratus lumborum, multifidus of L1-5, glute max, and medius. A document with approximate needle placement has been uploaded for reference.

The dry-needling team member will locate a trigger point and target the corresponding tissue when possible. If a trigger point is not identified, the provider will use a common insertion point for that muscle based on the provider's training. The provider will insert the needle following standard procedures for both direction and depth. Whenever possible, the provider will utilize a “bony backdrop," which means targeting the bone directly beneath the desired muscle. This approach ensures that the needle reaches the muscle's deep fibers. If a local twitch response is triggered, the needle will remain in the appropriate tissue. If no twitch response occurs, the needle will be pistoned up to five times. The provider will leave the needle in place for ten seconds before pistoning up to five more times, then leaving the needle stationary again. Pistoning refers to the movement of the needle up and down within the targeted tissue. If at any point a twitch response is observed, the needle will stay stationary. Needles will remain in place for as long as deemed appropriate. If no complications, the needles will be left in place for 20 minutes. If, at any time, participants wish to have the needles removed before the 20-minute mark, they may express this request, and the needles will be taken out. Once finished, the needles will be extracted and placed in the sharps disposal container.

For those randomized into the PENS group, The same procedures noted previously for dry needling will be followed. In addition to this, an alligator clamp from the e-stim device will be attached to the inserted needles once they are able to remain stationary. The needles that will be targeted with e-stim will include the bilateral L1 and L5 multifidus, glutes, and quadratus lumborum. The electrical current will run the L1 and L5 needle on the ipsilateral side while the current for the glutes and quadratus lumborum will run across the body.

Following this, the device will be turned on to deliver the electrical stimulation using the parameters detailed below. After 20 minutes of e-stim, the device will be turned off and the needles will be removed and placed in the sharp's disposal container.

Currently, there is no consensus on dry needling or dry needling with PENS practices. A 2022 scoping review by Perreault reported on 4 studies utilizing electrical stimulation with dry needling. Utilizing this scoping review's findings, this study will set the parameters for the e-stim unit to a low frequency (Hz) and high intensity. This will consist of a frequency of 2-8 Hz for low frequency and 150-270 Hz for high rate for each participant. A range will be used for patient comfort without compromising the therapeutic effect. An intensity (mA) set to a goal of visible muscle contraction as noted by the movement of the needle or patient report of a thumping or contraction feeling will be used and increased until the participant feels that it is strong but comfortable. The stimulation will be provided by an electro-acupuncture unit that uses either a 9-volt or D-Cell battery power source. The pulse waveform of the device is an asymmetric biphasic square wave and will be set to a continuous mode. The device creates a clicking noise and has a light that turns on when the device is powered on to alert the provider that stimulation is being provided for safety purposes. Based on the provider's experience, if the participant does not report feeling the stimulation at an expected voltage, the device will be powered down and assessed for any issues before reinitiating protocol.

The in-session Shimmer3 sensors will be removed after the session and will be cleaned.

<u>Post-Intervention Assessment - Final visit</u>
The 3rd visit will consist of post-intervention assessments, which will include all self-report measures, physical assessments, and QST outcomes. These will follow the same procedures. After completion of the assessments, participants will be asked for feedback on the procedure and their perceptions through a one-on-one semi structured. Feedback questions have been uploaded for review. Upon completion of the session, the research team member will collect the take-home sensor.

During Phase 1 and upon its completion, the PI will review all procedures for acceptability, feasibility, and risk management. If any procedures require modification, the IRB will be notified, and these will aim to take place prior to Phase 2.

Phase 2: Specific Aim 2

Phase 2 will conduct the protocol in those with cLBP and increase the intervention parameters. The subgroup of participants who will use the activity monitors will be given the devices at the initial session and will be collected on the final visit. The Shimmer3 units will be used during the intervention visits.

<u>Baseline assessment</u>
Baseline assessment will consist of the same procedures as Phase 1. However, to reduce the time burden in those with pain, the participants will have the option to complete the surveys either in the research lab or at home.

Additionally, prior to the end of the assessment, a study team member will assist the participant with downloading the MyDataHelps app and ensure the participant is enrolled on their personal devices. Up to 5 participants from each group will be selected to collect the EMA data. The team member will

ensure the participant understands how to operate the app and answer any questions the participant may have.

Intervention phase

For the intervention phase, participants will be in 1 of 3 groups: dry needling only, dry needling with high-rate PENS, dry needling with low-rate PENS. At the start of each intervention visit, participants will take a survey using REDCap to establish pain levels and will be asked questions related to medication use and functional impact before each intervention. These questions are designed to assess the impact and safety of the treatment and to gather information on any potential adverse events that may have occurred during participants' enrollment in the study. These questions are not expected to add additional time to the intervention session. Sensors will be applied if the participant was selected to use them.

-Dry Needling Interventions (Either Dry Needling Only or Dry Needling with PENS)

The dry-needling groups will receive the same procedures as in Phase 1 for their respective group. However, they will participate in 6 dry-needling sessions during this phase.

Post-intervention (2nd) Assessment

Post-intervention will consist of the same procedures as the baseline assessment. This assessment will occur after the dry-needling groups' intervention phase.

Final (3rd) Assessment

The final assessment will take place after the completion of the washout period of at least 2 weeks since 2nd assessment. Procedures will be the same as the baseline assessment except for the interview.

Additionally, at post-intervention assessment sessions, participants will take part in one-on-one interviews. The interview will be conducted by a researcher who is trained in qualitative interviewing. The interview will use a semi-structured guide and will be expected to take no more than 30 minutes to complete. A copy of the semi-structured interview guide has been uploaded for review. It will focus on the participant's perceptions of the study procedures, the intervention, and general feedback regarding the study. Once all procedures have been completed, a research team member will collect the activity monitor from the subgroup of participants using the ActiGraphs.

An interview guide will be used during the one-on-one interview phase. This interview will ask participants to provide their perceptions on the acceptability and opinions of the procedures and interventions as well as aiming to understand the impact on their quality of life. The interviews will be recorded using the Zoom platform with camera turned off. Recordings will be stored in the secure cloud platform.

Follow Up Survey

Participants will be asked to participate in a follow survey which will be electronically sent to the participants 1 month and 3 months following the final assessment. The survey will include the patient-reported outcome measures and a questions related the participants quality of life after the interventions. The secure survey platform, REDCap, will be used to send participants the surveys.

5. Sub-Study Procedures

Review of Standard of Care Procedures

The information gathered from the standard of care observations will be assessed for trends related to care and impact on participants' pain. This will be outlined in the original consent form for the study.

Participants will be allowed to have the data collected from the plan of care observation not reviewed for further analysis.

6. Criteria for Inclusion of Subjects

Both males and females between the ages of 18 and 65 will be included in this study.

Phase 1

Inclusion criteria will be healthy adults who report no pain for more than 1 day in the past 3 months in their lumbar region. Lumbar region will include posterior lumber musculature, lumbar spine, sacroiliac pain, or superior gluteal area pain.

Phase 2

Inclusion criteria will be adults experiencing chronic low back pain. Chronic low back pain will be identified as having pain the lumbar region for at least 3 months. The pain may be constant or episodic in nature. Participants will be included if they experience pain at least 75% of the days in the past 3 months. All pain levels will be included. The lumbar region will include posterior lumbar musculature, lumbar spine, sacroiliac pain, or superior gluteal area pain.

7. Criteria for Exclusion of Subjects

Exclusion criteria will include individuals who are currently seeking any form of medical treatment for lumbar conditions beyond routine physician follow-up appointments in order to avoid confounding variables, regardless of pain-free status. These may include but not limited to seeking treatment from a chiropractor, acupuncturist, massage therapist or medical procedures such as injections into the lumbar region for pain. Additionally, those with previous lumbar surgeries or those with previous major injuries to the lumbar spine that may have resulted in structural abnormalities that may compromise needle placement will be excluded. If surgical procedures did not alter structural alignment, then it will be allowed. For example, an approved procedure may include discectomy or nerve ablation while a not approved procedure would include a lumbar fusion or scoliosis rod placement. Additionally, if a person is experiencing radicular symptoms from a back injury, despite not feeling the symptoms in the lumbar region, will not be considered. Radicular symptoms will be defined as those present past the knee and/or are electrical in nature. Individuals with neurological conditions or those who need the services of another due to cognitive deficits will not be considered for this study.

Furthermore, as this study relies on an intact sensory system, participants with conditions that may affect sensory processing (e.g., peripheral neuropathy, skin conditions, or circulatory disorders) will be excluded through careful screening.

Additional exclusion criteria will include the following conditions identified as contraindications for dry needling: those with impaired sensitivity, taking anticoagulants, a compromised immune system, a local or systemic infection, an active tumor, history of lymph node removal, history of autoimmune disease, allergy to metals such as nickel or chromium, history of cosmetic procedures in the area, pregnant individuals, or osteoporosis. Contraindications will be considered if relevant to and impacting the testing or treatment areas. For example, an active tumor in a distal area, such as an extremity, would not be considered a contraindication; however, an active tumor in the area of the abdomen would be a contraindication. Review of medical history and study eligibility will be conducted by study staff who are qualified medical professionals.

Non-English-speaking subjects will be excluded from the study due to the need to understand any communication while dry-needling procedures are taking place.

8. Sources of Research Material

This study will generate information about the acceptability and feasibility of study procedures. This information will be used to generate a study protocol which that will be used in future research.

9. Recruitment Methods and Consenting Process

The potential subjects of this study will not be the investigator's patients. The PI or a member of the research team will recruit participants through the UTMB broadcast email system, flyer postings, and standing announcements in UTMB classes or meetings.

Only the PI and research team will have access to participant information. Once participants express interest, a research team member will contact the potential participant. Potential participants will be asked initial screening questions via phone or email. If the participant is eligible, the research team member will ask when the participant will be able to schedule their study session. Potential participants will also be sent short video links which are meant to provide education on the intervention and assessment procedures to help the potential participant make an informed decision.

Consent Process

In order to reduce the time burden of the visit and reduce the risk of a pain flare, participants will have the option to be consented electronically or in-person.

If the potential participant prefers to be consented electronically, they will be sent a video link of the PI reading through the consent form and, if no questions, they will be asked to sign and return the document. If the participant has questions, they will be asked to wait to sign until they have had the chance to ask all questions.

If the potential participant prefers to be consented in person, a physical consent forms will be provided to participants. Once the potential participant has an opportunity to read the form, the research team member will ask if there are any questions and if the procedures are understood. If yes, the potential participants will be asked if they are still willing to participate. If yes, the potential participant will be asked to sign the consent form and provide the physical copy of the study sociodemographic form and other self-report measures. Potential participants will be provided a seat, clipboard, and pen for the signing consent and filling out the sociodemographic form to ensure participant comfort.

Once consented, participant data will be given a unique study code and de-identified. Any data analysis or tracking of data will use this unique code only. In order to protect privacy, only one participant will be tested at a time, with only the PI and/or research team in the room at the time of data collection.

As the research team consists of faculty at UTMB, to minimize undue influence or coercion, student participation in the study will be sought only from students where research team members are not the primary faculty for or have grading responsibility over student participants. If a student volunteers for the study and is in a class that the PI helps teach, the PI will ensure that he has no grading responsibilities of the student during the semester.

No vulnerable populations will be considered for this study.

Phase 1:

Recruitment will be conducted through UTMB announcements, flyers, emails, and verbal announcements at meetings and classes. A research team member will distribute recruitment information and screen participants through electronic communications such as email or phone.

Once recruited, potential participants will be scheduled for informed consent and study participation at a mutually available time for both the research team and the potential participant.

Phase 2:

Recruitment procedures will include all Phase 1 procedures. Additionally, research team members will seek participant recommendations from the clinical UTMB enterprise.

10. Potential Risks

The potential risks associated with all procedures are minimal.

In this study, the use of a wearable sensor, the ActiGraph LEAP will be used to monitor the activity of the participants. Fitbit products may cause skin irritation. Prolonged contact may contribute to skin irritation or allergies in some users. To reduce irritation, the investigators will instruct the participants to: (1) keep it clean; (2) keep it dry; (3) don't wear it too tight, and (4) give the wrist a rest by removing the band for an hour after extended wear (upon waking). If the participant notices skin irritation, they will be instructed to remove the device and notify the investigators. If the symptoms persist longer than 2-3 days after removing the device, the participant will be encouraged to consult with their doctor. The estimate of this occurrence's probability is low and would be mild. However, participants will be screened for previous skin irritation with watches to assess risk and if the risk is deemed high for skin irritation, the participant will be notified of the risk.

The ActiGraph LEAP uses photoplethysmography sensor technology which is a heart rate tracking feature that may pose a risk to participants with certain health conditions. If a participant is identified as having any of the following conditions when they are screened for participation, they will be asked to consult with their doctor prior to use: a heart condition, are taking any photosensitive medicine, have epilepsy or are sensitive to flashing lights, have reduced circulation or bruise easily, or have tendonitis, carpal tunnel syndrome, or other musculoskeletal disorders. The known risk is exacerbation of their condition. The overall estimation of this occurrence's probability is low and rare. Participants will be screened for these conditions and risk will be assessed and if the risk is deemed high for exacerbation of the medical condition, the participant will be notified of the risk. Since the ActiGraph LEAP is a commercially available wearable sensor, the risk of exacerbation of medical condition would be similar to standard of care of sleep monitoring

The APDM Opals and Shimmer 3 pose a similarly minimal risk to wearers and participants as the ActiGraph LEAP devices. To ensure participants' safety during the data collection for all data collection and motor task performance, the researchers will ensure that the participants have intact skin with absence of wounds and each device will be disinfected before and after each participant using the recommended manufacturer's specifications: 70% or greater isopropyl alcohol, 10% bleach solution, or hydrogen peroxide wipes.

Potential risks of QST may include temporary subjective discomfort and psychological stress while assessing mechanical, visual, and pain thresholds. Participants may experience brief sensations of heat, cold, pressure, or mild pain that are calibrated to be within safe limits and immediately reversible upon stimulus removal. For example, participants can expect to potentially experience aching, tingling, burning sensations and numbness because of cold exposure. These symptoms are common and considered normal symptoms resulting from exposure to cold. While rare, some participants may experience temporary skin redness or increased sensitivity at testing sites that typically resolves within minutes to hours. The thermal stimuli of conditioned pain modulation are precisely controlled and include built-in safety limits to prevent any risk of tissue damage. To avoid tissue damage, strict temperature and time guidelines will be followed. All mechanical pressure testing will stay within established safety parameters.

Participants may experience subjective discomfort or mild pain, as well as psychological stress, particularly those with pre-existing pain conditions. To mitigate this, participants will be informed of all procedures and potential sensations that would be considered normal. Additionally, subjects will be provided with clear instructions for test termination if discomfort becomes excessive. They will have full control to stop the testing at any point. Participants skin will be assess before and after for any abnormal skin changes or breaks. The research team will be trained in proper QST administration and

will continuously monitor participants for any adverse reactions. The testing environment will be comfortable and private to reduce any psychological discomfort. Overall, when conducted according to standardized protocols by trained personnel, QST poses minimal physical and psychological risks that are transient and reversible.

Potential risks of dry needling include pain with needle insertion, muscle soreness, fatigue of needled muscle, bruising, feeling faint or dizzy, infection, feelings of unwellness, neurological sensations such as tingling, and/or emotional responses such as anxiety. Potential risks of electrical stimulation include fatigue of the muscles. Potential risks of exercise include feelings of tiredness, sweating, muscle fatigue and/or soreness, and increased heart rate. The potential risks of QST are minimal. Risks include discomfort and a potential increase in perceived pain due to sensitivity related to temperature or pressure testing.

Potential risks of soreness are common for dry needling techniques along with increased heart rate for exercise. These risks, when experienced, may be mild or moderate in nature. All other risks are considered rare and mild in nature if they occur. Dry needling is a common practice in physical therapy and as such is a standard of practice along with exercise and the use of electrical stimulation. Compared to exercise alone, conventional dry needling practices possess many of the same risks that exercise would induce, such as soreness and muscle fatigue.

These risks will be mitigated through several procedures. First, all dry needling techniques will be performed by trained and licensed physical therapists who are experienced in dry needling techniques. The team will be well prepared to prevent issues and respond quickly and appropriately to any risk. The equipment used is also designed to reduce pain and discomfort through the needles having a lubricant on them and being sharp. Participants will be advised on any post-procedure risks, such as delayed bruising or muscle soreness. The participants will be provided with contact information for a member of the team in case of any additional issues. Additionally, participants will be informed during the consenting process of all of these potential risks prior to their enrollment.

The research team will have access to basic first aid, such as band-aids and bandages, to reduce physical risks. Participants will be advised to continue movement during the day to help reduce delayed onset muscle soreness (DOMS) and provide education on the use of ice if DOMS develops over the first 48 hours post-session. Although not expected, if the participant has any pain or concerns 1-week post-session, they will be advised to seek additional medical advice from their primary care provider.

Other potential risks include:

- Loss of time - No additional surveys or information will be requested beyond the completion of the study.
- Emotional or psychological distress - Participants will be allowed to take a break from the sociodemographic survey and will be allowed to return without losing already entered data. Participants will be allowed to skip questions that they do not wish to answer as well as will be allowed to terminate the survey at any point.
- Loss of confidentiality or identity breach - Confidentiality will be protected to the extent that is allowed by law. All data will be stored electronically using UTMB cloud storage. The data will only be retrievable with the research team members' unique usernames and passwords. Only the Primary Investigator and team members will have access to the data.

11. Subject Safety and Data Monitoring

Standard safety procedures will be conducted with performing dry needling to reduce any potential for infection. This will include the use of gloves for the intervention provider, the use of rubbing alcohol to disinfect the gloves, the use of rubbing alcohol and a clean cotton ball to disinfect the participant's skin, and the use of sterile dry needles. In the event of an adverse event, the research team members are trained healthcare professionals and will be able to administer CPR or other healthcare services if required. In case of a participant feeling unwell, they will be offered the opportunity to lie down and rest until recovered.

The Principal Investigator (Dr. Pontiff) will be responsible for monitoring the safety environment of participants and ensuring that referral to appropriate medical care and coverage is provided to all participants if necessary. The PI is also responsible for monitoring procedures during conduct of the study for each participant, including eligibility, enrollment, data collection, evaluation of study outcomes, problems with informed consent, and participant safety and well-being.

This study is not a clinical trial; however, a data safety and monitoring plan will be in place and include the following activities to optimize the identification of risks or any adverse events:

- Review of screening results weekly by PI
- Immediate reporting of adverse events by team members to PI
- Quarterly review of collected data by PI and CO-I

To ensure safety, Dr. Pontiff will provide a monthly review of participant safety and safety to continue the study based on data collected that month.

The PI will review screening data weekly during recruitment periods. The PI will ensure that any values indicating ineligibility and/or unsafe practices are flagged. Flagged participants may be excused from the study or instructed on safer practices as needed. These decisions will be made in consultation with the Co-I, Dr. Brusola.

Drs. Pontiff and Brusola will review study data monthly. Again, the team will identify any values indicating unsafe practices or potential adverse events that participants may not have reported.

Though not expected for this project, in case of any cardiac event, the PI or a trained member of the research team will provide healthcare services while another member of the team seeks medical services by calling 911. If a participant faints and is unresponsive for more than 10 minutes, emergency services will also be called. All members of the research team will be basic life support certified.

Raw data will be managed in Microsoft Excel (Office 365, Microsoft). Once cleaned and appropriately organized, it will be transferred to SPSS for analysis. For monitoring of data collected, all data will be de-identified using a unique study participant code assigned to the data. Once assigned, all data will be stored on the UTMB-encrypted cloud server and password-protected. Demographic data will be used for publication but not directly linked to outcome reporting. Data will be stored with an anticipated deletion 3 years following finial participant data collection.

12. Procedures to Maintain Confidentiality

All data collected will be confidential. The risk of breached confidentiality of potentially sensitive data is minimal and comparable to the risk inherent in any human participants' research project. We will take standard precautions to ensure that personal health information is not identifiable as well as special precautions due to use of an app, including:

MyDataHelps™ will be used as the one of the data collection platform for our study. MyDataHelps™ complies with the security and privacy controls defined by NIST 800-53 Rev. 4 at the FISMA Moderate baseline and regularly undergoes external formal assessments by a FedRAMP-accredited Third Party Assessment Organization (3PAO). MyDataHelps™ has been granted the Authorization to Operate (ATO) by the National Institutes of Health (NIH). The MyDataHelps™ platform is built on top of the CareEvolution HIEBus platform which is HIPAA compliant and Meaningful Use certified.

MyDataHelps™ will be used to collect survey data, including data from EMAs. Data collected by MyDataHelps™ will never be used for advertising, never be sold, securely stored in the United Statess by CareEvolution. Data collected will be collected via MyDataHelps™, deidentified, assigned to the participant's study number, and automatically transferred into REDCap for data storage. The integration between MyDataHelps and REDCap enhances data security and confidentiality in clinical research studies. Participant data collected through MyDataHelps is seamlessly transferred to REDCap using secure API connections, ensuring that sensitive information remains protected throughout the data flow process. The MyDataHelps-REDCap integration will allow study personnel to leverage advanced features such that enables secure access to real-world health data. Additionally,

the integration supports the use of unique participant identifiers, with MyDataHelps participant IDs matching REDCap Record IDs, further maintaining data confidentiality and integrity across both platforms. Data will be accessible only to the study personnel and used for the purposes of this study.

ActiGraph complies with General Data Privacy Regulation (GDPR) and implements technological and organizational controls around data privacy and protection. ActiGraph has established technical and organizational controls to mitigate information security risks and protect against cybersecurity threats. AcitGraph's are both HIPPA compliant and FDA cleared (K231532, K181077, K080545)

The Opal by Clario uses hardware-based encryption. All data stored on the devices is encrypted and is adheres to storage specifications developed by the Trusted Computing Group. All data will be transferred from the device or streamed to a password protected computer as soon as possible. Similarly, the Shimmer3 devices also uses data encryption and secure data storage protocols that comply with security standards. All data will be either streamed directly or quickly transferred to as soon as possible to a password protected computer.

Paper copies of screening forms and logs will be kept in a locked file cabinet in the CHPPRR labs or PIs private office, requiring badge access or key access. Unique study ID numbers will be used on these forms to match them to individual participants. The database matching ID numbers to identifying information will be individually password-protected and kept separately on the password-protected server (UTMB cloud server).

Data collected on measurement equipment will be uploaded to the server as soon as possible after collection. This includes all sensor related data. Then, it will be erased from the equipment. ID numbers will be used for participant identification on all measurement equipment as an added layer of protection. No identifying data will be kept on measurement equipment.

13. Potential Benefits

The generalizable benefits of the study include improving the understanding of how acceptable dry needling practices are and the development of an optimal battery of self-reported outcomes for future research. This information may help with physical therapy treatments for those with disabilities or pain related to the lumbar area. Additionally, the information from this study will help future research. While pain reduction and improved function is not the direct intent of this project, it is potentially an indirect benefit of participation in this study.

14. Biostatistics

The feasibility of this phase 1 pilot project will be assessed through several methods. First, recruitment procedures and retention rates will be evaluated. The procedures of interventions and assessment will be reviewed for efficiency and practicality. The perceptions of the intervention and procedures will also be sought by the participants to incorporate the participant with lived experience information. These evaluations will look to determine in the processes, instruments, and measurements are ideal for future use. Additionally, the PI will assess resource utilization such as time and budgetary needs to determine if there is an appropriate allotment. This assessment of the pilot will aim to identify any modification which need to be made for future studies and generate data which may be reviewed to help support the need for additional research.

Sample size of Phase 1 based on the "Rule of 12" as a minimum for pilot studies as increasing higher does not significantly rise the confidence interval.[17,18] It is recognized that 30 participant (10 per group) is to small to provide a reasonable power or precision.[19] However, 30 participants is a common sample size for pilot and feasibility studies and can demonstrate a normal distribution with analysis.[20,21] As this study is designed to test the procedures and implementation of the protocol, 12 healthy and 30 individuals was found to be sufficient to demonstrate the feasibility of the work and explore potential trends in the data.

Demographic data will be assessed based on the following analysis:

Variable	Type of Data	Potential data analysis
Age	ratio	Mean and standard deviation
Sex	nominal	Frequency and percentage
Gender	nominal	Frequency and percentage
Race	nominal	Frequency and percentage
Relationship status	nominal	Frequency and percentage
Current job status	nominal	Frequency and percentage
Highest grade finished	ordinal	Frequency and percentage
Annual household income	ordinal	Frequency and percentage
overall health status	ordinal	Frequency and percentage
Time of back pain	ordinal	Frequency and percentage
Frequency of back pain in the past month	ordinal	Frequency and percentage

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