Resilience Skills Self-Management for Chronic Pain (PRISM Study)

NCT03304613

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UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

INFORMATION ABOUT THIS FORM

You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

Please take time to review this information carefully. After you have finished, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

1. GENERAL INFORMATION ABOUT THIS STUDY AND THE RESEARCHERS

1.1 Study title: Resilience Skills Self-Management for Chronic Pain (PRISM Study)

1.2 Company or agency sponsoring the study: Department of Anesthesiology, University of Michigan

1.3 Names, degrees, and affiliations of the researchers conducting the study:
Afton L. Hassett, PsyD, Associate Research Scientist, Department of Anesthesiology, University of Michigan
David Williams, PhD, Professor, Department of Anesthesiology, University of Michigan
Chad M. Brummett, MD, Associate Professor, Department of Anesthesiology, University of Michigan
Terri Voepel-Lewis, RN, PhD, Associate Research Scientist, Department of Anesthesiology, University of Michigan
Daniel Clauw, MD, Professor, Department of Anesthesiology, University of Michigan
Jenna Goesling, PhD, Assistant Professor, Department of Anesthesiology, University of Michigan
Alexander Tsodikov, PhD, Professor of Biostatistics, University of Michigan
Stephanie Moser, PhD, Data Analyst, Department of Anesthesiology, University of Michigan

2. PURPOSE OF THIS STUDY

2.1 Study purpose:
This study will test different ways to improve pain and functioning experienced by people with chronic spine pain. Participation in the study involves four research visits (including this screening session), the completion of questionnaires, some functioning test (e.g., walking for 6 minutes) and fasting blood draws. There will also be weekly phone calls and online skills-building activities for two of the three groups.

3. INFORMATION ABOUT STUDY PARTICIPANTS (SUBJECTS)

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?
Men and women between the ages of 35 and 65 with a primary diagnosis of back or spine pain from the Back and Pain Center at the University of Michigan who also have pain that is more widespread (i.e., meet the criteria for fibromyalgia) can take part in this study.

3.2 How many people (subjects) are expected to take part in this study?
We expect to enroll 300 patients over the course of this study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

If you agree to take part in this study and sign this consent form, you will be enrolled in the study. The study requires 4 visits with the research team. These will take place either at the Back and Pain Center, or via a video conference or phone visit. Your initial visit will involve going over the study requirements in detail along with an electronic medical records (EMR) review, completing questionnaires, and may include a physical functioning test (that mostly consists of walking and standing and sitting), clinical data collection, urine pregnancy test if potentially pregnant, and a fasting blood draw. If you are not fasting at this initial visit, you may be asked to return for a fasting blood draw within the next 5 days. The blood samples will be processed by our team in the Chronic Pain and Fatigue Research Center and our collaborators at the Blackburn Lab at University of California at San Francisco. You will not be offered any genetic testing as analysis will be anonymous. With or without the blood draw, you will be randomly assigned (like drawing straws) to one of three groups:

1. Thoughts and Self-Management (eCBT)
2. Coping and Self-Management (PRISM)
3. Standard Care

All three groups will receive standard medical care including physician visits, medication maintenance, physical therapy as indicated, and patient education. The Standard Care group will not have any additional activities; however, those in the other two groups will take part in a self-management program delivered largely online by our medical assistants.

If you are assigned to one of the two self-management groups, the medical assistant will provide an overview of the program and show you how to access the study websites that feature the group modules (FibroGuide / PRISM). You will be asked to complete one module per week for 8 weeks. An example of the modules for eCBT include: being more active, improving sleep, relaxation training, reframing thoughts, and better communication. Examples of the PRISM modules include: being more active, improving sleep, performing kind acts, relaxation, savoring and mindfulness, and reframing thoughts. The materials you will need for the modules including forms for the written aspects of the module (worksheets) will be provided in the first visit and also available online. You will keep a study journal, recording the total number of minutes dedicated to study-related activities daily. The medical assistant will call you on a weekly basis to act as your “coach” for the program. Your study coach will provide instructions and answer your questions.

Participants in all three groups will be contacted by phone to schedule the first follow-up visit that will occur around eight weeks after this initial visit. During follow-up visits, changes in medications, new diagnoses, and other interventions for your pain, including changes in exercise, will be logged. You will complete a similar set of questionnaires and may get another fasting blood draw. Six and twelve months later, you will be contacted again for another similar follow-up visit where you will again complete questionnaires, and may complete a physical functioning test and a fasting blood draw. The study team will also send text message reminders prior to follow-up visits.

Each blood draw will be up to 15ml of blood (about 1 tablespoon).

As a subject participating in this research study, you have certain responsibilities that may apply to this study, such as ensuring that you arrive at all of your scheduled appointments, follow directions appropriately and report any adverse events to study personnel that may take place during the study.

4.2 How much of my time will be needed to take part in this study?
You will have 4 assessment visits with the research team for this study. Each assessment visit will take approximately one hour, for a total of 4 hours. There is the initial study visit, a visit 8 weeks later, a visit 6 months after that and a final follow-up visit 12 months later (total of approximately 14 months). For the participants assigned to the self-management groups, you will receive a weekly call from your medical assistant coach (approximately 10-15 minutes) and engage in program activities, including study modules, every week requiring about an hour or two of your time each week (approximately 15 minutes a day). You may choose to put in more or less time.

4.3 When will my participation in the study be over?
Your participation in the study will be over after your 12 month follow-up visit.

4.4 What will happen with my information and/or biospecimens used in this study?
With appropriate permissions, your samples and collected information may also be shared with other researchers, here, around the world, and with companies.

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

5. INFORMATION ABOUT 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?
The known or expected risks are:

- *Discomfort associated with being asked personal questions about health history and the completion of questionnaires.* Any participant becoming distressed while completing questionnaires will be encouraged to seek clarification from the research staff of any questions that they find to be unclear or troubling. All participants are told that they have the option to terminate participation without penalty and/or will be assisted in arranging medical/ psychiatric help including, if necessary, emergency treatment.

- *Therapeutic intervention*. Our interventions could cause emotional discomfort in as much as participants are asked to reflect on their lives and their symptoms. However, we expect negative effects to be extremely rare.

- *Breach of Confidentiality.* A breach of confidentiality will be considered a “definitely related” Serious Adverse Event. As such, it will be reported to the University of Michigan IRBMED within 7 days of occurrence, and a remediation plan will be put in place immediately. A number of safeguards to minimize this risk are described below.

- *Blood draw.* There is a slight risk of developing a small hematoma (bruise) at the site of the blood draw.

The researchers will try to minimize these risks by being available for questions regarding any issues that are related to the study. 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. OTHER OPTIONS

6.1 If I decide not to take part in this study, what other options do I have?
Your health care provider will discuss with you all other options.

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.

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 changes and you need treatment that is not allowed while you are taking part in the 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 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 researchers’ number listed in section 10.1.

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?
Yes, you will receive a check for $50 for each of the four assessment for a potential total of $200.

8.3 Who could profit or financially benefit from the study results?
At this time, nobody will profit financially from the study results. 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.

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

The information below describes how your privacy and the confidentiality of your research records will be protected in this study.

9.1 How will the researchers protect my privacy?
The blood samples will be sent to the lab for analysis as anonymous (deidentified). All identifying information will be kept indefinitely within a secure database housed at the University of Michigan. The database is password protected and only accessible by research staff.

9.2 What information about me could be seen by the researchers or by other people? Why? Who might see it?
Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study. Information about you may be obtained 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
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Demographic information
- Personal identifiers

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.

- Study sponsors or funders, 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
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers 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 the study team to give information to government agencies. For example, 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.

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

9.3 What happens to information about me after the study is over or if I cancel my permission?
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 the University of Michigan Health System, 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 Question 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 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).

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:	734-998-6939
Study Coordinator:	Sana Shaikh
Mailing Address:	325 E Eisenhower Pkwy Ste 100 Ann Arbor, MI 48108
Telephone:	734-763-5226

You may also express a 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 (For International Studies: US Country Code: 001)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a 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. (*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.)* You will receive a copy of this signed and dated informed consent.

12. SIGNATURES

Consent/Assent 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.

Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

For use only if required by sponsor:

Date of Birth (mm/dd/yy): _____

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.

Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____