Cover Page

Title Mindfulness-based Cognitive Therapy for the Chronic Pain-early Cognitive Decline Co-morbidity Among Older Black Individuals in the Community; The Feeling of Being Open Pilot S

Consent Form Version Date: 7/25/2024

Protocol Title: Mindfulness-based cognitive therapy for the chronic pain-depression co-morbidity among older Blacks in the community; The Quiet Focus Open Pilot

Principal Investigator: Tony V Pham, MD, MScGH

Site Principal Investigator:

Description of Subject Population: Black adults with chronic musculoskeletal pain and depression

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 history of chronic pain and depression. We are doing this research to improve chronic pain and depression in patients and further refine our cultural adaptation of mindfulness-based cognitive therapy ("Quiet Focus"). If you agree, you will complete a program comprised of 1.5 hour sessions once a week for 8 weeks. You will also complete questionnaires at three timepoints (before, right after the program, and 3 months after the program) and complete an optional exit interview to provide feedback on the Quiet Focus program. You will be in the study for approximately 5 months if you decide to stay for the whole study and will

have access to the Quiet Focus program 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 discussing certain topics of completing questionnaires.

We cannot promise any benefits from taking part in this research study. However, possible benefits may include your ability to cope with pain and depression, improved function, and improved 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 pain counseling or treatment.

You will be paid up to $315 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.

Tony V Pham, MD, MScGH is the person in charge of this research study. You can call him M-F 9-5 at (617)-726-0469. You can also call Nomin Enkhtsetseg M-F 9-5 at (617) 468-6618 with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call Nomin Enkhtsetseg at (617) 468-6618 .

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

Why is this research study being done?

We are doing this research to test a culturally tailored mindfulness-based cognitive therapy ("Quiet Focus") aimed at improving chronic pain and depression among Black individuals in the community.

Who will take part in this research?

We are asking you to take part in this research study because you are an older Black adult who meets criteria for chronic musculoskeletal pain and depression, and have answered questions that indicate you might benefit from reducing the impact of your conditions.

About 8 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 participate in an 8 week program comprised of 8 1.5 hour sessions once a week. The program is a cultural adaptation of a known mind-body program mindfulness-based cognitive therapy that has evidence for improving chronic pain and depression.

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 sociocultural background; your physical, cognitive, and emotional well-being; and your perceptions of the program. 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 the program virtually for sessions that you cannot make in-person. 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 program, 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.

Quiet Focus Sessions 1-8
You will participate in 8 Quiet Focus program sessions. Sessions are available live either in-person at Central Boston Elder Services or virtually. The following are each session's contents: (1) body scan, raisin exercise, (2) body scan, mindful breathing, pleasant events calendar, (3) mindful breathing, 3-minute breathing space (3MBS), unpleasant events calendar, (4) sitting meditation, automatic thoughts, the 3-minute breathing space, (5) sitting with difficulties, meditation, the 3-minute breathing space, coping, (6) cognitive de-centering, sitting meditation, 3-minute breathing space, (7) nourishing-draining exercise, relapse prevention planning, and (8) body scan, applying mindfulness to daily life. You will have continued access to the program platform and content for up to 6 months after completing the program.

Post-Test Assessment (30 minutes)
After finishing the 8th 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 no 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 psychiatrist and principal investigator, Dr. Tony V Pham, will be immediately informed.

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 whole genome studies. These banks may also analyze and store DNA samples, as well. These central banks will store your genetic information and 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 samples and whole genome information with these banks. However, we cannot predict how genetic 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 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 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?

It is possible that participants will find some topics and questions to be emotionally upsetting, or that they may experience some psychological discomfort while discussing their experiences during the open pilot. A study psychiatrist will be present during all sessions and ready to address psychological discomfort and/or emotional issues should they arise.

Collecting identifiable information carries the risk of loss of confidentiality. However, we will take numerous steps to minimize this risk. Study data will be maintained in a locked filing cabinet and on password protected computers on Partners encrypted Storage Fusion Architectures (SFA). Interviews and questionnaire data will not become part of the your medical record and will not contain medical record numbers or names. Hardcopies of study related data and forms will be stored in a lockable file cabinet. Participant information will remain confidential by keeping identifying information (name and subject number) in a separate locked file cabinet. Only the investigators and study staff specified on the consent form will have access to this information. Prior to the audio-recorded interview, participants will be instated not to share identifiable information, and if they do, it will be omitted by study staff in the transcription process.

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 overall stress and symptom management of chronic pain and depression, and that you experience a better quality of life.

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

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 consist of broad-based training methods that are not tailored to any particular individual. If you would like formal mental healthcare or personalized instruction, 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. If given these referrals, you would be responsible, per standard billing practices.

Participation in this research study does not mean that you cannot seek other forms of treatment for chronic pain and depression, 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?

We respect your time and will reimburse you $105 for the first set of surveys (baseline assessment), $105 for the second set of surveys (post-test assessment), and $105 for the third set of surveys (3 months post-test assessment). Overall, you can earn up to $315 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 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:

- 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 researchers within or outside Mass General Brigham, for use in other research as allowed by law.

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.

Even with these measures to protect your privacy, 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 completely 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 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 identifiable 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 Date Time (optional)
or Person Obtaining Consent

Consent Form Version Date: 7/25/2024