Mass General Brigham

Research Consent Form
General Consent Form Template
Version Date: December 3, 2024

Subject Name:

MRN or DOB:

Subject Identification

Protocol Title: Does Acceptance and Commitment Therapy (ACT) Improve Disability in Chronic Migraine? A Randomized Headache Center Trial

Principal Investigator: Paul Rizzoli, MD

Site Principal Investigator:

Description of Subject Population: Graham Headache Center patients diagnosed with chronic migraine.

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 have chronic migraine. We are doing the research to investigate whether a particular behavioral therapy, Acceptance and Commitment Therapy (ACT), can help reduce disability in patients, like you, with chronic migraine when compared to usual treatment alone. If you agree, you will be assigned by chance to one of two groups, one will get training in ACT and the other will not. We will then have you answer questionnaires at several points in the study. You will be in the study for 12-14 months if you decide to stay for the whole study.

The main risks of being in the study are possible discomfort completing the questionnaires and loss of privacy and/or confidentiality.

You might benefit from being in the study if you are selected for the ACT group since this may improve your headache condition. There is no direct benefit to those in the usual care group, but your participation may help to benefit others from the findings of this research study.

You will be paid $200.00 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.

Paul Rizzoli, MD is the person in charge of this research study. You can call him/her at 617-983-7580 **M-F 9-5**. You can also call **Emma Weizenbaum, PhD at 617-983-7580, M-F 9-5,** with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call **Emma Weizenbaum at 6-7-983-7580. M-F 9-5.**

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?

The purpose of this research is to investigate whether a particular behavioral therapy, Acceptance and Commitment Therapy (ACT), can help reduce disability in patients with chronic migraine when compared to usual treatment alone. Behavioral therapies, that can include forms of meditation and mindfulness, have been used to treat patients with a number of conditions, including chronic pain. ACT is a newer behavioral therapy. This research is designed to find out if it reduces levels of disability in patients with chronic migraine.

Who will take part in this research?

Study participants will be drawn from patients attending The Graham Headache Center clinic with a diagnosis of chronic migraine. We expect to enroll 40 patients in this study. This study is sponsored by the Graham Headache Center. You will be in the study for a period of 12-14 months. If you choose to take part in this study, we will ask you to sign this consent form before we do any study procedures.

What will happen in this research study?

Your treating headache provider is usually the person who will refer you to the study. Before the study starts, there will be a screening visit. The screening visit will take about 30 minutes. It can be completed by phone. We will review with you the qualifications for entry into the study and answer any questions you may have. We will review your medical record to confirm the diagnosis of chronic migraine. If you qualify, we may be able to complete the consenting process during this visit. After you sign the consent, you will be assigned by chance to one of two groups and will complete the baseline questionnaires.

Once you enter the study as a participant you will be assigned to one of two groups. Group A will receive training in ACT and will practice the therapy on a regular basis at home while

continuing usual migraine treatment in the clinic. Group B will continue usual migraine treatment in the clinic and will not receive ACT training. Neither you nor study personnel know to which group you will be assigned; the selection will be made randomly by computer once you enter. You have a 50-50 chance of being assigned to either group, like the flip of a coin. Nothing else about your medical care changes; you will continue to be followed by your same provider.

Prior to starting the study and at 3, 6 and 12 months after starting the study (or after ACT training if so selected) you will be asked to fill out a series of questionnaires about how you are doing, about your ability to function with headache and other aspects of your headache problem. The questionnaires can be completed at home and forwarded to us. Total time to complete the questionnaires should be no more than 20-30 minutes.

If you are selected for ACT training, you will be assigned to a small group of participants who will be given training online by an ACT therapist. There are 8 weekly training sessions (usually in the evening) over 2 months, each lasting 45-60 minutes. After that, ACT participants are asked to practice the therapy at home on their own. Practice sessions can last 10-15 minutes every day or every other day.

We will provide all participants a paper diary and ask you to record medications you take to treat your individual headaches (i.e. abortive medications).

No in-person visits are needed in this study. No blood work or other procedures are required. Nothing else about your current headache care changes.

Audio/Video Recording
No audio or video recording will take place. Training sessions will be conducted over the internet using digital video technology, e.g. Zoom or Teams (hosted by Mass General Brigham), however no recordings will be made of the sessions.

Privacy/Confidentiality/Data Security
All the answers you provide to us will be stripped of direct identifiers (like name or MRN) and those direct identifiers will be replaced with a unique study code. A coded key will be maintained in a secure, password protected location and will only be available to study staff. Only study staff will know whose answers are whose, through use of the coded key. Data that does identify you, like consent forms and financial information, will be kept separately from coded questionnaire data.

We will do our best to keep your participation in this research study confidential to the extent permitted by law; however, it is possible that other people may need to review the research

records and may find out about your participation in this study. For example, the following people/groups may check and copy records about this research:

- The Office for Human Research Protections in the U. S. Department of Health and Human Services
- MGBrigham's Institutional Review Board (a committee that reviews and approves research studies) and the Office for Research Integrity and Assurance

We anticipate that your participation in this study presents no greater risk than everyday use of the Internet.Please note that email communication is neither private nor secure. Though we are taking precautions to protect your privacy, you should be aware that information sent through e-mail could be read by a third party.

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?

The main risks to participating in this research would be the possibility of loss of privacy or loss of confidentiality. To minimize these risks, we will be de-identifing all information you provide by instead using a coded key to protect your information. Also, meetings are conducted using Zoom or Teams hosted by Mass General Brigham. Additionally, it is possible that some could find some aspects of the ACT training lengthy or stressful.

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

Those in the ACT treatment group could benefit from the therapy and could note improvement in headache-related disability. From this research, we hope to learn more about the benefits of ACT in the headache population and to possibly consider offering it more widely to our headache patients.

What other treatments or procedures are available for your condition?

All study participants will continue to receive usual care from their providers. There are multiple treatments available for chronic migraine. These can be discussed with your provider.

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?

Participants will be compensated $50.00 for each set of questionnaires completed. Total compensation if you complete the study would be $200.00.

Your name and contact information may need to be shared with MGBrigham finance staff to process your payment, but they will not receive any research data or other details about the study.

Payment for participation in research may be considered taxable income. MGBrigham requires tracking for compensation that is paid to you; this may include your name and contact information. If you receive $600 or more in a calendar year, you may be contacted to provide additional information (e.g., Social Security Number) for tax reporting purposes. This information is stored confidentially and separate from research data.

We may use your samples and information to develop a new product or medical test to be sold. The Sponsor, hospital, and researchers may benefit if this happens. There are no plans to pay you if your samples or information are used for this purpose.

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

You will not be charged to participate in this study. There is no charge for the ACT training. The usual care that you receive from your provider is not covered by the study and is billed to your insurance.

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: NA

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)

Consent Form Version:
12/3/2024