UNIVERSITY OF MINNESOTA

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Informed Consent Form

Integrated Supported Biopsychosocial Self-Management for Back Related Leg Pain

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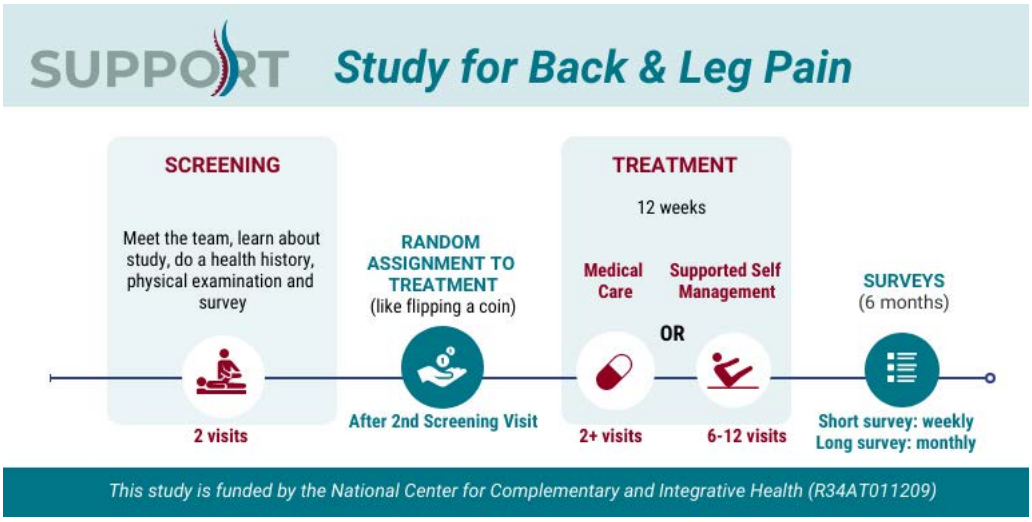
About The SUPPORT Study

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.

Purpose of the study– Back pain with leg pain is a common problem in adults. The main purpose of this study is to see if it is possible to conduct a larger study comparing a supported self-management treatment to medical care for back and leg pain. Our goals are to see if people like you are willing to participate in the study and also to find out what people like and dislike about the two treatment approaches and the research study overall. Study participation is about **7** months.



Risks of study participation – you may experience one or more of the following risks:

- Discomfort from answering personal questions
- Supported Self-Management: Mild physical discomfort or soreness due to exercises and hands-on treatment, and feeling emotional after talking about your pain and how it affects your life
- Medical Care: Potential side effects from medications

Benefits of study participation– you may experience some benefits including the following:

- New knowledge about what causes back and leg pain and what you can do about it
- Improvement in your back and leg pain symptoms
- Improvement in your ability to do your daily activities

Alternative treatments – Participating in this study is optional. If you do not participate, you can choose one of the following options for your back and leg pain:

- Continue with your current treatment
- Seek a new treatment
- Choose no treatment

What is research?

Clinical trials are a form of research that looks at new ways to prevent, detect, or treat disease. The goal of clinical trials is to determine if treatments work and are safe. Clinical trials can also look at other aspects of care, such as improving the quality of life for people with chronic illnesses.

People participate in clinical trials for a variety of reasons. Healthy volunteers say they participate to help others and to contribute to moving science forward. Participants with an illness or disease also participate to help others, receive newer treatments, and/or to have the additional care and attention from the clinical trial staff.

Clinical trials provide an opportunity to help researchers find better treatments for others in the future.

What should I know about being in a research study?

- Someone will explain this research study to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision 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 a supported self-management treatment to medical care for back and leg pain. Our goals are 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 treatment approaches 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 back and leg pain. The following pages describe what you can expect in this study.

First Screening Visit (2-3 hours)

- Research staff will review this consent form with you and answer your questions.
- You will complete surveys about yourself, your back and leg pain, health history, medications, and drug and alcohol use.
- If you are female and are able to get pregnant, you will be asked to take a pregnancy test. Women who are pregnant, trying to get pregnant, or nursing cannot take part in this study. This is because some of the medications may not be safe during pregnancy or when nursing.
- A licensed healthcare provider will talk to you about your health and do a physical exam to assess your back and leg problem.

- If you are currently receiving care for your back and leg pain (e.g., prescription medication, physical therapy, chiropractic care, massage therapy, etc.), you will need to stop this treatment to participate in the study.

Second Screening Visit (up to 1 hour)

- Research staff will briefly review the study with you and answer your questions.
- You will be told the results of the assessment from the first screening visit and whether or not you qualify for the study.
- If we think you have a back and leg problem that requires additional tests or treatment that is different from what we are studying, we will refer you to your primary care provider.
- If you are eligible for the study, you will complete additional surveys about your back and leg pain and your overall physical, emotional, and social health.
- Random Assignment and First Treatment:
    - If you qualify for the study, you will be randomly assigned (like flipping a coin) to one of the treatments described below.
    - Previous research has shown both of these treatments may reduce back and leg pain. However, we don't know how these treatments compare to one another.

<u>Important things to consider:</u>

- Neither you nor the research team can choose which treatment you will get
- You must be willing to receive either treatment
- You have an equal chance of being assigned to each treatment
- Once you are assigned to a treatment, we will schedule your first treatment visit. The first visit occurs within a few days.

Study Treatments

- Treatments for the study will take place at the research clinic. Some study visits may also take place by videoconferencing (i.e. Zoom) or phone, if needed.
- The treatment period is 3 months long and all study treatments are provided free of charge. You do not need to use your insurance and no co-pays are required.
- The clinical providers in the study are licensed in the State of Minnesota and have experience working with adults with back and leg pain.
- All participants will receive an information booklet about back and leg pain (e.g., what you can do on your own, what causes it, etc.).
- The number of visits you need depends on which treatment you get.
    - For Supported Self-Management, you need to attend at least 6 visits.
    - For Medical Care, you need to attend at least 2 visits.
    - After that, you and your provider will decide together if you need more visits.
- We ask that you not seek other treatment outside of this study for your back and leg pain during the 3-month treatment period. If you think you need additional treatment that is not provided in the study (e.g., due to an emergency), please let the research staff know. After 3 months, you may seek any care you want. If you experience an aggravation of your low back and leg pain (e.g., a "flare up") while you are still in the

study (before 6 months), your provider will work with you to decide if you can receive additional study treatment visits.

- All your treatment visits will be video or audio recorded for quality assurance. If you do not want your treatment visits to be recorded, please let us know and we will not record them. There is a section near the end of this form where you can indicate your willingness to have treatment visits recorded.

1. **Supported Self-Management (SSM) –** you can expect the following from this treatment:
   - 60 minute visits done in person at the clinic. These visits can also be done by videoconferencing (i.e. Zoom), if needed.
   - Treatment is provided by licensed physical therapists or chiropractors.
   - This treatment will focus on looking at how your pain affects your physical, mental, and social health. You will learn exercises and techniques you can use to manage your back and leg pain on your own. Examples include back exercises, stress reduction strategies (like relaxed breathing, guided imagery and muscle relaxation), and how to communicate with others about your pain. You will also receive spinal manipulation if indicated, a hands-on treatment to help reduce pain symptoms and improve the function in your back joints and muscles.

2. **Medical Care–** you can expect the following from this treatment:
   - Up to 30 minute visits are done in person at the clinic. These visits can also be done by videoconferencing (i.e. Zoom) or phone, if needed.
   - Treatment is provided by a licensed nurse practitioner.
   - This treatment will focus on working with the nurse practitioner to decide the best medication for you. The medications used in this study are based on previous research and the American College of Physicians' guidelines.
   - Medicines used in this study include over-the-counter and/or prescription medications shown to help people with back and leg pain:
     - Nonsteroidal anti-inflammatory drugs (NSAIDS) like Ibuprofen, Aleve, Aspirin, etc.
     - Pain relievers such as Acetaminophen, Tylenol, etc.
     - Pain Patches like Lidoderm, Salonpas, etc.
     - Muscle relaxants such as Flexeril, Skelaxin, etc.
     - Corticosteroids like Prednisone, Medrol, etc.
     - Benzodiazepines such as Xanax, Ativan, etc.
     - Anti-seizure medications for pain like Gabapentin, Neurontin, Lyrica, etc.
     - Antidepressants for pain such as Amitriptyline, Cymbalta, etc.
     - Weak opioids such as Tramadol or Tylenol with Codeine may be used for episodes of severe pain
   - Strong opioids (e.g. morphine, oxycodone), spinal injections, and surgical procedures are NOT offered in this study.
   - You will pick up the medications at the pharmacy or retailer of your choice.
   - The study will pay for all the medications recommended for your back and leg pain.
     - You will be given a MasterCard gift card (ClinCard) to pay for the medication. (See Compensation below for more information about the gift card)

Surveys
A link to each internet-based survey will be sent to your email. If you do not have internet access, we will call you and collect the information over the phone. You will complete surveys weekly and monthly for 6 months. We will remind you to complete the surveys. Completing these surveys is very important and you must be willing to complete them to participate.

Weekly Surveys
- Each weekly survey will have 2-4 questions and will take less than 5 minutes to complete.
- They will come on the same day each week.
- The questions will ask about how often you experience back and leg pain each week and how severe the pain was.

Monthly Surveys
- Each monthly questionnaire will take 30-45 minutes to complete.
- They will come at the same time each month.
- The questions will ask about your back and leg pain, general health, and wellbeing. You will also answer questions about potential side effects from study treatments, medications, health problems and any healthcare you received for your back and leg pain.

Compensation
You will be compensated up to $150.00 for participating in the study.
- You are not compensated for attending screening visits
- You are not compensated for attending treatment visits, but we pay for your treatments.
- You are compensated for completing surveys.

Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Weekly Surveys
$10.00	$10.00	$40.00	$10.00	$10.00	$30.00	$40.00**

**You must complete at least 80% of the weekly surveys to be compensated this amount. These funds will be provided at the end of the study.

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 inactivity (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.

Payment you receive as compensation for participation in research is considered taxable income. If payment to an individual equals or exceeds $600 in any one calendar year, the University of Minnesota is required to report this information to the Internal Revenue Service (IRS). Research payments to study participants that equal or exceed $600 during any calendar year will result in a FORM 1099 (Miscellaneous Income) being issued to you and a copy sent to the IRS.

Risks to Study Participation

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 and video/audio recordings: 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 the screening physical examination: There is a risk that you may experience mild physical discomfort during or after the examination.
- 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 Supported Self-Management (SSM): The risks associated with SSM are considered low. The most common side effects of exercise and manual therapy (hands on therapy) include mild physical discomfort and soreness in the muscles/joints of the lower back, hip, or buttock regions. This usually goes away within a day or two. If heat is used, burns are possible. If lotion is used, skin irritation may occur. More serious complications with manual therapy are extremely rare, which could include nerve damage, injuries to the spinal discs, spinal fractures, or bleeding beneath the skin. The chance of serious complications is estimated to be 1 per one million treatments of the lower back.

  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. relaxed breathing, guided imagery, problem solving, communication with others etc.).

- Risks associated with Medical Care: The most common risks are potential side effects to various medications. The study clinician will discuss in detail the possible side effects from any medication they recommend or prescribe. Together you will make a shared decision

about the best medication for you. Two of the most commonly prescribed medications for back and leg pain are non-steroidal anti-inflammatory drugs (NSAIDs) and muscle relaxants.

Common NSAIDs include Celebrex, Motrin, Ibuprofen, Naprosyn, Advil, Aspirin, and Aleve. The most common side effect from NSAIDs is stomach irritation or indigestion. Other common side effects include: nausea, stomach bleeding or ulcers, vomiting, diarrhea, constipation, fluid retention, decreased appetite, rash, dizziness, headache, and drowsiness. NSAIDs should be used with caution if you have kidney or liver disease, or are severely dehydrated.

Common muscle relaxants include Flexeril, Robaxin, and Skelaxin. The most common side effects associated with muscle relaxants include drowsiness and fatigue, dry mouth, blurred vision, and nausea, constipation, diarrhea and muscle weakness.

Other medications that may be prescribed and their potential side effects include:

1) Pain relievers such as Tylenol or Acetaminophen: allergic reactions like skin rash, itching, swelling of the face, lips, or tongue, breathing problems, fever or sore throat, nausea, headache, upset stomach. Large doses, especially in combination with alcohol, can cause serious liver problems that cannot be cured.

2) Anti-seizure medications used for pain like Gabapentin or Neurontin: constipation, diarrhea, dry mouth, nausea, clumsiness, difficulty speaking, drowsiness, dizziness, blurred vision.

3) Topical pain patches such as Lidoderm or Salonpas: burning or stinging sensation, skin irritation, swelling or redness, dizziness, drowsiness, confusion.

4) Corticosteroids like Prednisone or Medrol: headache, increased appetite, weight gain, mood changes, difficulty falling asleep (if taken close to bedtime), muscle weakness, blurred vision, bruising, increased body hair growth. When these are taken over a long period of time, they may increase your chance of developing certain infections and decrease your bone density (e.g., osteoporosis).

5) Minor tranquilizers such as Xanax or Ativan: drowsiness, confusion, dizziness, headache, loss of balance, slurred speech, constipation, nausea, dry mouth, chemical dependence, heart and lung problems.

6) Antidepressants used for pain like Amitriptyline or Cymbalta: nausea, indigestion, diarrhea, constipation, loss of appetite, sleep problems, headache, low sex drive, dry mouth, weight gain, heart problems.

7) Weak opioids used for episodes of severe pain like Tramadol or Tylenol with Codeine: nausea, dizziness, constipation, vomiting, drowsiness, headache, increased risk of seizure, and chemical dependence.

Benefits to Study Participation

There may be no direct benefit to you by participating in this study. You may experience one or more of the following, but it is not guaranteed.

- New knowledge about what causes back and leg pain and what you can do about it
- Improvement in your back and leg pain symptoms
- Improvement in your ability to do your daily activities

Alternate Treatments
There are alternatives to taking part in the study. You can continue with your current form of treatment, seek a new treatment, or choose no treatment. There are many options available outside of this study: physical therapy, chiropractic care, medication, massage, acupuncture, steroid injections, and others. The research team can discuss these options and answer questions regarding alternatives to research study participation.

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.

No Charge to Participate
There is no cost for you to take part in the study. None of the research procedures or treatments will be billed to you or your health insurance.

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. If you agree to have your treatment sessions video/audio taped, the files will be stored on a HIPAA secure password protected server. Access will be given only to researchers necessary to evaluate quality assurance of the research procedures. 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;
    - The National Center for Complementary and Integrative Health (NCCIH)
- 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.
    - Greenphire (ClinCard)

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.

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 if 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?
No

What will be done with my data when this study is over?
Your data will not be used for any future research after this study is complete.

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). Your decision to withdraw from this study will

have no effect on your current or future relationship with the University of Minnesota.

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.

You may be asked if you want to participate in future research conducted by any members of this team. Your name and contact information would be collected. You do not need to agree to participate in future research.

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

To share feedback privately with the University of Minnesota Human Research Protection Program (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	
	The investigator may audio or video record me for quality assurance purposes. The research team will not share these recordings with anyone outside of the immediate study team.
	The investigator may contact me in the future to see whether I am interested in participating in other research studies by Drs. Brent Leininger or Gert Bronfort

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent