Influence of Noxious Electrical Stimulation on Chronic Pain from Knee Osteoarthritis

NCT04628013

IRB Consent Forms for Aims 1 & 2
Original approval date: 07/15/2020
Renewal/Amendment #1: 08/04/2021
Renewal/Amendment #2: 06/21/2022

UNIVERSITY OF NEW ENGLAND
CONSENT FOR PARTCIPATION IN RESEARCH

Project Title: Influence of Noxious Electrical Stimulation (NxES) on Chronic Pain

AIM 1

Principal Investigator(s): Scott K. Stackhouse, PT, PhD

Introduction:

- Please read this form. You may also request that the form is read to you. The purpose of this form is to give you information about this research study, and if you choose to participate, document that choice.

- You are encouraged to ask any questions that you may have about this study, now, during or after the project is complete. You can take as much time as you need to decide whether or not you want to participate. Your participation is voluntary.

Why is this research study being done?

Individuals with chronic knee pain are commonly treated with a combination of medication, physical therapy and exercise, and depending on the source of pain, a surgery is sometimes needed. We are investigating the use of a less commonly used treatment to relieve chronic knee pain. We are looking to see how a single treatment of noxious (slightly painful, but tolerable) electrical stimulation (NxES) impacts the pain levels and duration of pain in your knee. This is a non-invasive (on top of the skin) treatment that includes stimulation using electrodes (small stickers connected to wires) that are temporarily placed on your knee in order to deliver short periods of stimulation.

Who will be in this study?

Approximately 22 individuals will participate in this study. You have volunteered or been invited to participate in our research study examining the use of noxious electrical stimulation on the knee to decrease pain because you have reported chronic pain in your knee.

You are eligible for this study if:

- Your age is between 50-90
- Current chronic knee joint-related pain of at least 6-months in duration and a pain rating of at least 30/100 (0 = no pain; 100 = worst imaginable pain) over the last 24 hours.

You will be screened for and excluded from this study if you:

- Have any prior experience with noxious electrical stimulation in a treatment course of physical therapy
- Knee joint injections in the last 3 months
- History of knee arthroplasty in the involved knee (total hip arthroplasty OK)
- Surgical history in the last 6 months
- History of any chronic pain conditions (ex: fibromyalgia, rheumatoid arthritis)
- History of cardiovascular, pulmonary or neurologic disorders
- History of dementia/cognitive impairment
- History of diabetes with sensory loss in legs
- Unable to climb/descend a flight of stairs
- You will be asked to list all prescription and non-prescription medications and the study principal investigator will review them to see if there is a potential effect on your pain processing system.

What will I be asked to do?

Testing will take place over 4 sessions in Blewett 107A & B on the Portland Campus of the University of New England.

Approximate duration of each session:

Session 1 – 45 minutes
Session 2 – 2.0 hours
Session 3 – 45 minutes
Session 4 – 45 minutes

	Session 1 (45 min)	**Session 2 (2 hrs)**				**Session 3 (45 min)**	**Session 4 (45 min)**
Test (described below)	Familiarization	Pre Tests		Post-test Immediate	Post-1 hr	Post-24 hr	Post-72 hr
KOOS, ICOAP (surveys)	X		One NxES Treatment				
PSQ, PDQ, DASS-21, PCS, BRS (surveys), PASE	X						
BPI (survey)	X	X			X	X	X
Pain at Rest, 5xSTS (VAS), 2-MWT (VAS)		X		X	X	X	X
PPT, HTS, CPM	X	PPT		PPT	X	X	X

Session 1: We will review this consent form, sign it and you will receive a copy. You will complete numerous surveys that are standardized assessments of your thoughts and feelings about pain and pain experiences. We will then familiarize you with each of the tests we will perform during your next 3 sessions:

Surveys: KOOS (Knee injury & Osteoarthritis Outcome Score), ICOAP (Intermittent and Constant Osteoarthritis Pain), PSQ (Pain Sensitivity Questionnaire), PDQ (Pain Detect Questionnaire), DASS-21 (Depression Anxiety and Stress Scale), PCS (Pain Catastrophizing Scale), BRS (Brief Resiliency Scale), BPI (Brief Pain Inventory), PASE (Physical Activity Scale for the Elderly) (see description of surveys below).

Familiarization of procedures:
Functional Testing and Stimulation: 5xSTS (Five-Time-Sit-to-Stand), 2-MWT (2-Minute Walk Test), electrical stimulation (see details below).

Sensory Testing: PPT (pressure pain threshold), HPT (heat pain threshold), HTS (heat temporal summation), CPM (conditioned pain modulation) (see details below).

Session 2: You will complete one survey. We will then complete pain and functional testing as well as sensory testing (as demonstrated in Session 1), both immediately before and immediately after a treatment of NxES. Then the testing will be repeated again after 1 hour.

Session 3 (24 hours later): Pain, functional assessments and sensory testing will be conducted during this session along with one survey.

Session 4 (72 hours after Session 2): Pain, functional assessments and sensory testing will be conducted during this session along with one survey.

Testing Details:

Questionnaires:

- KOOS (Knee injury & Osteoarthritis Outcome Score) This survey asks for your view about your knee. This information will help us keep track of how you feel about your knee and how well you are able to do your usual activities.
- ICOAP (Intermittent and Constant Osteoarthritis Pain) This survey asks for details regarding pain over the last week.
- PSQ (Pain Sensitivity Questionnaire) This survey asks for your perception of various physical stimuli that you may experience in daily life.
- PDQ (Pain Detect Questionnaire) This survey asks about how you would describe your pain.
- DASS-21 (Depression Anxiety and Stress Scale) This survey asks about depression, anxiety, and stress symptoms.
- PCS (Pain Catastrophizing Scale) This survey asks for your thoughts in response to actual or potential pain.
- BRS (Brief Resiliency Scale) This survey asks questions about stress.
- BPI (Brief Pain Inventory) This survey asks about your pain intensity and interference of pain in activities.
- PASE (Physical Activity Scale for the Elderly) This survey reviews your physical activities over the last 7 days.

Objective Functional Assessment:

- 5xSTS (Five-Times-Sit-to-Stand): With arms crossed over your chest, you will rise from a chair and return to the seated position as quickly as possible five times.
- 2-MWT (2-Minute Walk Test): You will walk as far as you can in two minutes on a small walking course in the laboratory.

Sensory Testing:

- PPT (Pressure Pain Threshold) - Pressure pain threshold testing will occur on your wrist. One of the investigators will use a hand-held pressure probe with a 1-cm rubber tip to

apply increasing amounts of pressure to your wrist until you indicate the first presence of pain, after which, the pressure will immediately be removed. This test will be repeated once after at least a 30-second rest. We will repeat this test on your knee as well.

- HTS (Heat Temporal Summation) - We will run the HTS on your knee. First the temperature of the probe will deliver brief pulses of heat (one pulse every 15 seconds) until you rate the feeling of the heat as just above the pain threshold. The summation tests will consist of 10 heat pulses delivered at the heat level that you identified (just above pain threshold). These pulses will rise and fall rapidly from a baseline of 107.6°F to a peak determined by your rating and then back to baseline at a rate of 14.4°F/second. Heat pulses will be delivered at a rate of 1 pulse every 2.5 seconds. During this test, you will rate your perception of the heat pain intensity for each of the 10 heat pulses using a standardized rating scale.

- CPM (Conditioned Pain Modulation): For the Conditioned Pain Modulation (CPM) test we will repeat the Pressure Pain Threshold (PPT) assessment as described above for the knee. This time, however, we will assess the PPT of your affected knee while your opposite hand is in an ice bath (42.8-46.4°F) for a total time of 2 minutes or until you cannot tolerate the ice bath any further. PPT will be performed at 30 seconds and 90 seconds of immersion, if possible.

Treatment:

- Noxious Electrical Stimulation (NxES) Intervention: We will identify a comfortable position for you (seated or lying) to receive 20 minutes of electrical stimulation on the sides of your knee. The stimulation will be in a pulse pattern with the current on for 10 seconds and off for 10 seconds. The intensity of stimulation will be gradually raised over the first ~ 2 minutes of stimulation. You will identify when the stimulation first becomes painful and we will dose the stimulation to a perception of “prickly, vibratory pain” of 5/10 on a 0 to 10 scale.

What are the possible risks of taking part in this study?

- **Heat and pressure pain testing**: This study involves measuring of both heat and pressure pain. The discomfort from testing may also produce some anxiety. The pain experienced during the testing is temporary. The skin over the testing area may have pressure marks, redness, and be sensitive after testing for several minutes to hours. The potential for equipment problems exists, but the equipment is highly reliable and contains safety features to limit temperature exposure, with a maximum temperature exposure of 125.6°F. All equipment is checked regularly for safety.

- **Noxious Electrical Stimulation (NxES):** Electrical nerve stimulation may cause temporary discomfort/pain as we are asking for the intensity of the stimulation to be dosed up to a 5/10 perception of “prickly, vibratory pain” using a 0 to 10 rating scale, where 0 is no pain, and 10 is the severest pain imaginable. The skin under the electrode sites will commonly become red after application, this response is temporary and generally resolves within a few hours of the treatment. We will carefully check your skin prior to application and afterwards to reduce risk of an electrical burn. Research personnel will also monitor the participant’s perception of the stimulation and will adjust

the intensity as necessary to keep the stimulation at the same perceptual level throughout treatment.

- **Functional Assessments (5xSTS, 2-MWT):** The risks of injury are very small during this study however there is risk that you will experience knee buckling and/or increased knee pain during these activities and possible loss of balance and falling during these tests. This risk is small since the activities are the same as the ones you perform every day. The risks are minimized by letting you do the activities at your own pace and by letting you rest whenever needed.

Updated Risks due to SARS-CoV-2/COVID-19

The University of New England and its Institutional Review Board places the highest priority on the safety and protection of research participants. If you are considering whether to participate in an in-person study visit, it is important to understand that your study participation may include increased travel outside of your home and increased exposure to other members of the public, which may increase your risk of exposure to COVID-19. Because of this, the University is providing the following information to you regarding COVID-19 and what you may expect during your study visit.

General Information about COVID-19

• COVID-19 is a respiratory virus spread mainly from person-to-person. It is also possible that a person can get COVID-19 by touching a surface or object that has the virus on it, and then touching their mouth, nose, or eyes.

• Current ways to minimize the risk of exposure to COVID-19 include physical distancing (maintaining at least 6 feet of space from other people), proper hand hygiene, and disinfecting surfaces that are frequently touched by other people.

• According the CDC, some people are more likely than others to become severely ill, which means that they may require hospitalization, intensive care, or a ventilator to help them breathe, or they may even die. People at increased risk for severe illness are adults over the age of 65 and people with certain underlying medical conditions, as set forth in contemporary CDC guidance. Please tell the research staff during your remote screening if any of these apply to you.

What you can expect during your Research Visit

• You are encouraged to come to the study visit alone, if possible.
• Within 24 hours before your study visit, you will be screened for symptoms of COVID-19 and asked a few questions about recent contact with other people and any recent travel you may have done.
• When you arrive for your study visit:
  o We will provide you a surgical mask and face shield to wear at all times.
  o You will be screened for symptoms of COVID-19 again.
  o All study visit areas will have University-approved hand sanitizer available in the area that you are encouraged to use frequently.

• The research staff will be wearing a special face mask, and will be wearing other personal protective equipment (PPE) such as face shields.
• The research staff will maintain at least 6 feet of physical distance from you whenever possible.
• The University is following all current State and Federal guidelines for cleaning rooms and equipment between each study visit.

What are the possible benefits of taking part in this study?

It is possible that you will not receive any direct benefit from participating in this study. It is also possible that you may experience some decrease in knee pain. These improvements may only be short-term. The data obtained from this study may lead to further research in a clinical population.

What will it cost me?

There are no costs associated with the participation in this study. You will be compensated with a $50 honorarium for the completion of the study (4 sessions). If you do not complete all 4 sessions, partial compensation of $25 will be provided for your time.

How will my privacy be protected?

Your testing will occur on UNE's Portland Campus in Blewett 107A and B, which are private rooms only accessible to research investigators and staff of the Department of Physical Therapy. All data obtained in this study will be kept confidential. Names will only be known to the investigators. A numeric code will be assigned to each participant, ensuring that names will not be linked directly to data collected. The results of this study will be presented in group-form to University of New England faculty and students, at professional meetings, or in professional publications. Any personal identifying information will not be included in these presentations or publications.

How will my data be kept confidential?

- All data obtained in this study will be kept confidential. Names will only be known to the investigators and a numeric code will be assigned to each participant, ensuring that names will not be linked directly to data collected.
- A secure, encrypted electronic database will be kept by Principal Investigator that links your name to the assigned numeric code. This will only be accessible by the study Principal Investigator (Scott Stackhouse) research investigator (Katherine Rudolph) and the Study Coordinator (Susan LaVerriere).
- Your de-identified data will be stored in password-protected computers and in locked file drawers in the Principal Investigator's/Study Coordinator's office or lab.

- All data and consent forms will be kept for at least 3 years and until publication of results, after which, consent forms and data codes will be shredded.
- De-identified baseline experimental pain data may be kept for addition to a laboratory normative database.
- Please note that the Institutional Review Board may review the research records.

What are my rights as a research participant?

- Your participation is voluntary. Your decision to participate will have no impact on your current or future relations with the University.
- Your decision to participate will not affect your relationship with the study investigative team.
- You may skip or refuse to answer any question for any reason.
- If you choose not to participate there is no penalty to you and you will not lose any benefits that you are otherwise entitled to receive.
- You are free to withdraw from this research study at any time, for any reason.
    - If you choose to withdraw from the research there will be no penalty to you and you will not lose any benefits that you are otherwise entitled to receive.
- You will be informed of any significant findings developed during the course of the research that may affect your willingness to participate in the research.
- If you sustain an injury while participating in this study, your participation may be ended.

What other options do I have?

- You may choose not to participate.

Whom may I contact with questions?

- The researchers conducting this study are
    - Scott Stackhouse, PT, PhD (Principal Investigator)

- For more information regarding this study, please contact Scott Stackhouse at his office phone (207-221-4581) or via email (sstackhouse@une.edu).

- If you choose to participate in this research study and believe you may have suffered a research related injury, please contact Scott Stackhouse at his office phone (207-221-4581) or via email (sstackhouse@une.edu).

- If you have any questions or concerns about your rights as a research subject, you may call Mary Bachman DeSilva, Sc.D., Chair of the UNE Institutional Review Board at (207) 221-4567 or irb@une.edu.

Will I receive a copy of this consent form?

- You will be given a copy of this consent form.

Participant's Statement

I understand the above description of this research and the risks and benefits associated with my participation as a research subject. I agree to take part in the research and do so voluntarily.

Participant's signature or
Legally authorized representative

Date

Printed name

Researcher's Statement

The participant named above had sufficient time to consider the information, had an opportunity to ask questions, and voluntarily agreed to be in this study.

Researcher's signature

Date

Printed name

UNIVERSITY OF NEW ENGLAND
CONSENT FOR PARTCIPATION IN RESEARCH

Project Title: Influence of Noxious Electrical Stimulation on Chronic Pain

AIM 2 (6 session treatment)

Principal Investigator(s): Scott K. Stackhouse, PT, PhD

Introduction:

- Please read this form. You may also request that the form is read to you. The purpose of this form is to give you information about this research study, and if you choose to participate, document that choice.

- You are encouraged to ask any questions that you may have about this study, now, during or after the project is complete. You can take as much time as you need to decide whether or not you want to participate. Your participation is voluntary.

Why is this research study being done?

Individuals with chronic knee pain are commonly treated with a combination of medication, physical therapy and exercise, and depending on the source of the pain, a surgery is sometimes needed. We are investigating the use of a less commonly used treatment to relieve chronic knee pain. We are looking to see how 6 treatments of noxious (slightly painful, but tolerable) electrical stimulation (NxES) impacts the pain levels and duration of pain in your knee. This is a non-invasive (on top of the skin) treatment that includes stimulation using electrodes (small stickers connected to wires) that are temporarily placed on your knee in order to deliver short periods of stimulation.

Who will be in this study?

Approximately 22 individuals will participate in this study. You have volunteered or been invited to participate in our research study examining the use of noxious electrical stimulation on the knee to decrease pain because you have reported chronic pain in your knee.

You are eligible for this study if:

- Your age is between 50-90
- Current chronic knee joint-related pain of at least 6-months in duration and a pain rating of at least 30/100 (0 = no pain; 100 = worst imaginable pain) over the last 24 hours.

You will be screened for and excluded from this study if you:

- Have any prior experience with noxious electrical stimulation in a treatment course of physical therapy
- Knee joint injections in the last 3 months
- History of knee arthroplasty in the involved knee (total hip arthroplasty OK)
- Surgical history in the last 6 months
- History of any chronic pain conditions (ex: fibromyalgia, rheumatoid arthritis)
- History of cardiovascular, pulmonary or neurologic disorders
- History of dementia/cognitive impairment
- History of diabetes with sensory loss in legs
- Unable to climb/descend a flight of stairs
- You will be asked to list all prescription and non-prescription medications and the study principal investigator will review them to see if there is a potential effect on your pain processing system.

What will I be asked to do?

Testing will take place over 9 sessions in Blewett 107A & B on the Portland Campus of the University of New England.

Approximate duration of each session:

Session 1 – 1 hour
Session 2 – 1.5 hours
Session 3-7 – 1.0 hour
Session 8 – 45 minutes
Session 9 – 45 minutes

	Session 1 (1 hour)	**Session 2 (1.5 hours)**			**Session 3-7 (30-60 min)**		**Session 8 (45 min)**	**Session 9 (45 min)**
Test	Familiarization	Pre Test	NxES Treatment	Post-0 hr	Pre Test	NxES Treatment	72 hrs after last NxES	4 wks after last NxES
KOOS, ICOAP	X						X	X
PSQ, PDQ, DASS-21, PCS, BRS, PASE	X							
BPI	X	X			X*		X	X
Pain at Rest, 5xSTS (VAS), 2-MWT (VAS)		X		X	X*		X	X
PPT	X	X		X	X*		X	X
HTS & CPM	X						X	X

* measures recorded at the start of sessions 5 & 7 only

Session 1: We will review this consent form, sign it and you will receive a copy. You will complete numerous surveys that are standardized assessments of your thoughts and feelings about pain and pain experiences. We will then familiarize you with each of the tests we will perform during your next 8 sessions:

Surveys: KOOS (Knee injury & Osteoarthritis Outcome Score), ICOAP (Intermittent and Constant Osteoarthritis Pain), PSQ (Pain Sensitivity Questionnaire), PDQ (Pain Detect Questionnaire), DASS-21 (Depression Anxiety and Stress Scale), PCS (Pain

Catastrophizing Scale), BRS (Brief Resiliency Scale), BPI (Brief Pain Inventory), PASE (Physical Activity Scale for the Elderly) (see description of surveys below).

Procedures:
Functional Testing and Stimulation: 5xSTS (Five-Time-Sit-to-Stand), 2-MWT (2-Minute Walk Test), electrical stimulation (see details below).

Sensory Testing: PPT = pressure pain threshold; HPT = heat pain threshold; HTS = heat temporal summation; CPM = conditioned pain modulation (see details below).

Session 2: You will complete one survey. We will then complete pain and functional testing as well as sensory testing (as demonstrated in Session 1), both immediately before and immediately after a treatment of NxES.

Session 3-7 (2-3 sessions/week for 2 weeks): In all sessions you will receive a treatment of noxious electrical stimulation. In sessions 3, 5 and 7 you will also complete the BPI survey and we will complete functional and sensory testing before the noxious electrical stimulation.

Session 8 (72 hours after session 6): Pain and functional assessments as well as sensory testing will be conducted during this session.

Session 9 (4 weeks after session 6): Pain and functional assessments as well as sensory testing will be conducted during this session.

Scheduling Note: Sessions 2-7 must be completed within 18 calendar days.

Testing Details:

Questionnaires:

- KOOS (Knee injury & Osteoarthritis Outcome Score) This survey asks for your view about your knee. This information will help us keep track of how you feel about your knee and how well you are able to do your usual activities.
- ICOAP (Intermittent and Constant Osteoarthritis Pain) This survey asks for details regarding pain over the last week.
- PSQ (Pain Sensitivity Questionnaire) This survey asks for your perception of various physical stimuli that you may experience in daily life.
- PDQ (Pain Detect Questionnaire) This survey asks about how you would describe your pain.
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- PASE (Physical Activity Scale for the Elderly) This survey reviews your physical activities over the last 7 days.

Objective Functional Assessment:

- 5xSTS (Five-Times-Sit-to-Stand). With arms crossed over your chest, you will rise from a chair and return to the seated position as quickly as possible five times.
- 2-MWT (2-Minute Walk Test): You will walk as far as you can in two minutes on a small walking course in the laboratory.

Sensory Testing:

- PPT (Pressure Pain Threshold) - Pressure pain threshold testing will occur on your wrist. One of the investigators will use a hand-held pressure probe with a 1-cm rubber tip to apply increasing amounts of pressure to your wrist until you indicate the first presence of pain, after which, the pressure will immediately be removed. This test will be repeated once after at least a 30-second rest. We will repeat this test on your knee as well.

- HTS (Heat Temporal Summation) - We will run the HTS on your knee. First the temperature of the probe will deliver brief pulses of heat (one pulse every 15 seconds) until you rate the feeling of the heat as just above the pain threshold. The summation tests will consist of 10 heat pulses delivered at the heat level that you identified (just above pain threshold). These pulses will rise and fall rapidly from a baseline of 107.6°F to a peak determined by your rating and then back to baseline at a rate of 14.4°F/second. Heat pulses will be delivered at a rate of 1 pulse every 2.5 seconds. During this test, you will rate your perception of the heat pain intensity for each of the 10 heat pulses using a standardized rating scale.

- CPM (Conditioned Pain Modulation): For the Conditioned Pain Modulation (CPM) test we will repeat the Pressure Pain Threshold (PPT) assessment as described above for the knee. This time, however, we will assess the PPT of your affected knee while your opposite hand is in an ice bath (42.8-46.4°F) for a total time of 2 minutes or until you cannot tolerate the ice bath any further. PPT will be performed at 30 seconds and 90 seconds of immersion, if possible.

Treatment:

- Noxious Electrical Stimulation (NxES) Intervention: We will identify a comfortable position for you (seated or lying) to receive 20 minutes of electrical stimulation on the sides of your knee. The stimulation will be in a pulse pattern with the current on for 10 seconds and off for 10 seconds. The intensity of stimulation will be gradually raised over the first ~ 2 minutes of stimulation. You will identify when the stimulation first becomes painful and we will dose the stimulation to a perception of “prickly, vibratory pain” of 5/10 on a 0 to 10 scale.

What are the possible risks of taking part in this study?

- **Heat and pressure pain testing**: This study involves measuring of both heat and pressure pain. The discomfort from testing may also produce some anxiety. The pain experienced during the testing is temporary. The skin over the testing area may have pressure marks, redness, and be sensitive after testing for several minutes to hours. The potential for equipment problems exists, but the equipment is highly reliable and contains safety features to limit temperature exposure, with a maximum temperature exposure of 125.6°F. All equipment is checked regularly for safety.

- **Electrical Nerve Stimulation:** Electrical nerve stimulation may cause temporary discomfort/pain as we are asking for the intensity of the stimulation to be dosed up to a 5/10 perception of “prickly, vibratory pain” using a 0 to 10 rating scale, where 0 is no pain, and 10 is the severest pain imaginable. The skin under the electrode sites will commonly become red after application, this response is temporary and generally resolves within a few hours of the treatment. We will carefully check your skin prior to application and afterwards to reduce risk of an electrical burn. Research personnel will also monitor the participant’s perception of the stimulation and will adjust the intensity as necessary to keep the stimulation at the same perceptual level throughout treatment.

- **Functional Assessments (5xSTS, 2-MWT):** The risks of injury are very small during this study however there is risk that you will experience knee buckling and/or increased knee pain during these activities and possible loss of balance and falling during these tests. This risk is small since the activities are the same as the ones you perform every day. The risks are minimized by letting you do the activities at your own pace and by letting you rest whenever needed.

General Information about COVID-19

• COVID-19 is a respiratory virus spread mainly from person-to-person. It is also possible that a person can get COVID-19 by touching a surface or object that has the virus on it, and then touching their mouth, nose, or eyes.

• Current ways to minimize the risk of exposure to COVID-19 include physical distancing (maintaining at least 6 feet of space from other people), proper hand hygiene, and disinfecting surfaces that are frequently touched by other people.

• According the CDC, some people are more likely than others to become severely ill, which means that they may require hospitalization, intensive care, or a ventilator to help them breathe, or they may even die. People at increased risk for severe illness are adults over the age of 65 and people with certain underlying medical conditions, as set forth in contemporary CDC guidance. Please tell the research staff during your remote screening if any of these apply to you.

What you can expect during your Research Visit

• You are encouraged to come to the study visit alone, if possible.
• Within 24 hours before your study visit, you will be screened for symptoms of COVID-19 and asked a few questions about recent contact with other people and any recent travel you may have done.
• When you arrive for your study visit:
  o We will provide you a surgical mask and face shield to wear at all times.
  o You will be screened for symptoms of COVID-19 again.
  o All study visit areas will have University-approved hand sanitizer available in the area that you are encouraged to use frequently.

• The research staff will be wearing a special face mask, and will be wearing other personal protective equipment (PPE) such as face shields.

• The research staff will maintain at least 6 feet of physical distance from you whenever possible.
• The University is following all current State and Federal guidelines for cleaning rooms and equipment between each study visit.

What are the possible benefits of taking part in this study?

It is possible that you will not receive any direct benefit from participating in this study. It is also possible that you may experience some decrease in knee pain. These improvements may only be short-term. The data obtained from this study may lead to further research in a clinical population.

What will it cost me?

There are no costs associated with the participation in this study. You will be compensated with a $50 honorarium for the completion of the study (9 sessions). If you do not complete all 9 sessions, partial compensation of $25 will be given for your time.

How will my privacy be protected?

Your testing will occur on UNE's Portland Campus in Blewett 107A and B, which are private rooms only accessible to research investigators and staff of the Department of Physical Therapy. All data obtained in this study will be kept confidential. Names will only be known to the investigators. A numeric code will be assigned to each participant, ensuring that names will not be linked directly to data collected. The results of this study will be presented in group-form to University of New England faculty and students, at professional meetings, or in professional publications. Any personal identifying information will not be included in these presentations or publications.

How will my data be kept confidential?

- All data obtained in this study will be kept confidential. Names will only be known to the investigators and a numeric code will be assigned to each participant, ensuring that names will not be linked directly to data collected.
- A secure, encrypted electronic database will be kept by Principal Investigator that links your name to the assigned numeric code. This will only be accessible by the study Principal Investigator (Scott Stackhouse), research investigator (Katherine Rudolph) and the Study Coordinator (Susan LaVerriere).
- Your de-identified data will be stored in password-protected computers and in locked file drawers in the Principal Investigator's/Study Coordinator's office or lab.
- All data and consent forms will be kept for at least 3 years and until publication of results, after which, consent forms and data codes will be shredded.
- De-identified baseline experimental pain data may be kept for addition to a laboratory normative database.
- Please note that the Institutional Review Board may review the research records.

What are my rights as a research participant?

- Your participation is voluntary. Your decision to participate will have no impact on your current or future relations with the University.
- Your decision to participate will not affect your relationship with the study investigative team.
- You may skip or refuse to answer any question for any reason.
- If you choose not to participate there is no penalty to you and you will not lose any benefits that you are otherwise entitled to receive.
- You are free to withdraw from this research study at any time, for any reason.
    - If you choose to withdraw from the research there will be no penalty to you and you will not lose any benefits that you are otherwise entitled to receive.
- You will be informed of any significant findings developed during the course of the research that may affect your willingness to participate in the research.
- If you sustain an injury while participating in this study, your participation may be ended.

What other options do I have?

- You may choose not to participate.

Whom may I contact with questions?

- The researchers conducting this study are
    - Scott Stackhouse, PT, PhD (Principal Investigator)

        - For more information regarding this study, please contact Scott Stackhouse at his office phone (207-221-4581) or via email (sstackhouse@une.edu).
- If you choose to participate in this research study and believe you may have suffered a research related injury, please contact Scott Stackhouse at his office phone (207-221-4581) or via email (sstackhouse@une.edu).

- If you have any questions or concerns about your rights as a research subject, you may call Mary Bachman DeSilva, Sc.D., Chair of the UNE Institutional Review Board at (207) 221-4567 or irb@une.edu.

Will I receive a copy of this consent form?

- You will be given a copy of this consent form.

_____

Participant's Statement

I understand the above description of this research and the risks and benefits associated with my participation as a research subject. I agree to take part in the research and do so voluntarily.

_____ _____

Participant's signature or
Legally authorized representative

Date

_____

Printed name

Researcher's Statement

The participant named above had sufficient time to consider the information, had an opportunity to ask questions, and voluntarily agreed to be in this study.

_____ _____

Researcher's signature

Date

_____

Printed name