utmb Health | School of Health Professions
Department of Physical Therapy and Rehabilitation Sciences

The University of Texas Medical Branch at

Galveston More Than Minimal Risk Consent Form

Protocol Title:	PINPOINT Study- Pain Intervention with Needling: Pilot of Integrated Neuromodulation Techniques - Phase 2
IRB Number:	25-0109
Sponsor:	School of Health Professions' Center for Health Promotion, Performance & Rehabilitation Research; HEAL National K12 – NIH NINDS
Principal Investigator:	Ryan Pontiff, PhD, DPT, PT
Study Contact:	Ryan Pontiff, PhD, DPT, PT, 301 University Blvd, Galveston 77555 Phone: (409) 772-0310 Email: rypontif@utmb.edu

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Please read this consent form carefully, and do not hesitate to contact the principal investigator with any questions or concerns you may have before deciding whether to participate. Taking part in this research study is voluntary. *You do not need to participate, and you may stop at any time.*

Why am I being asked to take part in this research study?

This is phase 2 of this study.

You are being asked to participate in this study because you are between the ages of 18 and 65 with low back pain that has lasted for 3 or more months. Your participation in this study is completely voluntary. You may refuse to participate or stop your participation in this research study at any time without penalty or loss of benefits and without jeopardizing any care or services you are receiving or will receive at UTMB.

Key Information

The key information that follows can help you learn more about this research study. It can also help you decide whether or not to take part in the research. Please read the entire consent form or have someone read it with you. If there is anything that you do not understand, please talk to the study doctor or team to have your questions answered before signing the consent form

Voluntary Participation & Right to Withdraw	Your decision to be in this study is voluntary. You may choose not to take part in this research study or may choose to leave the research study at any time
Purpose	The study's purpose is to determine the effects of three different dry needling sessions on pain and quality of life for those with chronic low back pain. Dry needling is a therapeutic procedure in which a very thin, monofilament needle is inserted through the skin to reach a target tissue like a muscle to help reduce pain, improve muscle activation, and increase blood flow. Dry needling has also been shown to improve nervous system function.
Key Reasonable Foreseeable Risks and Discomforts	Risks or discomforts from this study might include potential discomfort and soreness in the low back related to dry needling. Risks may also include neurological effects and possible infection. The research team has attempted to minimize this risk by having licensed physical therapists certified in dry needling perform all study procedures. There is a minimal risk of loss of confidentiality regarding data collection and recorded information. All research information about you will be handled confidentially (private) and consistent with other health-related medical records.
Reasonable Expected Benefits	The study will not directly benefit you; however, there is potential for increased muscle performance in the lower back, and your participation will help us better understand the effects of different forms of dry needling on muscle and nervous system function.
Length of Participation	Phase 1 will last approximately 3-4 months. Phase 2 will last approximately 9-12 months. Phase 1 will participate in 3 physical visits Phase 2 will participate in 9 physical visits and 2 additional electronic survey requests.
Procedures	If you choose to participate in Phase 2, you will be asked to participate in an initial assessment (visit 1), session sessions (visits 2-7), a repeat assessment session (visit 8) a final assessment with an interview (visit 9), and 2 electronic surveys (session 10-11). You will also have short daily questions about your symptoms. You will be compensated for your participation in this study.

Alternative to Study Participation	Before joining the trial, you should talk to your doctor about alternative approved treatment options for your condition, and whether or not this trial is a good choice for you. Before agreeing to join, you should review the information in the rest of the consent form.
Costs Related to Participation	You may incur costs by participating in this trial. Participants will be reimbursed for parking fees if applicable In addition, the sponsor will pay you for your time participating in the trial.
Compensation and Medical Treatment for Research-Related Injuries	If you experience an injury caused by your participation in this research, the medical treatment of your injury may or may not be paid for. More information on medical treatments for research-related injuries is available in the consent form.

This overview only includes some of the information you need before deciding whether to take part. Additional details are given in the full consent document, which can be found on the following pages. Be sure to review the rest of this consent form before deciding about participation.

DETAILED RESEARCH CONSENT

What is the purpose of this research study?

This study is being conducted to determine the best suitability and workability of the study procedures. Phase 1 will test these procedures in healthy adults before they are performed in those with low back pain (Phase 2).

We want to learn how dry needling helps people with long-lasting back pain. We also want to know if adding small electrical pulses to the needles (called percutaneous electrical nerve stimulation (PENS)) works better than just using needles alone. If you choose to participate, you will be asked to perform baseline assessments, will receive one of the following interventions: dry needling only, dry needling with high-rate PENS, or dry needling with low-rate PENS, followed by an additional assessment.

The National Institute of Health (NIH) through the HEAL National K12 program is paying UTMB for their work on this study.

Am I required to participate?

Your participation in this study is completely voluntary. You may refuse to participate or withdraw your participation in this research study at any time without penalty or loss of benefits to which you are otherwise entitled. Refusing to participate or withdrawing from this study will not otherwise impact your medical care at UTMB. There are alternatives to participating in this research study, such as:

- Go to a physical therapist who might use hands-on treatment, heat or cold packs, sound waves for deep heat, electrical pads, or teach you exercises

- See a chiropractor
- See a special doctor who might give you shots or acupuncture, discuss surgery, or suggest other treatments.

How long will this study last?
If you agree to take part, your participation will last for 11 visits, which will occur on different days. Depending on the schedule, this may take up to 2 months for in-person sessions. Then, 2 electronic surveys will be completed 1 and 3 months after the last in-person session. This study will occur between June 2025 and June 2026 or until 30 participants are recruited.

How many people will take part in this study?

About 12 distinct people will participate in Phase 1. These individuals will not roll over to the next phase. About 30 participants will be included in Phase 2. Participants from the Galveston/Houston area will be enrolled at UTMB.

What tests and procedures are involved as part of this research study?

Once you agree to participate in this study and you sign this consent form, you will be asked to complete the following tests and procedures:

Some of the procedures may be similar to previous medical care, but the current procedures are only done because you are participating in this research study. If you participate, you will have a total of 9 in-person and 2 survey study sessions. The potential time requirements are in the table under Potential Study Timeline and Requirements.

Initial screening questions will be completed by phone or email. Data collected from the surveys may be used as part of the research study. All surveys will be completed and stored in the REDCap platform. REDCap is a secure web application for building and managing online surveys and database and assists with research study operations.

If you agree to participate in this study, you will receive a questionnaire about your general medical history and questions related to your current condition. You may also choose to complete these at home. The questionnaire will take approximately 20-30 minutes to complete. The examination procedures will ensure that you are eligible to participate in the study. You will then participate in an assessment to gather your initial information. Before your next visit, you will be randomly assigned into one of three session groups consisting of (1) dry needling only, (2) dry needling with high-rate PENS, or (3) dry needling with low-rate PENS. The session sessions will consist of 6 sessions scheduled at a rate of 2-3 a week. Once the 6 sessions are completed, you will participate in a post-session assessment (Visit 8). There will be at least a 2-week break between the post-intervention assessment and your final in-person visit, consisting of a repeat of the assessments and a short one-on-one interview. During the time between your initial visit and the third assessment (Visit 9), you will be asked to answer short daily questions on your personal device about your symptoms. After your final visit, you will be sent an electronic survey assessing your symptoms 1 and 3 months later.

Randomization means that participants are put into groups by random assignment. We will use computer software to decide your session throughout the study. More details of the session options are also described below.

Assessment Visits

Wearable Sensors

Participants may be asked to wear small devices that stick to your skin or go on your wrist. These devices measure how your body moves and works. You might wear them for a few hours or a few days. You might be asked to wear the sensors during your visits and/or given a device to take home and wear during your participation in the study. These sensors collect information such as heart rate, how much you move, how well you move, and several over measurements of health.

Ecological Momentary Assessments

We will ask you to download an app on your phone such as MyDataHelps. . This will allow us to ask you short questions on your phone once a day in the evening to learn about how you feel and how you are doing.

Quantitative Sensory Testing

We will test how you feel with different images, touches, temperatures, or small pains. For example, we might touch your skin with a small brush or put something warm or cool on your skin to see if you can feel it. Some of these test components may be a little uncomfortable.

Physical Assessment

We will check your ability to walk, get in and out of a chair, and move your low back. These are like the tests you might do at the doctor’s office.

Self-Report Outcomes

We will ask you to answer questions about how you feel and how you are doing. You will mark your answers on paper or a computer. These questions help us understand if you are in pain or having trouble doing everyday activities.

Interview

On your Visit 9, in addition to the testing, we will ask you to participate in a one-on-one interview to obtain your opinion of the study's acceptability and feasibility. This interview will be audio recorded and transcribed. We will use an alias during the interview to prevent any of your information from being identifiable.

Intervention Visits

Dry Needling

We will use very thin needles that look like the ones used in acupuncture. We put these needles into tight spots in your muscles to help with pain and make your muscles work

better. When we put the needles in, you might feel a dull ache, a small cramp, or a quick sharp feeling. These feelings usually go away the longer the needles stay in. Some people don't feel the needles at all. We will put up to 14 needles in certain spots on your back. The needles will stay in for 20 minutes. During this time, try to relax and keep your lower back still. After 20 minutes, we will remove all the needles and throw them away. Our researchers know how to do this session very well. They have had lots of training and use this session with their patients often. You can ask us to stop the session at any time if you want to.

Dry Needling with PENS

Dry needling with PENS is like regular dry needling but adds small electrical pulses to help your muscles even more. After we put the needles in your back, we attach small clips (like tiny alligator clips) to the ends of the needles. These clips connect to a special machine that sends gentle electrical pulses through the needles. This machine runs on a battery like the ones in smoke alarms and is used by many doctors who help people with pain. You will get different types of electrical pulses depending on which group you are in for the study. In one group, the pulses will make your back muscles twitch a little bit that you can see, but only as much as feels OK to you. In the other group, you will feel a strong but comfortable tingling feeling without your muscles moving. The needles with the electrical pulses will stay in your back for 20 minutes.

Potential Study Timeline and Requirements

Visit number	Purpose	Potential Time Commitment
1	Initial assessment and testing	2 hours
2 - 7	Sessions scheduled at 2-3 times a week	1 hour
8	Post session assessment and testing	2 hours
	2-week break between sessions	
9	Post session assessment and testing plus interview This information will assist in understanding what aspects of the study were acceptable to you and what aspects were feasible.	2.5 hours
10	Electronic survey 1 month after last session	30 minutes
11	Electronic survey 3 months after last session	30 minutes
	Total time in study	5 months

*If using a wearable sensor, participants will wear a device similar to a wristband while in the study, and will be asked to wear additional sensors while present during study visits

No additional tests or procedures will be needed for this study.

What are the possible risks for choosing to participate in this research study?

The risks in this study are small. You might feel some soreness in your trunk, arms, or legs after we examine you. This kind of soreness happens to about 1 to 25 out of every 100 people. There is also a chance that the session might cause back pain. To keep you safe, only trained doctors (physical therapists) who know how to do dry needling will do all the study procedures. All these doctors have special training in the sessions used in this study. There is also a small chance that your private information might be seen by someone who shouldn't see it. We will keep all your information private, just like doctors do with your regular medical records.

Study Procedure/Intervention

Because of your participation in this study, you are at risk for the following side effects. You should discuss these with the researchers and your regular health care provider.

Most Common Side Effects	Frequent (30 out of 100 people)	Occasional (15 out of 100 people)	Rare (Less than 1 out of 100 people)
Serious			
Less Serious			
Minor		Pain when we put in the needle Sore muscles a day or two later	Bruising Small amount of Bleeding

Psychological Stress

Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions, take a break, or stop your participation at any time.

Loss of Confidentiality

Any time information is collected, there is a potential risk of losing confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

Risks to Sperm, Embryo, Fetus or Breast-fed Infant

Males: There are no specific risks associated with being a male.

Females: If you are part of this study while pregnant, you may harm the unborn child. For that reason, pregnant individuals cannot participate in the study.

Are there risks related to withdrawing from the study?

If you decide to withdraw from this study early, please discuss your decision with the principal investigator. No additional forms or procedures are needed to be completed to withdraw from the study. There is no risk to you if you withdraw from the study. If you choose to withdraw from the study, a research team member will attempt to contact you to gather information about what may have led to your withdrawal. This information will help the research team design future studies. A team member will make 2 attempts to connect with you after your withdrawal. If unable to connect with you, the research team will make no further attempts to connect.

If I agree to take part in this research study, will I be told of any new risks that may be found during the course of the study?

You will be informed of any new information regarding risks that becomes available during the study that is important for your health and safety or could cause you to change your mind about participating.

What are the potential benefits for participating in this research study?

Participating in this study may reduce your pain and improve your quality of life. However, there is no guarantee or promise that you will receive any benefit from this study. We hope the information learned from this study will benefit other people with similar conditions.

Will I be reimbursed for participating in this study?

You will be reimbursed a flat rate per visit, for a potential total of $405. See table below for a reimbursement by visit breakdown. You will be reimbursed for each visit that you complete, even if you do not complete the overall study. You will be issued a UTMB ClinCard, which is a debit card that your funds are loaded onto following completion of all appropriate study visits. Funds will be approved and loaded onto your card when a study visit is completed. The funds will be available within 48 hours and can be used at your discretion. You will be issued one card for the duration of your participation. If your card is lost or stolen, you can contact customer service at 1-866-952-3795. To issue you a new ClinCard, we will collect some information about you, including name, address, telephone number, date of birth, email address, if applicable, and your social security number (if you are a U.S. citizen). All information is securely stored and will be deleted from the system once the study has been completed and the funds on the card have been used.

Potential earnings by visit for a total of $405	
1	$60
2-7	$30 each
8	$60
9	$75
10*electronic survey	$15
11*electronic survey	$15

Compensation for participation in research may be considered taxable income. The IRS requires that compensation greater than or equal to $600 be reported to the IRS as required by law. Personal information about you, such as your name, address, and Social Security Number (SSN) or Tax Identification Number (TIN), may be provided to the IRS by the participating site for tax purposes. If you receive $600 or more in a calendar year, you may be provided with a 1099 tax form from the sponsor, site, or vendors working on behalf of the sponsor for tax purposes. If you prefer not to receive payment for this study, you may alert your study site.

If I agree to take part in this research study, can I be removed from the study without my consent?

Yes. The researchers may decide to take you off this study if:

- Your medical problem remains unchanged or becomes worse.
- The researchers believe that study participation is no longer safe for you.
- The researchers believe that other interventions may be more helpful.
- The sponsor or the FDA stops the research for any reason.
- You are unable to keep appointments or to follow the researcher's instructions.

Will my insurance provider or I be charged for the costs of any part of this research study?

No. Neither you, nor your insurance provider, will be charged for anything related to this research study (i.e., the Screening Procedures, Experimental Procedures, or Monitoring/Follow-up Procedures described above).

However, the standard medical care for your condition (care you would have received whether or not you were in this study) is your responsibility (or the responsibility of your insurance provider or governmental program). You will be charged, in the standard manner, for any procedures performed for your standard medical care.

What will happen if I am harmed as a result of taking part in this study?

It is important that you immediately report any illness or injury to the research team listed at the top of this form, regardless of whether you think it is related to this study.

Compensation for an injury resulting from your participation in this research is not available from the University of Texas Medical Branch at Galveston.

You will be responsible for paying any costs related to illnesses and medical events not associated with the study. There are no plans to provide other forms of compensation. However, you are not waiving any of your legal rights by participating in this study.

Is this a clinical trial?

This study is not considered a clinical trial.

How will my information be protected?

Your privacy is important and your participation in this study will be kept confidential. However, absolute confidentiality cannot be guaranteed. In an effort to protect your privacy, the study staff will use code numbers or letters to identify your health information instead of your name, whenever possible. If the results of this study are reported in public settings like medical journals or conferences, you will not be identified.

What happens to the data collected in the study?

If you join this study, your data and/or specimens will be used to answer the research question and publish the study findings. You will not own your research data. If researchers use your data or specimens to create a new product or idea, including those that may have commercial value, you will not financially benefit from those efforts.

UTMB researchers and their collaborators may use the data and/or specimens collected in this study for future research purposes and may share some of the data and/or specimens with others. UTMB will do our best to protect and maintain your data and/or specimens in a safe way. One of the ways we protect data and/or specimens is by limiting the uses of the information and the type of information that is shared, especially your personal information. This may occur through de-identifying the data, data sharing agreements and review by oversight groups within UTMB.

In limited circumstances, data and/or specimens may be used or shared with types of information that may be likely to identify you, such as your name, address or medical record number for future research purposes at UTMB, only after the research has been reviewed and approved by the UTMB Institutional Review Board (IRB). The UTMB IRB will review whether additional consent from you is required.

Generally, if your data and/or specimens are used/shared without any personal identifiers or with information that is less likely to identify you (such as the date of a procedure), further review and approval is not needed.

Sharing data is part of research and may increase what we can learn from this study. Often, data sharing is required as a condition of funding or for publishing study results. It also is needed to allow other researchers to validate study findings and to come up with new ideas. Your data may be shared with researchers at UTMB and other institutions, for-profit companies, sponsors, government agencies, and other research partners. Your data may also be put in government or other databases/repositories.

Because science constantly advances, we do not yet know what future use of research data may include. This future research may be unrelated to the current study and may include outside collaborators.

Data sharing could change over time and may continue after the study ends.
The use and sharing of your data is required for participation in this research study. If you are not comfortable with the use and sharing of your data in future research without further consent, you should not participate in this study.

How will my privacy be protected?
Your privacy is important and your participation in this study will be kept confidential. However, absolute confidentiality cannot be guaranteed.

By signing this consent form, you give us permission, called your "authorization," to collect, use, and disclose your personal health information. We have strict regulations, including Federal and State laws, designed to protect information about you. This includes information learned from the procedures described in this consent form. The research team may also collect other information from you, including your name, your address, your date of birth, and information from your medical records. Please understand that health information used and disclosed may include information relating to HIV infection, drug abuse, alcohol abuse, behavioral health, and psychiatric care.

Other professionals at UTMB, such as your doctor(s) and the Institutional Review Board, may also see your information. We make this information available to your doctors for your safety. Please inform your doctor If you think this study might affect your medical care.

People outside of UTMB may also need to see and review your information for this study. UTMB does not allow identifiable information collected during the study to be released to people outside of UTMB except as required by law or otherwise stated in this consent form. Examples include government agencies, such as the Food and Drug Administration (FDA), individuals who monitor the study for safety purposes, other study location sites, and companies that sponsor (help organize or pay for) the study.

We cannot do this study and cannot use and distribute your information without your authorization. You do not have to sign this form. However, if you choose not to sign it, you cannot be in the study. Your care or the benefits you receive from UTMB will not be affected if you decide not to be in the study.

You may change your mind and revoke (take back) this authorization at any time. Even if you revoke this authorization, researchers may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must contact the principal investigator in writing.

All results obtained in this study will be kept confidential and only available to the research study team. Your individual information will not be reported, only the results of all participants as a group.

Data or specimens collected in this research might be de-identified and used for future research or distributed to another investigator for future research without your consent.

Data will be protected on a password protected device. Devices will be kept securely in a badge or key accessible environment. These areas will only be accessed UTMB authorized personnel.

How long does this authorization to use my information last?
When you sign this form, you agree to let us collect, produce, and share health information about you as we described in this form. Your authorization does not end.

Who can I contact with questions about this research study?
If you have any questions, concerns, or complaints before, during, or after the research study, or if you need to report a research-related injury or bad side effect, you should immediately contact Ryan Pontiff, PT, PhD, DPT at 409-772-0310 or, if after office hours, at 409-772-0310 or Liza Durgens at 281-620-4902.

This study has been approved by the University of Texas Medical Branch Institutional Review Board (IRB). If you have any concerns, complaints, suggestions, or questions regarding your rights as a participant participating in this research study, or if you would like more information about the protection of human subjects in research, you may contact the IRB office at irb@utmb.edu.

Initial: _____

Consent to Participate

Sign below only if you understand the information given to you about the research and you choose to take part in this research study. Make sure that all your questions have been answered. If you decide to take part in this research study, a copy of this signed consent form will be given to you.

Printed Name of Subject	Signature of Subject	Date	Time

With language that is understandable and appropriate, I have discussed this project and the items listed above with the participant.

Printed Name of Person Obtaining Informed Consent	Signature of Person Obtaining Informed Consent	Date	Time

If a witness is required:

Printed Name of Witness	Signature of Witness	Date	Time