Official Title: Web-TIRELESS Aim II - Feasibility open pilot of web-based mind-body treatment to enhance resilience among patients with painful nontraumatic upper extremity conditions and comorbid risky substance use

NCT ID: NCT06366633

Date of Document: 6/28/2024

Mass General Brigham

Research Consent Form
General ConsentFormTemplate
Version Date: November 2022

Subject Name:

MRN or DOB:

Subject Identification

Protocol Title: Open Pilot of web-based mind-body treatment to enhance resilience among patients with painful nontraumatic upper extremity conditions and comorbid risky substance use

Principal Investigator: Jafar Bakhshaie MD, PhD

Site Principal Investigator: N/A

Description of Subject Population: Adult patients with a painful non-traumatic hand, arm, or shoulder condition diagnosis and comorbid risky substance use

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.
If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Key Information

We are asking you to be in a research study. This form will tell you what you should expect if you agree to be in the study. You will find more information about each of the following points later in this form.
It is your decision whether or not to join the study. We are asking you to be in this study because you are a patient with a painful non-traumatic hand, arm, or shoulder condition that indicated use of a substance. We are doing this research to improve coping and pain management in patients and further refine our on-demand mindfulness-based pain management program (i.e., Web-TIRELESS). If you agree, you will complete questionnaires at two timepoints (before and after the program), participate in four on-demand web-based program sessions, and complete an optional interview to provide feedback on the Web-TIRELESS program. You will be in the

study for approximately five weeks if you decide to stay for the whole study and will have access to the Web-TIRELESS platform for up to 6 months following your completion of the program.
There are no foreseeable risks associated with participation however you may experience feelings of discomfort when confronting your relationship with pain and substances.
We cannot promise any benefits from taking part in this research study. However, possible benefits may include your ability to cope with pain and substance use urges, improved function and emotional wellbeing.
If you decide not to be in the study, some other things that might help your condition are psychotherapy, physical therapy, and/or addiction counseling or treatment.
You will be paid up to $150 for taking part in this research study. You will find more information about the payment amount for each visit and a plan if you do not complete all study visits later in this form.
You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.
Jafar Bakhshaie MD, PhD is the person in charge of this research study. You can call him **M-F 9-5** at **832-538-8333**. You can also call **Nadine Levey M-F 9-5** at **617-724-8431** with questions about this research study.
If you have questions about the scheduling of appointments or study visits, call **Nadine Levey at 617-724-8431.**

If you want to speak with someone **not** directly involved in this research study, please contact the Mass General Brigham IRB. You can call them at 857-282-1900.
You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research
- Any pressure to take part in, or to continue in the research study

Detailed Information

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.

Why is this research study being done?

We are doing this research to test a novel asynchronous web-based program (Web-TIRELESS) aimed at decreasing disability, pain, substance use, and related distress in patients with painful nontraumatic upper-extremity conditions who use substances.

Who will take part in this research?

We are asking you to take part in this research study because you are an adult patient, have a diagnosis for a painful nontraumatic upper-extremity condition, and have answered questions that indicate you might benefit from support to decrease the impact of your condition.
About 12 people will take part in this phase of the research study.
The National Center for Complementary and Integrative Health of the National Institutes of Health is paying for this research to be done.

What will happen in this research study?

If you choose to participate in this study, we ask that you sign this consent form before participating in any study activities. As a part of this study, you will receive access to a web-based platform that consists of 4 on-demand 30–45-minute video program sessions. The program (Web-TIRELESS) was designed in-house at Mass General Brigham by Dr. Jafar Bakhshaie, his study team, and several orthopedic hand and arm specialists. Web-TIRELESS is designed to be completed within 4 weeks (one session per week) though you can complete the 4 sessions at a slower pace. We will teach you how to best use this platform to get the most out of the Web-TIRELESS program. Study staff will work with you individually to schedule your 20–30-minute Web-TIRELESS information session (held over Zoom) according to your availability.

Setup and Baseline Assessment (45 minutes)

During this portion of the study, you will fill out several questionnaires online, through a secure system. The survey questions will ask you about your condition, pain, relationship with

substances, distress, coping, and ability to engage in activities of daily living. You will complete these questionnaires from any private location. Please note, that you must have internet access in order to complete the surveys.

You will also meet with study staff over Zoom for approximately 30 minutes to learn how to access and best use the Web-TIRELESS platform. Regardless of how tech savvy you are, we want to make sure you have instruction to get the most out of the program. Prior to this session, you will receive a Zoom meeting link for your information session. Zoom is a free and secure online videoconferencing software program that is currently used to provide care for patients at Mass General Brigham. Study staff will provide you information on how to access the video conferencing platform. We will launch the video conferencing in a private and secure area. To protect your privacy we ask that you do not take screenshots, photographs, or recordings of any kind with any electronic equipment. A video meeting is similar to us visiting you at home. We may learn more about your home and the people living with you than we would during a visit at the hospital. For example, we may learn information from you that must be reported to public health or public safety authorities. Please ask the research staff if you have any questions about this prior to your video visit.

Web-TIRELESS Sessions 1-4

You will participate in 4 Web-TIRELESS program sessions. Sessions are entirely on-demand and we encourage you to complete them at your own pace. Each session is between 30 to 45 minutes long and will teach you information and skills to help you adapt in new ways to your painful condition. At the conclusion of each session, you must pass a short interactive quiz in order to "unlock" the following session. In between sessions, you will be encouraged to practice the skills you learned from the previous session and log your practice (skill[s] and duration of practice) within the Web-TIRELESS platform. You will have continued access to the program platform and content for up to 6 months after completing the program.

Once a week, we ask that participants complete a brief survey while enrolled in the program. We welcome you to complete this survey either online or with a member of study staff over the phone. Independent of this survey, we also call participants approximately once a week to check in, keep you motivated, and problem-solve any barriers to program engagement.

With your permission, we would like to send you text messages to remind you to use our platform and encourage you to practice the program skills. Text messages by mobile/cell phones are a common form of communication. This research study involves sending you text messages that are relevant to the research study. Texting over mobile/cell phones carries security risks because text messages to mobile/cell phones are not encrypted. This means that information you send or receive by text message could be intercepted or viewed by an unintended recipient, or by

your mobile/cell phone provider or carrier. Below are some important points about texting in this study:

- Text messages are not encrypted, and therefore carry security risks. This research study and Mass General Brigham are not responsible for any interception of messages sent through unencrypted text message communications.
- You will be responsible for all fees charged by your carrier's service plan for text messaging. This research study and Mass General Brigham are not responsible for any increased charges, data usage against plan limits or changes to data fees from the research texts
- Text messages will only be read during business hours. Texts sent on nights or weekends will not be read until the follow business day.
- Text messaging should not be used in case of an emergency. If you experience a medical emergency, call 911 or go to the nearest hospital emergency department.
- You may decide to not send or receive text messages with staff associated with this research study at any time. You can do this in person or by sending the research number a text message that says "Stop Research Text."
- Your agreement applies to this research study only. Agreeing to other texts from Mass General Brigham, for example appointment reminders, is a separate process. Opting out of other texts from Mass General Brigham is a separate process as well.
- It is your responsibility to update your mobile/cell phone number with this research study in the event of a change.
- Text messages will not contain protected health information such as last name, date of birth, mailing address, etc.
- You have the right to refuse these texting reminders. Your decision will not impact your ability to participate in the study. You can opt out of these text messages at any time.

I have had the chance to ask questions about texting with staff associated with this research study. I have been informed of the risks and other information covered above and consent to the use of unencrypted text communications associated with this research study (initial below):

Yes: _____ No: _____

Post-Test Assessment (30 minutes)

After finishing the 4th program session, you will be asked to complete the post-test assessment. Similar to the baseline assessment, you will receive a secure link to the questionnaires which can be completed from a private location of your choosing. We ask that you complete these surveys in a location with internet access.

Exit Interview (20 minutes)
You have the option to attend a 20-minute exit interview held via Zoom. During the interview a member of study staff will ask about your experiences using the platform, your perceptions of the program, and your feedback to improve the platform and/or program. All exit interviews will be audio recorded to ensure all participant feedback is integrated for future research phases. These recordings will be accessible only to study staff and stored on encrypted devices.
Withdrawal: Participation in this study is voluntary. You can refuse to answer any questions, and you can withdraw from the study at any time. Refusal to participate in this study will in n way impact your access to or quality of medical care within or outside the Mass General Brigham network. If you choose to withdraw, you will not undergo no further evaluations.
Confidentiality: Your research study information will only be identified with the study number available only to the study staff. The information will be stored electronically in a file that is only accessible to study staff. Confidentiality will only be suspended in the case of a psychological emergency. If a member of the study staff is concerned that you may cause harm to yourself or others, the study psychologist and principal investigator, Dr. Jafar Bakhshaie, will be immediately informed.

What are the Terms of Use of the Web-TIRELESS Website?
The Web-TIRELESS platform was developed and maintained by members of study staff. In order to use the platform, you are required to accept the terms of use before participating. You will be responsible for any data charges related to using the Web-TIRELESS platform. You are responsible for creating and maintaining your account information securely. Study staff will have access to your username but not your account password. Your username will be stored within the platform and internal study documents, all of which are stored on MGB-encrypted devices. We may terminate your account based on your status of participation. If you choose to drop out or are withdrawn from the study, your account and access to the platform will be terminated. Following the completion of all the study sessions (approx. 5 weeks), you will be granted access to the platform for the following 6 months, after which your access will be terminated. The Web-TIRELESS Study reserves the right to terminate your account at any time. You will be informed of your account termination and why in advance by a member of study staff. All content shared on our platform remains the intellectual property of the respective users but will be subject to use by the researchers for data analysis purposes. Your user data will be deidentified and stored in secure locations at Mass General Brigham. By signing this document, you acknowledge and agree to abide by the terms outlined in this consent form.

How may we use and share your samples and health information for other research?

The information we collect in this study may help advance other research. If you join this study, we may remove all information that identifies you (for example, your name, medical record number, and date of birth) and use these de-identified samples and data in other research. It won't be possible to link the information or samples back to you. Information and/or samples may be shared with investigators at our hospitals, at other academic institutions or at for-profit, commercial entities. You will not be asked to provide additional informed consent for these uses.

Will you get the results of this research study?

You and your doctor should not expect to get information about the results of the research study or the results of your individual participation in the research study. We will study information from many people. It could take many years before anyone knows whether the results have any meaning. There is a small chance that we could find out something from the study that might be important to your health. If this happens, we may contact you to find out if you would like to learn more. However, even if we find something important to your health, we cannot guarantee that you will be contacted.

What are the risks and possible discomforts from being in this research study?

There are no foreseeable physical risks from taking part in this research. However, you may experience feelings of discomfort when completing assessments or study activities related to your relationship with pain, psycho-social factors, and substances.

What are the possible benefits from being in this research study?

We cannot promise any benefits to you from taking part in this research. However, it is our hope that your ability to cope with your condition and pain severity improves. Others with painful nontraumatic upper-extremities may benefit in the future from what we learn in this study.

What other treatments or procedures are available for your condition?

You will be able to continue treatment as usual with your medical team. Participation in this research does not mean you cannot seek other treatment for your painful condition, including physical therapy, medications, and other forms of support. In fact, we ask that you continue your regular course of treatment with you medical providers in addition to taking part in this study.

Can you still get medical care within Mass General Brigham if you don't take part in this research study, or if you stop taking part?

Yes. Your decision won't change the medical care you get within Mass General Brigham now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.
We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should you do if you want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed. Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will you be paid to take part in this research study?

We respect your time and will reimburse you $60 for the first set of surveys (baseline assessment) and $90 for the second set of surveys (post-test assessment). Overall, you can earn up to $150 from taking part in this study. Payment for the two assessments will be processed at one time directly following the conclusion of your participation. If you drop out of the study before the Post-Test Assessment, your payment for the Baseline Assessment will be processed as soon as possible. The payments will be made by check, and we will need to collect your SSN/TIN and a valid U.S. address to complete this payment process.

What will you have to pay for if you take part in this research study?

All program content, materials, and assessments are paid for by study funds. The study will not provide you with a computer, cellphone, or internet access. You must own or have access to a device with internet access in order to participate.
Study funds will pay for certain study-related items and services. We may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs.

What happens if you are injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.
Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.
If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the beginning of this consent form.

If you take part in this research study, how will we protect your privacy?

Federal law requires Mass General Brigham to protect the privacy of health information and related information that identifies you. We refer to this information as “identifiable information.”

In thisstudy,wemaycollectidentifiableinformationaboutyoufrom:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable information and why they may need to do so:

- Mass General Brigham researchers and staff involved in this study The sponsor(s) of the
- study, and people or groups it hires to help perform this research or to audit the research
- Other researchers and medical centers that are part of this study
- The Mass General Brigham ethics board or an ethics board outside Mass General
- Brigham that oversees the research A group that oversees the data (study information) and
- safety of this study Non-research staff within Mass General Brigham who need identifiable information to do
  their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research) People or groups that we hire to do certain work
- for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)
- Other: N/A

Some people or groups who get your identifiable information might not have to follow the same privacy rules that we follow and might use or share your identifiable information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your identifiable information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your identifiable information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your identifiable information for any mailing or marketing list. However, once your identifiable information is shared outside Mass General Brigham, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your identifiable information does not expire.
The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifiable information **will not** be used for these purposes without your specific permission.

Certificate of Confidentiality

A federal Certificate of Confidentiality (Certificate) has been issued for this research to add special protection for information and specimens that may identify you. With a Certificate, unless you give permission (such as in this form) and except as described above, the researchers are not allowed to share your identifiable information or identifiable specimens, including for a court order or subpoena. Certain information from the research will be put into your medical record and will not be covered by the Certificate. This includes records of medical tests or procedures done at the hospitals and clinics, and information that treating health care providers may need to care for you. Please ask your study doctor if you have any questions about what information will be included in your medical record. Other researchers receiving your identifiable information or specimens are expected to comply with the privacy protections of the Certificate. The Certificate does not stop you from voluntarily releasing information about yourself or your participation in this study.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your identifiable information for research; however, if you don't sign it, you can't take part in this research study.
You have the right to withdraw your permission for us to use or share your identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.
If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if
- any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
  I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

_____
Print Name

_____ _____ _____
Subject Signature Date Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

_____
Print Name

Signature of Study Doctor or Person Obtaining Consent	Date	Time (optional)

Consent Form Version: V1.0;6/28/24