Partners for Pain & Wellbeing Equity: A Randomized Trial of Community Supported Complementary and Integrative Health Self-management for Back Pain

Informed Consent Form – English
IRB Approved May 8, 2023

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University of Minnesota

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Partners4Pain Study
Informed Consent form

partners4pain.org

Better Together

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ABOUT THE PARTNERS4PAIN STUDY
The following is a short summary to help you decide whether to be a part of this research study. More detailed information is given later in this form.

All study materials are offered in English. If English isn't your primary language, this form, and some other materials are currently available in Spanish.

Purpose of the Study
The goal of this study is to work with people who have back or neck pain. We also want to work with people who have not been included in back and neck pain studies. Examples include Black, Indigenous and People of Color, and people with less money.

We would like to learn what people think about two educational programs (Partners4Pain or Keys to Wellbeing). This information will be used to improve the programs so they meet peoples' needs. The programs will then be tested in a future, bigger study. This study will then help others in the community get resources to help with pain.

Study participation is up to 3 months; there is no charge to be in the study.

Risks of Participation - you may experience one or more of the following risks:
- Discomfort from answering personal questions or participating in a group program
- Mild physical discomfort from doing exercises
- Feeling emotional when doing mind-body exercises (e.g., meditation, guided imagery)
- Feeling nervous or uncomfortable when talking about your pain or overall health
- Changes to how your back or neck pain feels

Potential Benefits - you may experience some benefits including the following:
- Learning new information about pain and ways to take care of it
- Learning new information about overall health and wellbeing
- Experiencing health benefits, including decreased stress and increased wellbeing
- Experiencing improvement in pain symptoms
- Experiencing improvement in the ability to do daily activities

Alternative treatments – Participating in this study is optional. If you do not participate, you can choose one of the following:

- Continue with what you are currently doing for treatment
- Seek a new treatment
- Choose no treatment

What is research?
The Partners 4 Pain study is a small study. It is focused on developing ways to do a larger clinical trial in the future. Clinical trials are a form of research that looks at new ways to prevent, detect, or treat health conditions. The goals of clinical trials are to determine if new treatments are safe and effective. They are also used to explore what participants think of new treatments.

People take part in clinical trials for different reasons. Some people participate to help others and help science move forward. Other people take part so they can receive newer treatments. They also may want the additional care and attention from the research staff. Clinical trials can be a way to help researchers find better treatments for others in the future.

What should I know about being in a research study?

- A member of the research staff will explain this study to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decisions will not be held against you.
- You can ask all the questions you want before you decide to participate or not.

Why is this research being done?
This study is being done to prepare for a larger study comparing two educational programs for taking care of your back or neck pain, and overall well being. One of our goals is to see if people like you are willing to participate in the study. We also want to find out what people like and dislike about the two programs and the research study overall.

Why am I being asked to take part in this research study?
You are being asked to take part because you have neck or back pain. The following pages describe what you can expect in this study.

How long will the research last and how much does it cost?
Your participation is up to 3 months long. There is no charge to take part. You will be given a list of important study dates and locations for in-person visits.

Will I qualify for this study?
To see if you qualify for the study, you will need to do the following:

1. Attend a First Screening Visit (up to 1.5 hours).
   The purpose of this visit is for you to learn about the study and make a decision about whether or not you would like to take part. We also want to make sure that the programs are a good fit for the type of pain you have and that it is safe for you to participate.
   a. You can attend this visit face-to-face using Zoom or in-person at one of our locations.
   b. A research staff member will review this consent form with you. We will go through it section by section and answer your questions. If you agree to take part in the study, you and the staff member will sign the consent form together.
   c. You will complete a survey that helps the research team learn more about you. It will include questions about you, your pain, overall health and life situation (e.g., access to health services and food). It is okay to skip questions you don't feel comfortable answering.

2. Attend a Second Screening Visit (up to 1 hour).
   The purpose of this visit is for you to talk to study staff and get your questions answered. We also will collect additional information to learn more about your pain and your health. Together, we will decide if the study is a good fit for you.
   a. You can attend this visit face-to-face using Zoom, in-person at one of our locations, or by phone.
   b. We will review study details with you and answer questions you may have. It is important that you feel comfortable taking part in the study.
   c. You will complete another survey. It will include questions about you, your pain, overall health and social circumstances (e.g., access to health services and food). It is okay to skip questions you don't feel comfortable answering.
   d. If you qualify for this study and you want to participate, you will be entered into the study. We will use a process called randomization (like the flip of a coin) to decide which educational program you will take part in.

   <u>Important things to consider:</u>
   - Neither you or the research staff can choose which program you will get.
   - You have an equal chance of getting into each of the programs.
   - You will be told which program you will be in.

Educational Programs
The purpose of you taking part in the educational programs is for you to try them out and see what the experience is like for you.

- You will attend **9 sessions, 1 time per week, for 9 weeks.**
- The sessions will happen at the same time each week
- Each session is 90 minutes long (1.5 hours)
- These are group programs. Other people with pain from the community will participate in the sessions at the same time as you.
- Everyone will receive a workbook with activities to complete during the sessions and at home. You will be given additional resources to use (e.g., printed tip sheets, access to a website with videos to watch)
- While you are in the study, you can continue to do the things you normally do for your pain. This includes treatments like medication, physical therapy, heat, exercise.
- You can attend your educational program online **using Zoom <u>OR</u> in-person** at one of our locations. You get to choose how you want to attend the sessions.
- It is very important for the study that you attend as many of the program sessions as possible. If you are unable to attend a session, please contact the study staff.

<u>Zoom Sessions</u>

- You will be with others in a 'virtual room', using Zoom.
- The Zoom App we use is secure and private. It allows people to see and talk to each other using a device like a computer, tablet, or smartphone. You will need one of these devices if you decide to participate on Zoom. The device you use should have a working camera, microphone, speakers, and internet access.
- If you choose to take part using Zoom, you will do ALL sessions in Zoom.

- If you would like to take part using Zoom but do not have the equipment or Internet access needed, let us know. We may be able to provide a private space and equipment at one of our locations for you to join the Zoom sessions.

In-Person Sessions
- You will be with others, in a private room, at one of our locations
- Free parking will be available

Partners4Pain
This group program will teach you about different things you can do to manage your pain. You will watch educational videos and do workbook activities. You will learn and practice different exercises and strategies for your pain. These include back and neck exercises (like strengthening and stretching), mind-body exercises (like meditation, relaxed breathing, guided imagery, and muscle relaxation), problem solving, and how to communicate with others about your pain. You will also have an opportunity to take part in discussions with other group members.

Keys to Wellbeing
This group program will teach you about different things you can do to improve your health and wellbeing. You will watch educational videos and do workbook activities. You will be introduced to different health-related topics. Topics include information and tips about health, pain and wellbeing; keeping active and well; the importance of rest and relaxation; nutrition; working with meaning and purpose in your life, and sorting health facts from fiction. You will learn and practice some physical exercises for your overall health. You will also have an opportunity to take part in discussions with other group members.

Month 2 Follow-Up Survey (up to 40 Minutes)
The purpose of the Follow-Up Survey is for you to share information about how you feel about your pain and overall health after completing the program. We would also like to learn about your opinions about the program and the study overall.
- At the end of the 9 week program, you will be given a survey to complete. This can be done by email or over the phone with the research staff.
- This survey is similar to the ones you completed at the First and Second Screening Visits (at the beginning of the study).
- The survey will include questions about your pain and overall health. You will also be asked about what you liked and didn't like about the programs and the study. It is okay to skip questions you don't feel comfortable answering.
- You will receive regular reminders to complete the survey.
- It is very important for the study that you complete the survey.

Compensation
You will be compensated up to $330.00 for participating in the study.
- You will be compensated for attending two screening visits → Visit 1 = $20.00 and Visit 2 = $20.00
- You will be compensated for attending each of the educational program sessions → Sessions 1-9 = $30.00 per session (total of $270.00)
- You will be compensated for completing the Month 2 Follow-Up Survey → $20.00

Payment will be made using a pre-paid debit card called Greenphire ClinCard. It works like a bank debit card. Hold onto this debit card. We will load the funds to the same card during the study.
You may use this card at any store that accepts MasterCard or you can use a bank machine to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals (ATM use) and lack of activity (no use for 6 months). We will give you an information sheet that answers common questions about the debit card. You will also receive a cardholder agreement. Be sure to read all of this information for details about fees.

The debit card system is administered by an outside company. The company, Greenphire, and MasterCard, will be given your name and address. They will use this information only as part of the payment system. Your information will not be used for any other purposes and will not be given or sold to any other company.

Risks to Study Participation
Every study has risks. The risks in this study are low. We will assess you carefully to make sure it is safe for you to participate in this study. You will not be allowed to participate if we think you have an increased risk of experiencing serious risks or side effects from the study. The following are possible risks:

- Risks associated with study records: There is a very small risk of breach of confidentiality and privacy. We comply with the University's security standards to protect your information. See Privacy and Confidentiality below for more information.

- Risks associated with interviews and surveys: Completing the surveys may cause you to feel uncomfortable when answering personal questions. To reduce this risk, you may choose not to answer certain questions.

- Risks associated with the Partners4Pain program: The risks are considered low. The most common side effects of exercise include mild physical discomfort and soreness in the muscles/joints of the spine (neck and back), hip, or buttock regions. This usually goes away within a day or two. You also may experience some short-lasting emotional discomfort during and outside the sessions when talking about your pain and how it affects your life, and when practicing some of the exercises and strategies you are given (e.g., meditation, relaxed breathing, guided imagery, etc.). Some people also get anxious or nervous in group settings.

- Risks associated with the Keys to Wellbeing program: You may experience some muscle and joint soreness when taking part in suggested physical activities outside the sessions. This is usually mild and short-lasting. You also may experience some short-lasting emotional discomfort during and outside the sessions when talking about your health and wellbeing. Some people also get anxious or nervous in group settings.

- It is normal for people who have back and neck pain to experience changes in their condition over time. Sometimes people notice a change in how their pain feels, how bad it is, how often it occurs, and how it impacts their life. This may occur while you are in the study.

BENEFITS OF STUDY PARTICIPATION
There may be no direct benefit to you from participating in this study. Some participants may experience the following, but this is not guaranteed:

- Learning new information about pain and ways to take care of it
- Learning new information about overall health and wellbeing
- Experiencing health benefits, including decreased stress and increased wellbeing
- Experiencing improvement in pain symptoms
- Experiencing improvement in the ability to do daily activities

Alternative Options
Participating in this study is optional. You may choose to do something different (e.g., try a new treatment) or not do anything at all. There are many options available outside of this study. These include treatments that you get from a healthcare provider, like physical therapy, chiropractic care, medication, massage therapy, acupuncture, steroid injections, and others. There are also things you can do in community settings like attending other programs (e.g. like yoga, Tai Chi, mindfulness, etc.). The research team can discuss these options with you and answer questions you may have.

Privacy and Confidentiality
Any information about you obtained from this research including identifiable medical information will be kept as confidential (private) as possible. All paper records related to your involvement in this research study will be stored in a locked file cabinet. Information obtained electronically will be safeguarded by the use of password-protected databases. Your identity on these records will be indicated by a case number rather than by your name, and the information linking these case numbers with your identity will be kept in a separate and secure location. Although every reasonable effort has been taken, confidentiality during Internet communication activities cannot be guaranteed and it is possible that additional information beyond that collected for research purposes may be captured and used by others not associated with this study.

What happens to the information collected for the research, including my health information?

We try to limit the use and sharing of your information, including research study records, any medical records and any other information about you, to people who have a need for this information. But we cannot promise complete confidentiality.

Overview

If you participate in this study, your information, including your health information, will be used and shared for purposes of conducting this research. As described later in this Consent Form, your information may also be used and shared for publishing and presenting the research results, future research, and any optional elements of the research you agree to in this Consent Form, which may include creating audio and video recordings of you. If you sign this Consent Form, you are giving us permission to use and share your health information for these purposes, and if we are using your medical records, you are giving permission to any health care providers who are treating you to share your medical records with us.

What health information will be made available?

Health information about you to be used and shared for the research includes those items checked by the research team below:

☐ Your medical records, which may include records from hospital and clinic visits, emergency room visits, immunizations, medical history and physical exams, medications, images and imaging reports, progress notes, psychological tests, EEG/EKG/ECHO reports, lab and pathology reports, dental records and/or financial records. These records may be used and shared for as long as this research continues.

☒ Information collected as part of this research study, including research procedures, research visits, and any optional elements of the research you agree to, all as described in this Consent Form. This information might not be part of your medical record, and may include things like responses to surveys and questionnaires, and information collected during research visits described in this Consent Form.

What about more sensitive health information?

Some health information is so sensitive that it requires your specific permission. If this research study requires any of this sensitive information, the boxes below will be marked and you will be asked to initial to permit this information to be made available to the research team to use and share as described in this Consent Form.

☒ My drug & alcohol abuse, diagnosis & treatment records _____ (initial)
☐ My HIV/AIDS testing records _____ (initial)
☐ My genetic testing records _____ (initial)
☒ My mental health diagnosis/treatment records ____ (initial)
☐ My sickle cell anemia records _____ (initial)

Who will access and use my health information?

If you agree to participate in this study, your information will be shared with:

- The University of Minnesota research team and any institutions or individuals collaborating on the research with us;

- Others at the University of Minnesota and M Health/Fairview who provide support for the research or who oversee research (such as the Institutional Review Board or IRB which is the committee that provides ethical and regulatory oversight of research at the University, systems administrators and other technical and/or administrative support personnel, compliance and audit professionals (Such as the Quality Assurance Program of the Human Research Protection Program (HRPP)) , individuals involved in processing any compensation you may receive for your participation, and others);

- The research sponsor(s), any affiliates, partners or agents of the sponsor(s) involved in the research, organizations funding the research, and any affiliates, partners or agents of the funding organization(s) involved in the research;

Sponsor: National Center for Complementary and Integrative Health (NCCIH) - part of the NIH.

- Organizations who provide accreditation and oversight for research and the research team, and others authorized by law to review the quality and safety of the research (such as U.S. government agencies like the Food and Drug Administration, the Office of Human Research Protections, the Office of Research Integrity, or government agencies in other countries); and

- Organizations that process any payments that may be made to you for participating in this study, and any other individuals or organizations specifically identified in this Consent Form.

Study Payments → Greenphire ClinCard

Transportation Plus -This applies only to participants who need the study's help with transportation services to attend study visits. This does not apply to participants who participate on Zoom or to those who arrange their own transportation.

Additional sharing of your information for mandatory reporting

If we learn about any of the following, we may be required or permitted by law or policy to report this information to authorities:

- Current or ongoing child or vulnerable adult abuse or neglect;
- Communicable, infectious or other diseases required to be reported under Minnesota's Reportable Disease Rule;
- Certain wounds or conditions required to be reported under other state or federal law; or
- Excessive use of alcohol or use of controlled substances for non-medical reasons during pregnancy.

How will my information be used in publications and presentations?

We may publish the results of this research in scientific, medical, academic or other journals or reports, or present the results at conferences. Information that makes it easy to identify you (such as your name and contact information, SSN and medical records number) will not be part of any publication or presentation. If you have an extremely unique or rare condition that is not shared by many others, it is possible that some people may be able to determine your identity even without these identifiers.

What will be done with my data and specimens when this study is over?

We will use and may share data for future research. They may be shared with researchers/institutions outside of the University of Minnesota. This could include for profit companies. We will not ask for your consent before using or sharing them. We will remove identifiers from your data which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your specimens or data.

Do I have to sign this Consent Form and give my permission to make my information, including my health information, available for use and sharing?

No, you do not have to sign this Consent Form. But if you do not sign, you will not be able to participate in this research study. Treatment available outside of the study, payment for such treatment, enrollment in health insurance plans and eligibility for benefits will not be impacted by your decision about signing this Consent Form.

Does my permission for making my health information available for use and sharing ever expire?

No, there is no expiration date.

May I cancel my permission for making my health information available for use and sharing?

Yes. You may cancel your permission at any time by writing to the researcher at the address on the first page of this Consent Form. If you cancel your permission, you will no longer be in the research study. You may also want to ask someone on the research team in canceling will affect any research related medical treatment. If you cancel your permission, any health information about you that was already used and shared may continue to be used and shared for the research study and any optional elements of the study to which you agree in this Consent Form.

What happens to my health information after it is shared with others?

When we share your information with others as described in this Consent Form, privacy laws may no longer protect your information and there may be further sharing of your information.

Will I be able to look at my records?

It is possible that the research team may not allow you to see the information collected for this study. However, you may access any information placed in your medical records after the study is complete.

Certificate of Confidentiality

To help protect your privacy, the National Institutes of Health has granted a Certificate of Confidentiality. The researchers can use this Certificate legally to refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings,

for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. It is unclear if the Certificate will work in foreign countries.

The Certificate does not prevent a researcher from reporting information learned in research when required by other state or federal laws, such as mandatory reports to local health authorities for abuse or neglect of children/vulnerable adults, or information to the Food and Drug Administration (FDA) when required in an FDA audit. However, the Certificate limits the researcher from disclosing such information in follow up civil, criminal, legislative or administrative legal proceedings if the information was created or compiled for purposes of the research.

You also should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

New Information
We will notify you if we learn about new information that may cause you to change your mind about taking part in the study.

Clinical Trial Registry
A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by US Law. 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.

Research Related Injury
In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner to you or your insurance company. If you think that you have suffered a research related injury, let us know right away. You do not give up any of your legal rights by signing this form. Be aware that your healthcare payer/insurer might not cover the costs of study-related injury or illnesses.

Voluntary Participation
Your participation in this research study is entirely voluntary. You may want to discuss this study with your family and friends and your care team before agreeing to participate. If there are any words you do not understand, feel free to ask us. The research team will be available to answer your current and future questions.

Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Minnesota. You can withdraw from this research study at any time. Any identifiable research or medical information obtained as part of this study prior to the date that you withdraw your consent will continue to be used and disclosed by the investigators for the purposes described above.

To formally withdraw from this research study, you should provide a written and dated notice of this decision to the principal investigator of this research study (see contact information on the first page of this form).

It is possible that the researchers may stop your participation in the study if, for example, your health status changes and it would be unsafe for you to continue.

Whom do I contact if I have questions, concerns or feedback about my experience?

This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

The University of Minnesota HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous. If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the University of Minnesota HRPP.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

Yes I agree (initial)	**Optional Elements**
	The investigator may contact me in the future to see whether I am interested in participating in other research studies by the Integrative Health and Wellbeing Research Program.
	I would like to receive notifications from Greenphire (ClinCard)

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____

Signature of Participant **Date**

_____

Printed Name of Participant

_____ _____

Signature of Person Obtaining Consent **Date**

_____

Printed Name of Person Obtaining Consent

WITNESS STATEMENT:

The participant was unable to read or sign this consent form because of the following reason:

☐ **The participant is illiterate**

☐ **The participant is visually impaired**

☐ **The participant is physically unable to sign the consent form. Please describe:**_____

☐ **Other *(please specify)*:**
_____

_____ _____

Signature of Witness **Date**

_____

Printed Name of Witness