Study Title: The Back Pain Consortium Research Program (The BACPAC Study)

NCT: NCT04870957

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UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title:
University of Michigan Mechanistic Research Center (BACPAC Study)

Company or agency sponsoring the study:
National Institutes of Health (NIH), National Institute of Arthritis Musculoskeletal and Skin Diseases (NIAMS)

Principal Investigators:
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Study Coordinator:
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1.1 Key Study Information

You may be eligible to take part in a research study. This form has important information that will help you decide whether to join the study. Take the time to carefully go over this information. You should talk to the researchers about the study and ask them any questions you may have. You can also talk to others such as your family, friends, or other doctors about joining this study. If you decide to join, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should think about the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to study visits in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find childcare, or make other plans. In your decision to participate in this study, think about all these matters carefully.

Who Responds to Different Chronic Pain Treatments

STUDY OVERIVEW

Study visits- 5 visits over 9 months

- Collect medical history and medications
- Collect blood and saliva
- Physical exam and function tests
- Imaging of back and hips

Visits may be in-person or virtual

PAIN GUIDE

You will be given access to a website called PainGuide

BACK PAIN TREATMENTS

Up to two treatment for your chronic low back pain for 8 weeks

- Physical Therapy & Exercise
- Mindfulness Based Stress Reduction (MBSR)
- Acupressure
- Duloxetine (medication)

Treatments may be in-person or virtual

RISKS AND BENEFITS

Risks

New symptoms such as:

- Muscle soreness with Physical Therapy
- Mental stress from thinking about your experience with chronic pain
- Medication-related side effects

Benefits

- Your pain may improve with treatments
- You will help researchers understand what treatments help treat chronic back pain

Alternatives: you can decide not be in this study and seek care from your physician. You are also free to leave the study at any time.

1.3 Randomization

This study involves a process called randomization. This means that the group or groups you are selected to take part in during the study are not chosen by you or the researcher. The study design divides study participants into separate groups, based on chance (1 out of 4 chance for each group). After you complete the first treatment, you may be randomly placed in a second treatment group. You will only be placed in the second treatment if your pain is still interfering with your ability to function. If you decide to be in the study, you need to be comfortable not knowing which study group you will be in. If you are not eligible for one of the treatments, then you might be placed in one of the other remaining treatments.

1.4 Medication Modification

For this study we may ask you to temporarily stop taking certain medications before and/or during the research study. If you decide to be in the study, you should understand that some symptoms that were controlled by that medication may worsen.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study Purpose

The aim of this study is to better understand who benefits from different chronic pain treatments and how these treatments work.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you do not want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

Individuals between the ages of 25 and 70 with chronic low back pain from Michigan Medicine.

Individuals with a history of an autoimmune disorder such as ankylosing spondylitis, rheumatoid arthritis, polymyalgia rheumatica, psoriatic arthritis, or lupus are not eligible for this study.

3.2 How many people are expected to take part in this study?

We expect to enroll up to 600 individuals over the course of this study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

Table 1 Summary of in-person vs online part of a study visit

May be completed virtually OR in-person
• Informed consent • Review of medical history • Study surveys
Must be completed in-person
• Physical exam • Blood, saliva & urine collection

By agreeing to take part in this study, you will be asked to take part in all of your study visits, complete study surveys every two weeks and participate in your assigned treatment. You will be asked to report any unwanted or harmful effects from the medications or any of the treatments you may take part in during the study.

- Walking & standing tests
- MRI of the back and hips

You will have 5 visits with the research team at the Back & Pain Center. These visits may be in-person, or a combination of in-person and online (virtual visit). This is summarized in Table 1 and described in detail below.

4.1.1 Study visit 1

At your first visit we will go over the study requirements by reviewing the informed consent form. Next, we will review your medical history and medications. You will also complete some surveys. If visits cannot be done in-person, this portion of the visit may be done on a video (virtual visit) or telephone call.

Figure 1 Harness placement for Low Back

The next part of visit must be completed in-person. You will have a physical exam completed by a study physician. This will be followed by physical function tests (i.e., walking, standing and sitting). Clinical data will be collected such as blood pressure, height, weight, urine pregnancy test (if eligible), saliva samples, and about 1 tablespoon of blood. This will be done for research and is not part of your clinical care. Next you will look at how your low back moves using the Pheno device. For these low back motion assessments, you will wear a vest and a belt harness (Figure 1) that contain motion sensors that measure how you move your low back. You will be asked to move your low back forward and back, bend side to side, twist left to right, as well as combinations of these motions.

The instructions for each test will be to perform the motion as fast or as far as you can comfortably. Note that if you are participating in one of our biomechanics laboratories, your motions may also be captured with one of our camera systems as well. These cameras do not capture any identifying information or images, but rather are used to track the sensors on the harnesses.

Additionally, an MRI of your back and hips will be done at the University of Michigan (UM) Hospital. This session may occur on the same day as the research visit or occur on a different day. An MRI machine uses magnets to create images of the inside of the body. MRI does not expose you to radiation. During the MRI, you will lie down inside the scanner. Before the MRI scan, we will have you complete an MRI Safety Screen to make sure it is safe for you. If you are a woman and able to become pregnant, we may ask you to provide us with a urine sample so that we can confirm that you are not pregnant.

Following this first study visit, you will be asked to track your symptoms over a 7-days using an electronic wrist device that looks like a watch. Questions to assess your pain, fatigue, and sleep quality will be asked at 3 timepoints throughout the day through the wrist device or sent via text message. You will then have access to a 4-week, online, self-management program for pain known as PainGuide.

During this time and throughout the study, you will be able to explore the online program and use this resource as often as you like.

4.1.2 Study visit 2

Once the 4-week PainGuide exploration part of the study is complete, you will take part in a second study visit. At this visit, you may be randomly assigned to 1 out of 4 treatments listed below. If your pain is much improved at this point, you may be asked to continue follow-up study visits with no additional treatments.

1. **Physical therapy and exercise:** If you are assigned to this group, you will take part in 10 physical therapy visits over the course of 8 weeks. During this time the physical therapist will also help you identify some daily exercises and stretches to do on your own at home. You will be keeping a log during this time to track how much exercise you are engaging in. PT sessions may be recorded for quality assurance.
2. **Mindfulness-Based Stress Reduction (MBSR):** If you are assigned to this group, you will take part in 9 group sessions. The group sessions will be divided into 8 weekly 2-hour sessions and one 6-hour "retreat". During these sessions you will practice mindfulness exercises directed by a MBSR therapist. You will also be asked to practice daily formal mindfulness at home using audio recordings of 30-45 minute guided meditation exercises. These audio recordings can be accessed online. You will be asked to keep a daily log to track your at-home practice. These sessions may take place in-person or virtually. MBSR sessions may also be recorded for quality assurance.
3. **Self-administered acupressure:** If you are assigned to the acupressure group, you will perform self-acupressure using a device called the "AcuWand." This will be done for 30 minutes daily, for 8 weeks. You will use a mobile application (app) called "MeTime" that will have daily instructions on how to use the AcuWand. Research staff will show you how to use the AcuWand and MeTime app. You will also keep a daily log to track your at-home acupressure sessions.
4. **Duloxetine**: If you are assigned to the Duloxetine group, you will receive an 8-week regimen of Duloxetine, an FDA-approved medication for chronic low back pain. You will record your dosage and any missed doses or side-effects you may have. Also, you will take part in three scheduled phone visits to discuss the use of this medication.

4.1.3 Study visit 3

After your first 8-week treatment, you will complete a third study visit. This will include a combination of in-person and virtual/telephone visits, as mentioned earlier in this section. At this time:

- *If your pain has greatly improved,* you will not be randomly assigned to another treatment. We will still ask you to complete the remaining study visits.

- *If there is only moderate improvement or mild improvement in your pain,* you will be randomly assigned to one of the other three treatments that you did not already receive.

4.1.4 Study visits 4 and 5

After the second 8-week treatment, you will have a fourth assessment visit and then one final study visit 3 months later. These study visits will also be done in-person and virtually. Throughout the study, you will also be asked to complete brief surveys online every other week.

4.2 Optional Deep Assessment Visits

If you meet additional study criteria, you may be invited to take part in two more study visits. These visits will be offered to 160 out of the 600 participants. This more in-depth assessment is referred to as the "deep" visit. These visits are to better understand what is causing chronic low back pain in your body. There are several parts of the deep visits: sensory sensitivity testing, imaging of the brain (fMRI), blood draw, and monitoring your vitals. Testing is done at one of Michigan Medicine's Domino Farms locations in Ann Arbor. You may also be invited to have a deep visit if you get a treatment on your own, outside of the study for your pain (described in section 4.3).

4.2.1 Who can take part in the optional deep visits?

Interested participants who are right-handed and are able to undergo an fMRI.

4.2.2 What will I have to do if I choose to participate in the optional deep assessments?

If you choose to take part in the deep visits, we will collect your vitals- such as heart rate, blood pressure and body temperature. We will also test your sensitivity to different stimuli, such as pressure-pain, vibration, sounds and images. This part of the visit will be completed at Domino Farms.

Additionally, you will be asked to go to a UM medical facility for imaging of your brain (fMRI). We will use fMRI to track areas of the brain that are involved in thinking about and processing pain. The fMRI scans and records your brain's physical structure and activity. The fMRI procedure involves lying on a padded table that slides into a hollow machine. You will lie in the scanner with a coil around your head. We will ask you to keep your head still so the magnet can get clear images of your head and the blood flow in your brain. Some of these images will be taken while you are resting and others during the sensory testing procedures described above. We will ask you to complete an MRI Safety Screening form for each fMRI scan to ensure it is safe for you. If it is determined that an fMRI poses minimal risk to you, you will be asked to lie on your back for up to 90 minutes in the scanner. After approximately 40 minutes of being in the scanner, we will help you out of the scanner for a short 15-20-minute break. During this break you will perform the physical movements (i.e., arching/bending your back). You will then be helped back into the fMRI to immediately scan your brain after these movements.

During the fMRI scan we will use a monitoring device to measure your breathing, temperature, heart rate and flushing in your skin. This device will use sensors placed above and below the heart and a belt placed just below your ribs. A gel may be placed on the skin below the sensor to improve signal quality. A sensor will be placed on the fingertips of the index and middle finger.

4.2.3 Deep Assessment Visits – Additional blood draw

Approximately 1 tablespoon of blood will be drawn during the first deep visit.

4.2.4 How much of my time will be needed to take part in the deep study visits?

For two deep visits, your total time commitment is 12 hours (6 hours per day) that will occur over the first 4 months of the study.

4.2.5 When will my participation in the study be over?

Your participation in the study will be over after your fifth study visit, approximately 9 months after your first study visit.

4.3 Upcoming non-study treatments triggering deep assessments

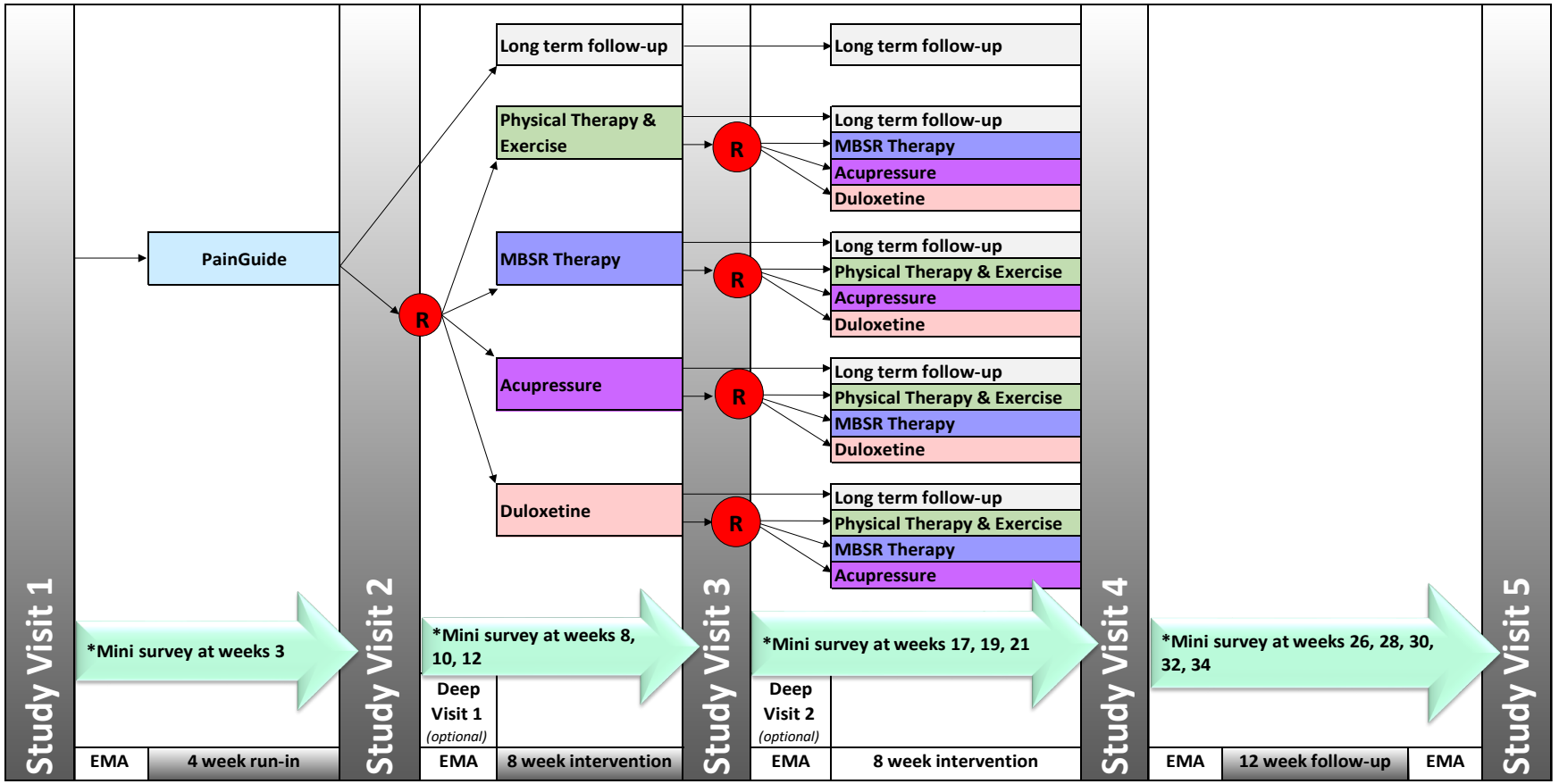
If you are scheduled to receive a pain intervention (such as an epidural steroid injection, facet joint injection or back surgery) as part of your clinical care while you are in the study, you may be eligible for an optional additional deep study visit.

You must meet the deep eligibility criteria to take part in these visits. We will ask about plans for new pain interventions every time we collect questionnaires. If you are interested in a deep visit, we will schedule this for you at Domino farms ***before*** your non-study treatment. You will also be asked to complete some online follow-up questions at 4 and 8 weeks after that non-study treatment.

4.4 Other non-study treatment triggering follow-up assessments

If you receive any treatments outside of the study (such as physical therapy, injection therapies or psychological or manual therapies etc.) while taking part in the study, you will be asked to complete two brief study surveys.

You will be asked about these treatments every time you complete questionnaires for the first 6 months of the study. If you answer yes, you will be asked to complete short follow-up questionnaires. These follow-up questionnaires will be emailed to you 4 weeks and 8 weeks after the treatment. You will only be asked to do this for the first such treatment.



R= Randomization
EMA= Pro-diary wrist device
MBSR=Mindfulness based stress reduction
***=completed remotely online**

Figure 2 BACPAC study visits and timeline

4.5 Genomic data sharing

4.5.1 What are we collecting?

We will collect and store information about your genes. The DNA contained in your genes holds the instructions that your body uses to grow and function. Your genes are responsible for your physical features such as eye color, blood type, and how your body breaks down medications. Genes can also be responsible for some medical conditions.

Genomic information relates to the structure and function of all the genetic material in the body.

4.5.2 Who sees this information?

As this research receives funding from the National Institutes of Health (NIH), we will submit your genomic information to a public repository approved by NIH. NIH is a national research agency and is part of the federal government.

We will label your genomic information with a code, instead of your name or other information that people could use to directly identify you. Even so, there is a possibility that when your genomic information is combined with other information available to researchers, either now or in the future, they may be able to identify a group you belong to (like an ethnic group or a disease population) or, less likely, you personally. NIH prohibits people from trying to identify individuals whose genomic information is in an NIH-designated repository.

We will submit your genomic information to a repository to be used for scientific purposes. A repository securely contains information from many people that can be used in medical research. Some repositories are maintained by the University of Michigan, some are maintained by the federal government, and some are maintained by private companies.

Researchers will have *controlled access* to your specific genomic information. Controlled access means that researchers will need approval from NIH in order to obtain genomic information from the repository.

4.5.3 What if I change my mind?

If you allow us to put your genomic information in the repository, you can change your mind later and ask us to remove it. Keep in mind, however, that we cannot take back information that other researchers have already obtained from the repository.

4.6 Collection for Future Research

4.6.1 What are we sharing?

Along with the main study, we may also use identifiable data and/or biospecimens for future research. Biospecimens could include blood, saliva, and genetic material. The future research may be the same as this study or may be completely different. We would also like your permission to keep the information collected in the main study, so that we may study it in the future.

We may share your medical information, blood, saliva and urine samples with other researchers, so that they can use it in their research. Their research may be like to this study or may be completely different.

Data collected in this study with the Pheno device, including sex, birth year, height, weight, motion assessment data, and answers to questionnaires as part of the planned equipment evaluation will be stored electronically in a digital cloud platform managed by Ohio State University. Data will be stored on secure and encrypted servers residing within the United States. Only OSU researchers or personnel authorized by OSU administration will have access to the cloud platform and the data you share with OSU. Note that your data may be shared with individuals outside of OSU.

There is a slight risk of breach of confidentiality or that someone might gain access to your data that is not authorized to do so. To protect against this risk, OSU will not be receiving identifying information with your data, will ensure that data is encrypted, and has gone through a thorough Security Risk Assessment at OSU to be able to store protected health information. Information that could be used to detect that you participated in the study or link your identity with your data such as birthdate, name, or contact information will NOT be shared with OSU or entered into this platform. Your collected data will be associated to you with a unique coded identifier such as SUBJ-00001 to protect your identity, and OSU researchers will not have the code to identify you. Since OSU will not have access to your contact information, they will not contact you in the future for any reason.

Your coded data will be combined with other similar spine databases in a data repository or data bank to support other related or unrelated research, development, and commercial purposes without additional consent from you. Your data will be stored indefinitely.

Any future use of your identifiable data and/or specimens will be done according to regulatory guidelines.

If you decide not to let us keep your samples and medical information for future research, you can still take part in the main study

4.6.2 Who sees this information?

Once we have shared your samples and medical information with other researchers, we will not be able to get it back. With permission, this information and samples may be shared with researchers here, around the world, and with companies.

If you agree, your data from the Pheno device, will be shared with Ohio State University. The university may sell or share your data with others, such as private companies, government agencies, or other universities. The university will be paid if your data are sold. Your data may be used to make new products or technologies. You will not be paid if these new products or technologies are sold or make money. You cannot choose how your data will be used. If you do not want to let others decide how your data will be used, then you should not donate your data.

Also, information or biospecimens may be stripped of identifiers and used for future research studies. This information may also be shared with researchers for future studies without additional informed consent.

4.6.3 What if I change my mind?

If you would no longer like your Pheno device data to be included in the data repository, you may do so by contacting the study team to end your participation. Your data will no longer be used for future efforts and will be removed from the data repository.

Even if you give us permission now to keep some of your samples and medical information, you can change your mind later and ask us to destroy it. Keep in mind, that once we have analyzed your samples we may not be able to take the information out of our research.

4.6.4 Will I benefit from this use?

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

You will not find out the results of future research on your blood, urine and saliva samples. Allowing us to do future research on your blood samples, saliva samples, and medical information will not benefit you directly.

4.7 How much of my time will be needed to take part in this study?

You will be asked to commit about 12 hours over 9 months for research visits and survey completion. Additionally, you will be randomized to treatments and the amount of time required will vary based on the treatment (see Table 2).

Table 2 Additional time required per treatment

Treatment	Time Commitment (hours)/Number of weeks
MBSR	22 hours/8 weeks
PT and Exercise	10 hours/8weeks
Duloxetine	1 hour/8 weeks
Acupressure	28 hours/8weeks
Optional Deep Assessment	12 hours/9 weeks

4.8 When will my participation in the study be over?

Your participation in the study will be over after your fifth assessment visit at approximately 9 months after your first visit.

4.9 What will happen with my information and/or biospecimens used in this study?

Your biospecimens and collected information may be shared with National Institutes of Health (NIH) and National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS).

With permission, your samples and collected information may be shared with researchers, here, around the world. We may also share this information with the companies. Additionally, this information may also be shared with the study sponsor.

Your identifiable private information or identifiable biospecimens will be stripped of identifiers and may be used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

Table 3 BACPAC Study Risks and Protections

Known/Expected Risks	Description of Risk	What will the researcher do to protect me
General Study- Risk and Protections		
Questionnaire Risks	Distress/ discomfort with health history questions	Participants are encouraged to clarify questions/ issues with staff. Such distress is expected to be rare.
Therapeutic Intervention	Emotional discomfort when asked about life or symptoms	
Breach of Confidentiality	Lab samples and inflammatory markers	Samples will be stripped of any identifying information before it they are shared.
	Possible loss of confidential medical information (see section 9 for more information)	Information will be stored in a locked room, locked cabinet. Electronic data will be stored on an encrypted database. For both, only authorized study staff will have access.
Blood Draw	Hematoma/ bruising at site of blood draw	Blood draw performed by trained professionals, who will apply pressure to reduce bruising
	Infection at site of blood draw	Collection done in sterile manner
	Feeling light headed or passing out (vasovagal symptoms)	Study team will be trained to address vasovagal symptoms
Imaging Risk (MRI, fMRI)	Metal objects in body can shift, causing damage	Additional safety screening questions make sure risk is low
	Metal objects worn/ carried can be pulled to magnet and can strike participant	
	Pacemakers can be disrupted	
	No known risks with the static magnetic field, could be unknown risks associated with exposure, especially to fetus.	
	Radio waves can heat metal objects in body causing burning	
	Risk of discomfort/anxiety being in a small space	Blankets and pads will be provided for patient's comfort

	Ringing in ears after fMRI	Participants will wear earplugs to reduce experience of loud noise
	Light touching sensation on skin surface causing mild discomfort but no harm	Test can be stopped at any time
Pheno Device	Light low back muscle fatigue or soreness the following day similar to a light workout following the motion assessment	Participants will be asked to perform the motions as fast or as far as you can COMFORTABLY
	Some motions from the motion assessment may flare-up your low back pain symptoms similar to other activities of daily living	
	Irritation, pinching, rubbing, or sticking of skin from motion harness components	Test can be stopped at any time
	Piercings or other wearable materials (e.g. insulin pump) snagging during the motion testing.	
	Loss of balance while performing the motion assessment causing a fall.	
	There is a very small risk of electrical leakage or electrical shock from the motion sensors, similar to the risk of using a battery powered electronic device such as a wireless mouse, smart watch, or a Fitbit activity monitor.	
	There is a very small risk of the sensors in the device interfering with a medical device. The risk of this happening is very unlikely as the Bluetooth signal used in the sensors is similar to that used in a wireless mouse or wireless headphones.	

	There is a very small chance that the data collected could be identified as yours or given to someone outside of the research study. The risk of this happening is very unlikely, but may increase in the future as technology changes.	Only coded data will be used for the Pheno device to minimize this risk
Pro Diary-Accelerometer	Discomfort or irritation wearing the device	Patient will be informed that it takes a day or two to get used to the device
PainGuide	No known risks	Participants may contact study staff with any concerns or questions
Intervention Risks and Protections		
Physical Therapy/ Exercise	Mild Muscle Soreness	Participants are encouraged to report what is causing pain/ fatigue, or if pain increase lasts more than 2 hours. Instructions will be given to help relieve pain, like ice packs
	Temporary Fatigue	
	Pain	
Mindfulness Based Stress Reduction	No known risks	Participants may contact study staff with any concerns or questions
Acupressure	No long-term risks	Participants may contact study staff with any concerns or questions
	Chance of bruising	Participants will be trained on correct amount of pressure to use with AcuWand. AcuWand has built-in "buzzer" to notify participant when the correct pressure is reached. Participant may withdraw from the intervention if it becomes uncomfortable
Duloxetine	Nausea, vomiting, dry mouth, diarrhea, fatigue, difficulty sleeping, dizziness, light-headedness, mood swings, sexual dysfunction, and rarely, allergic reaction.	Gradual dose escalation and ask participants to take medicine with food

	Increased risk of suicide	Exclusion criteria for at-risk populations of those under 25 or those with a history or active thoughts of suicide
	Unknown risk to fetus	**WOMEN** There could be risks to a fetus in this study. If you are pregnant or become pregnant during the study, these risks could affect you or your fetus. Women must agree to either abstain from sexual activities that could result in pregnancy or use at least one acceptable method of birth control (i.e. condom, IUD, pill) while taking part in this study. **MEN** Men must agree to either abstain from sexual activities that could result in pregnancy or use an acceptable form of birth control while taking part in the study. Acceptable forms of birth control are male latex condom (with or without spermicide) or vasectomy.
Deep Study Visits- Risks and Protections (if applicable)		
Deep- Sensory Testing	Skin reddening, indentation or bruising	All tests designed to be as brief as possible and follow safety standards. Tests can be stopped at any point. Usually, any discomfort goes away quickly.
	Headache/nausea related to visual stimulation	
	Cold or hot water, cold pack wrap, visual, or auditory tests could lead to mild discomfort	
Deep- fMRI	Same as imaging risks above	
Deep- Autonomic Nervous System (ANS) Monitoring	Sensor may cause irritation to the skin	Occurs rarely and test can be stopped at any time
	Allergic reaction to gel	Gel will not be used
	Burning sensation from gel	Gel will be removed
	General anxiety or unease	Test can be stopped at any time

	Finger probe may be uncomfortable	Probe can be removed at any time
Deep- Back Maneuvers	Temporary increase in low back pain before or during fMRI session	
Discomfort associated with the non- pharmacological interventions		You may withdraw from the study at any time and this will not affect your medical care

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?
The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

5.3 If I take part in this study, can I also participate in other studies?
Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?
You may not receive any personal benefits from being in this study. All information learned from this study could help medical persons better manage and treat patients with chronic pain.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?
Taking part in this study is voluntary. You have the right to choose not to take part in the study. Ask your regular doctors about other treatment options if you decide not to take part in the study.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 “Contact Information” (below).

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
No, there will be no harm to you in most of the interventions if you leave the study early; however, if you are in the duloxetine group, you will need to slowly decrease or *taper* your medications and should consult with study staff or your doctor. There may be some follow-up questionnaires that we will ask you to complete prior to ending your involvement with the study.

7.3 Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changed and you need treatment that is not allowed while you are taking part in this study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?
The study will pay for research-related items. Treatment or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researcher's telephone number listed in Section 10.1.

The study team has given you instructions about this research study. It is important that you follow these instructions carefully. If you get sick, have a medical complication, or are injured as a result of your being in the study, notify the study team immediately, at 734-763-5226. The doctor will either treat you or send you to another doctor for treatment. You or your health plan must pay for any treatment that is part of your usual medical care or that is related to a medical condition you may have. It is not the general policy of the federal funding agencies to compensate or provide medical treatment for human subjects in federally funded studies.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?
You could be paid $600 for your study participation and an additional $500 for completing the optional deep visits. You will be paid $50 for completing at least 80% of the related activities in your first treatment. For some scheduled treatments outside of the study (non-study treatments), you could get paid an additional $260 for completing a deep visit before that pain intervention. You will receive a non-monetary incentive (study logo water bottle and backpack) at the T2 and T3 visit. A breakdown of these payments can be found in Table 4.

8.3 Who could profit or financially benefit from the study results?
Drs. Harte, Clauw and Kruger, along with the University of Michigan, have an interest in the company which makes devices used in the study. In the future, they might receive a part of the profits from any sales of the devices or the company.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

TABLE 4: Study Activity	Payments
All Participants	**$600**
Study visits (5 total)	$40 ($200)
Blood draw	$10
Vitals and physical exam	$50
MRI	$90
Hospital parking	$5
Symptom monitoring (EMA-5 total)	$15 ($75)
Mini-assessments (12 total)	$10 ($120)
Completion of 1st treatment	$50
Optional Deep Visits	**$500**
Study visits (2 total)	$100 ($200)
fMRI and blood draw (2 total)	$145 ($290)
Hospital parking (2 total)	$5 ($10)
Unscheduled Deep Visit Triggered by Non-Study Intervention	**$260**
Study visit	$100
fMRI and blood draw	$145
Follow-up surveys (2 total)	$5 ($10)
Hospital parking	$5
Unscheduled Non-Study Treatment Follow-up	**$10**
Follow-up surveys (2 total)	$5 ($10)

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how your privacy will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?
All biospecimens and health information will be labeled with a study ID number. All identifying information, like name, birth date and medical record number will be removed (de-identified). This prevents any identifiable information from being linked back to you. This information will be shared with the National Institute of Health biorepository at the University of North Carolina.

Identifiers will be kept indefinitely in a secure database at the University of Michigan. The database is password protected and only accessible by research staff.

9.1.1 What is a Certificate of Confidentiality?

This research holds a Certificate of Confidentiality (CoC) from the National Institutes of Health (NIH). This means that we cannot be forced to disclose any research information that may identify you,

even under a court subpoena. In general, we will use the CoC to resist any demands for information that would identify you, except in the following cases:

- For anything you give consent for the researchers to disclose,
- If you share anything that by Federal, State, or Local law we must report to officials,
- For auditing by the U-M Institutional Review Board or the NIH, or
- For any research records you authorize us to release to others

9.1.2 Genetic Information Nondiscrimination Act (GINA)

The federal law called Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. However, GINA does not protect you against discrimination by companies that sell:

- life insurance
- disability insurance
- long-term care insurance

Under GINA:

- Health insurance companies and group health plans may not:
  - request your genetic information obtained in this study
  - use your genetic information when making decisions about whether you can receive insurance or how much your insurance costs you
- Employers with 15 or more employees may not use your genetic information obtained in this study when:
  - making a decision to hire, promote, or fire you
  - setting the terms of your employment

GINA does not apply to the following groups, although they all have policies that provide similar protections:

- members of the US Military receiving care through Tricare
- veterans receiving care through the Veteran's Administration (VA)
- the Indian Health Service
- federal employees receiving care through the Federal Employees Health Benefits Plans

9.1.3. ClinicalTrials.gov

A description of this clinical trial will be available on http://www.clinicaltrials.gov/. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?

By signing this form, you give us your permission to obtain, use, and share health information about you for this study. You must give this permission in order to take part in the study.

Medical information and billing records are called *protected health information (PHI).* PHI is protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). If you sign this form, we may obtain PHI about you from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records
    - including test results (X-rays, blood tests, urine tests, etc.)
- Mental health care records
    - except psychotherapy notes not kept with your medical records
- Alcohol/substance abuse treatment records
- Health plan/health insurance records
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Demographic information (you sex, age, ethnicity etc.)
- Personal identifiers (your name, Social Security number, birthdate, etc.)

There are many reasons why we or others might see or use information about you during or after this study. Examples include:

- We may need the information to make sure you can take part in the study.
- We may need the information to check your test results or look for side effects.
- University, government officials such as the Food and Drug Administration (FDA) and/or the IRB (a committee that reviews research to ensure that it complies with federal and institutional rules) may need the information to make sure that the study is done in a safe and proper manner.
- Companies sponsoring or paying for the study, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- We may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UMHS medical record.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- Federal or state law may require us to give information to government agencies. For example, we may report information in order to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article but would not include any information that would let others know who you are.

The results of this study may be published or presented at a scientific meeting. If your name or other information that might identify you will be used in the publications or presentations, we will ask for your separate written permission.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?

As a rule, the researchers will not continue to use or disclose information about you but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission, or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within Michigan Medicine, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Section 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission to use my PHI expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator:	Afton L. Hassett, Psy.D.
Mailing Address:	Chronic Pain & Fatigue Research Center 24 Frank Lloyd Wright Drive, Lobby M Ann Arbor, MI 48106
Telephone:	734-763-5226
Study Coordinator:	Elizabeth Banner
Mailing Address:	325 E Eisenhower Pkwy Ste 100 Ann Arbor, MI 48108
Telephone:	734-763-5226
Email:	BACPACstudy@med.umich.edu

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about the study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

Please check an option below:
I agree to be re-contacted in the future. ☐ Yes ☐ No _____(initials) Date:_____

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?
Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document that is signed and dated. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*

12. SIGNATURES

Consent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____Date of Signature: _____

Consent to video/audio recording/photography solely for purposes of this research

This study involves video and/or audio recording and/or photography. If you do not agree to be recorded, you can still take part in the study.

_____ Yes, I agree to be video/audio recorded/photographed.

_____ No, I do not agree to be video/audio recorded/photographed.

Print Legal Name: _____

Signature: _____

Consent to Collect for Unspecified Future Research

This project involves the option to allow the study team to keep your identifiable specimens/data for use in future research. I understand that it is my choice whether or not to allow future use of my specimens. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

_____ Yes, I agree to let the study team keep my specimens for future research.

_____ No, I do not agree to let the study team keep my specimens for future research.

Print Legal Name: _____

Signature: _____Date of Signature: _____

Consent for Participating in the Optional Deep Assessment

This project involves optional participation in a sub-study. I understand that it is my choice whether or not to take part in the sub-study. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

_____ Yes, I agree to take part in the optional deep assessments.

_____ No, I do not agree to take part in the optional deep assessments.

Print Legal Name: _____

Signature: _____

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____Date of Signature: _____