

Official Title: “Toward Thriving: A Set of Reflective Tools to Empower Chronic Pain Patients and Help Them Envision a Personal Path to Thriving”

NCT: NCT05847881

Date: 4/21/2023

UNIVERSITY OF MICHIGAN

CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title:

Toward Thriving (TT) Study

Company or agency sponsoring the study:

Michigan Institute for Clinical Health & Research – Community Engagement

Principal Investigator:

Hannah Smotrich, Associate Professor, Stamps School of Art & Design, University of Michigan

Study Coordinator:

Sana Shaikh, Back & Pain Center Research Program Manager, Anesthesiology, Michigan Medicine

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, 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 consider 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 and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find child care, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

This research is studying whether changing an individual's behaviors may have an impact as a treatment or outcome for chronic pain. The purpose of this pilot study is to introduce and test the usefulness of a reflective process meant to empower people with chronic pain and help support their resiliency and thriving. Your health-related information will be collected for this research study.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study the risks are minimal and may include mental discomfort. More detailed information will be provided later in this document.

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This study may offer some benefit to you now or others in the future by taking time and having structures to examine your supports and barriers, enhance positive emotions, gain health education, and clarify goals and values. Knowing more about the usefulness of these tools introduced in the study may help others in the future. You may also benefit from interactions with other people with chronic pain. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be approximately 15 hours.

You can decide not to be in this study. Alternatives to joining this study include speaking with your doctor about any concerns you may have.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

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

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

The purpose of this pilot study is to introduce and test the usefulness of a reflective process meant to empower people with chronic pain and help support their resiliency and thriving.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't 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 (over the age of 18) who have chronic pain. Chronic pain, for the purposes of this study, is defined as having pain, in any location, that has been present for greater than 3 months.

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

We expect 15-20 people to participate in this study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

In this study, participants will:

- Attend one kickoff meeting.
- Participate in at-home journaling activities for three weeks following the kickoff meeting. Journaling activities will ask participants to reflect on supports and barriers, challenges in daily life, key relationships, values, and goals. Journaling will use standard design research methods including writing, mapping, collage, and photography.
- Attend one interactive workshop session with other participants and share content from journaling activities.
- Attend an exit interview with researchers in May to give feedback about the usefulness of the tool. Interviews will be audio recorded.

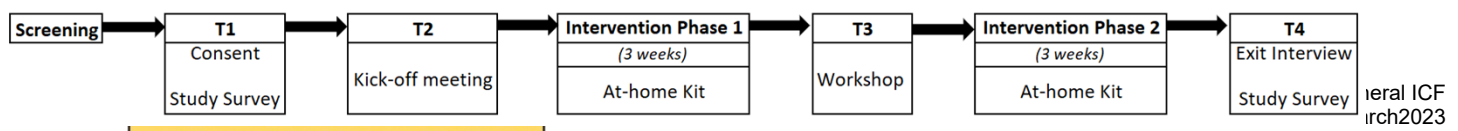


Figure 1 Study Timeline

Besides the information about the main study, the following information is specific to unspecified future use of identifiable data. We would also like your permission to keep some of your medical information collected in the main study, so that we may study it in future research. The future research may be similar to this study or may be completely different.

You cannot take part in the main study even if you decide not to let us keep your medical information for future research.

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

We may share your medical information with other researchers, so that they can use it in their research. Their research may be similar to this study or may be completely different. Once we have shared your medical information with other researchers, we will not be able to get it back.

Future use of your identifiable data and/or specimens will be conducted in compliance with applicable regulatory requirements.

You will not find out the results of future research on your data. Allowing us to do future research on your medical information will not benefit you directly.

With appropriate permissions, your collected information may also be shared with other researchers here, around the world, and with companies.

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

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

Participation will be approximately 15 hours (10 hours of at-home activities, 5 hours of in-person sessions) divided as follows:

- May kickoff meeting (1.5 hours)
- Daily journaling activities (approximately 15-20 minutes per day for 3weeks)
- Workshop (2 hours)
- Exit interview (45 minutes)

4.3 When will my participation in the study be over?

In addition to the time above, we will keep your information for a minimum of **3 years** after your participation and may keep indefinitely for future research.

4.4 What will happen with my information used in this study?

With appropriate permissions, collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information 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 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?

This is a minimal risk study. Potential risks or discomforts from this research include sharing personal information during the kickoff meeting, a workshop session with other participants, or with researchers during an exit interview. When participating in the project you do not have to answer any questions you do not want to answer. The researchers will try to minimize these risks by involving psychologists in the shared group activities (kickoff meeting and workshop session).

There is a possible risk of a breach of data confidentiality. Researchers will collect your personal information for purposes of compensation and communicating project logistics. At no point will this information be linked to the materials collected in the course of the project. Personal information will be stored in a secure location with restricted access and destroyed at the conclusion of the study.

Any material chosen to be published about this pilot project will not contain any information that can identify you.

The researchers will try to minimize these risks by de-identifying participant information when possible.

Additionally, there may be a risk of loss to confidentiality or privacy. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

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 might benefit from being in the study by taking time and having structures to examine your supports and barriers, enhance positive emotions, gain health education, and clarify goals and values. Knowing more about the usefulness of these tools introduced in the study may help others in the future. You may also benefit from interactions with other people 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?

This study is voluntary and you may leave the study at any time.

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".

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 if you leave the study before it is finished.

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?

There are no costs or billing for this 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 researcher's telephone 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?

You can receive up to \$250 for participating in this study.

You will receive a \$150 for completing the at-home activities in phase 1 and attending the workshop (T3). You will receive an additional \$100 after completing at home activities in phase 2 and exit interview (T4).

Because this study pays more than \$100, the University of Michigan will collect and safely store your name, address, social security number, and payment amount for tax reporting purposes. If you receive more than \$600 in payments in a calendar year, this information will be sent to the Internal Revenue Service (IRS) for tax reporting purposes and an extra tax form (Form 1099) will be sent to your home. If you are a University of Michigan employee, your research payments are tracked separately and are not included as part of your payroll.

8.3 Who could profit or financially benefit 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 the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?

Your research information will be stored in a locked cabinet and will not be made a part of your regular medical record. All electronic records will be stored on an encrypted database with access limited to study team members.

If you tell us or we learn something that makes us believe that you or others have been or may be harmed, we may be required to report that information to the appropriate agencies.

A description of this clinical trial will be available on <http://www.clinicaltrials.gov/>, as required by U.S. Law. 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.

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

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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.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI 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)
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Billing information
- Demographic information
- Personal identifiers
- Other information

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.

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.

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 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 to use my PHI expire?

Your permission will not expire unless you cancel it. 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: Hannah Smotrich

Email: smotrich@umich.edu

Telephone: 734-730-9134

Study Coordinator: Sana Shaikh

Email: BPCresearch@med.umich.edu

Telephone: 734-763-5226

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 (For International Studies, include the appropriate [calling codes](#).)

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.

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.)*
- Journal
- Appointment information

12. SIGNATURES

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Sig-A

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 [NAME OF STUDY TEAM MEMBER OBTAINING CONSENT] _____. 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 (mm/dd/yy): _____

Sig-B

Consent/Assent 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/CANNOT] 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: _____

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

Sig-D

Consent/Assent 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 (mm/dd/yy): _____

Sig-G

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 (mm/dd/yy): _____