Official Title: Addressing the Epidemic of Chronic Pain Among Older Adults in Underserved Communities; The GetActive+ Study

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Research Consent Form
General Consent Form Template
Version Date: November 2022

Protocol Title: iHOPE: a mind-body and activity program aimed at improving pain and function among older adults with chronic pain at Revere HealthCare Center (RHC)

Principal Investigator: Ana-Maria Vranceanu, PhD

Site Principal Investigator:

Description of Subject Population: Older adult patients at RHC with chronic pain

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 an older adult (55+) patient at Revere HealthCare Center (RHC), you have chronic pain, and you meet study criteria. We are doing the research to understand whether a pain management program we developed called GetActive+ meets the needs of older adults with chronic pain at RHC. If you agree, you will complete a baseline assessment, a 10-week long mindfulness and activity program, and a post-program assessment. You will be in the study for approximately 3 months if you decide to stay for the whole study.

The main risks of being in the study are privacy or confidentiality breaches of personal information captured via text messages, videoconferences, and session audio recordings and possible muscle soreness associated with increased activity levels.

You might benefit from being in the study because you may experience improvements in your ability to manage pain, your activity level (e.g., walking, active chores), your pain level and your mood.

If you decide not to be in this research study, some other things that might help your condition are psychotherapy, physical therapy, and medications.

You will be paid up to $655 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.

Ana-Maria Vranceanu, PhD is the person in charge of this research study. You can call him/her at [redacted] **, Monday through Friday, 9:00am to 5:00pm**. You can also call **Christine Ritchie, MD at** [redacted]**, Monday through Friday, 9:00am to 5:00pm** with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call [redacted]

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 [redacted]

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 understand whether a pain managements program we developed called *GetActive+* meets the needs of older adult patients with chronic pain at RHC. Ultimately, we aim to improve care options for older adults with chronic pain from all backgrounds.

Who will take part in this research?

We are asking you to take part in this research study because you are an older adult patient at RHC diagnosed chronic pain.

Up to 50 patients from RHC will take part in this phase of the research study.

The National Institute on Neurological Disorders and Stroke and the National Institute of Aging out of the National Institutes of Health are paying for this research to be done.

What will happen in this research study?

If you choose to participate in this study, we will ask you to sign this consent form before we do any study procedures. We will do this electronically during your first assessment. Before you sign the form, we will ask you to answer questions to determine whether you fit the study criteria. If you meet criteria and choose to take part in this research study, you will be asked to complete 2 assessments: baseline (before the program), and post-program (immediately after the program ends). The *GetActive+* program will have 10, 60-minute weekly group sessions.

All participants will receive a watch called an ActiGraph device to wear on your wrist for 7-days after your baseline assessment and post-program assessment. This device will help measure your activity levels over each of the 7-day periods and will allow us to tailor the *GetActive+* program to your individual needs. We will provide the ActiGraph device at no cost to you, assist you in setting up the device to communicate with your smartphone (if you have one), and provide instructions on how to use and sync the device. You will be required to use the device. If you have a compatible smartphone, we will ask that you download an application called CentrePoint, which you will use to sync the device. Prior to using the app, you will be required to accept the

standard terms of use. Your data will not be accessible by ActiGraph or any other party outside MGB. If you wish to learn more about the standard terms of use, study staff will provide you with CenterPoint's full policy. You are not required to use the CentrePoint app in order to participate. If you do not have a smartphone, we will discuss with you an individualized plan which would involve daily communication with study staff to ensure you wear the device for the full assessment period. For each of the 7-day periods, you will be instructed to consistently wear the ActiGraph watch, except while bathing, swimming, or charging the device. Once enrolled in this study, we will not share any of your information collected by the ActiGraph device. At the conclusion of the study, you may uninstall CentrePoint on your personal device.

Place of Visits: The *GetActive*+ group program will take place in person at RHC *or* virtually over Zoom. For the baseline and post-program assessments, you will be asked to come in person at RHC.

Study Schedule:

Baseline Visit (approximately 70 minutes)

You will come in person at RHC for the baseline visit. First, we will answer any questions you might have related to the study. Next, if you would like to take part in this study, you will sign this informed consent form. After informed consent you can proceed with the baseline assessment which will include:

- Self-Report Questionnaires: You will be asked to answer questions about your pain and how you currently manage it, your mood, your social support, and your activity level. We will also ask you to complete a demographic and clinical questionnaire. You will have the option to complete all questionnaires at home after the conclusion of the baseline visit. The self-report questions will take approximately 30 to 45 minutes.
- Walk Test: You will be asked to walk for 6 minutes, and we will measure the distance you cover. The entire walk test will take approximately 10 minutes.
- Enrollment Wrap-Up: You will learn more about the program, give you a patient manual, and discuss program expectations. Additionally, you will learn how to use study technology and receive materials. This session will take approximately 15 minutes
- ActiGraph Watch: We will ask you to wear an ActiGraph watch for 7-10 days starting with the day you complete the baseline visit. You will then either bring it back to us in person or mail it to us in a pre-paid envelope that we will give you. It will take about 15 minutes to give you the ActiGraph and provide you with detailed instructions.

Weekly *GetActive* + Group Sessions 1-10 (approximately 60 minutes each)

The *GetActive+* program was developed and optimized with feedback from older adults with chronic pain at RHC, and discussions with RHC clinicians. The program will be delivered by clinicians who have expertise in pain management. The program will consist of 10 in-person or virtual (i.e., over Zoom) group sessions with each session lasting 60 minutes. Sessions will take place at the same time every week for 10 weeks. Each of the group sessions will be audio-recorded to ensure that the clinicians are delivering the program properly.

As part of *GetActive+*:

- You will learn chronic pain symptom management techniques, strategies to become more active, and participate in various session exercises.
- You will interact with other patients who have chronic pain.
- You will set weekly activities of daily living goals with study staff and work to increase your time spent engaged in meaningful activities each week.
- You will be asked to do things outside the group sessions including meaningfully engaging in *active* activities of daily living for a specific amount of time, and practice program skills.

If you attend sessions remotely, study staff will provide you information on how to access Zoom (a 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. We would like to remind you that 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. We are required by law to report known or suspected child or elder abuse. If we make such report, the public health and safety authorities can use the information as they see fit and may end up sharing it with other government agencies. Please ask the research staff if you have any questions about this prior to your video visit.

<u>Post-Program Assessment (approximately 70 minutes)</u>

We ask that you come in person at RHC for the post-program assessment. The post-program assessment will be very similar to the baseline visit. The post-program assessment will include:

- <u>Self-Report Questionnaires:</u> You will be asked to answer questions about your pain and how you currently manage it, your mood, your social support, and your activity level. The self-report questionnaires will take approximately 30 minutes to complete.

- Walk Test: You will be asked to walk for 6 minutes, and we will measure the distance you cover. The entire walk test will take approximately 10 minutes.
- ActiGraph Watch: We will ask you to wear an ActiGraph watch for 7-10 days starting with the day you complete the post-program visit. You will then mail it to us in a pre-paid envelope that we will give you. It will take about 10 minutes to give you the ActiGraph and provide you with detailed instructions.

Post-Program Exit Interview (Optional):

After you complete post-program assessments, we will schedule individual exit interviews. These will take place either in person, over Zoom or the phone. During these exit interviews you will share your experiences as a participant in the program including things you liked and things we can improve upon. All exit interviews will be audio recorded. These recordings will be accessible only to study staff and stored on encrypted devices. These exit interviews will last approximately 30 minutes.

Confidentiality: Once enrolled in this study, we will not share your study information. 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 at your site, will be immediately informed. The principal investigator/s of the study will contact the participant by phone and do an immediate assessment and treatment planning.

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.

Receiving unencrypted text messages for this study

Text messages by mobile/cellphones are a common form of communication. The iHOPE research study involves sending you text messages using the Twilio app. You do not have to agree with receiving text messages in order to participate. Twilio is an MGH approved app that has been used in similar research studies. These text messages will include information about session reminders, reminders to complete homework logs, and activity prompts to complete before upcoming sessions. We will send these messages daily during the 10-week group intervention. Texting over mobile/cell phones carries security risks because text messages between mobile/cellphones are not encrypted. This means that information you send or receive by text message could be intercepted or viewed by someone other than staff involved with this research study, or by your mobile/cellphone provider or carrier.

Below are some important points about texting in this research study.

- Text messages are not encrypted, and therefore carry security risks. The iHOPE study and Massachusetts General Brigham, are not responsible for any intercepted messages sent through unencrypted text message communication.
- You will be responsible for all fees charged by your carrier's service plan for text messaging. iHOPE and Massachusetts General Brigham, are not responsible for any increased charges or changes to data fees from the research texts.
- Text messages will only be read during regular business hours. Texts sent on nights or weekends will not be read until the next 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 iHOPE at any time. You can do this in person or by sending the research number a text message that says, "Stop Text."
- Your agreement applies to this research study only. Agreements to other texts from Massachusetts General Brigham for example appointment reminders, is a separate process.

I have had the chance to ask questions about texting with staff associated iHOPE. I have been informed of the risks and other information covered above and consent to the use of unencrypted text communication associated with this research study.

Please select one of the following options:

I consent to text message reminders (please use your initials to indicate your response):

Yes: _____ **No: _____**

Mass General Brigham has an electronic system that lets your study doctors know if you are admitted to a Mass General Brigham Hospital, or if you visit a Mass General Brigham Hospital Emergency Department. We want to make sure the study doctors know about any possible problems or side effects that you experience while you are taking part in the study.

You have the right to withdraw from the study at any time without penalty. If you withdraw early, you will be compensated for your time in the study up to withdrawal.

Study Information Included in Your Electronic Medical Record: A notation that you are taking part in this research study may be made in your electronic medical record. Information from the research that relates to your general medical care may be included in the record (for example, lists of allergies, results of standard blood tests done at hospital labs).

In order to allow researchers to share test results, the National Institutes of Health (NIH) and other central repositories have developed special data (information) banks that analyze data and collect the results of studies. These central banks will store your samples and give them to other researchers to do more studies. We do not think that there will be further risks to your privacy and confidentiality by sharing your information with these banks. However, we cannot predict how your information will be used in the future. The samples and data will be sent with only your code number attached. Your name or other directly identifiable information will not be given to central banks. There are many safeguards in place to protect your information and samples while they are stored in repositories and used for research.

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. There is a small chance that we or the researchers involved 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?

Important risks and possible discomforts to know about include breach of privacy or confidentiality. The use of technology in this study carries some inherent security risks associated with text messaging, videoconferencing, and the use of audio recordings from study sessions. You may find it challenging or uncomfortable to actively participate during the group sessions. Lastly, there is a possibility that you experience muscle soreness from walking and increased activity levels. This is a normal physical response to increasing physical activity but may cause physical discomfort.

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

We cannot promise any benefits to you from taking part in this research study. It is our hope that the program will help you improve your ability to manage pain, decrease your pain, increase your ability to engage in meaningful activities and improve your mood. Additionally, we hope you benefit from building community and being with other older adults with chronic pain.

In the future, knowledge from this research study may benefit other adult patients with chronic pain.

What other treatments or procedures are available for your condition?

The program offered in this research study does not constitute individualized, personal care. The programs are broad-based skills training methods that are not tailored to any particular individual. If you would like formal mental healthcare or personalized instruction in mind-body

methods, we can give you a referral for psychological treatment that is suitable for you. For example, you may seek psychotherapy or medications outside of this research study or you may participate in other research studies for which you may qualify.

Participation in this research study does not mean that you cannot seek other forms of treatment for chronic pain, including medications or other forms of psychotherapy. In fact, we ask that you continue your regular medical treatment with your physician in addition to taking part in this research 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?

Yes, you will be paid $60 for completing the baseline visit and up to $100 for the 7-day baseline ActiGraph assessment (e.g., $10 per day for up to 7-days; additional $30 for 7 days of complete and valid data). In total, you can receive up to $160 for completing the baseline assessments.

If you choose to attend sessions in-person, you will also receive up to $150 worth of travel compensation (e.g., $15 per session for 10 sessions). All participants will receive a $50 bonus for

attending at least 8 of the 10 sessions. In total, you can receive up to $200 for attending all 10 sessions.

If you complete the post program assessments, you will receive $100 and up to $155 for the post-program ActiGraph data collection period (e.g., $15 per day for up to 7-days; additional $50 provided for 7 days of complete and valid data). In total, you can receive up to $255 for completing the post program assessments.

In addition to all the above, you will be given the opportunity to earn $25 for attending a post-program exit interview. If you choose to attend your exit interview in-person, you will receive an additional $15 for transportation to RHC. In total, you can receive up to $40 for completing the optional exit interview.

Overall, the maximum amount you can earn is $655. Payment will be submitted in segments at three distinct time points (i.e., after the baseline visit, final group session, and post-program exit interview) and may take up to 6 weeks to process. The payments will be made by check, and we will need to collect your SSN/ITIN 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?

There will be no cost to you. All of the group sessions and study assessments will be paid for by study funds. If you attend group sessions via Zoom but do not have access to a personal device that can log you into sessions, we will provide you with a smart device. The type of device will be depended on study funds and device availability. We ask that you return the device at the conclusion of your participation.

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 this study, we may collect identifiable information about you from:

- 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:

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.

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)

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