NYU Langone Health

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| **Official Title:** | Treatment for Migraine and Mood (Team-M): A Pilot Trial of a Mindfulness-based Training Program |
| **NCT Number**: | NCT04992494 |
| **Study Number:** | 20-01911 |
| **Document Type:** | Informed Consent Form |
| **Date of the Document:** | • October 7, 2021 |

# Research Subject Informed Consent Form

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| **Title of Study:** | TREATMENT FOR MIGRAINE AND MOOD (TEAM-M): A PILOT TRIAL OF A MINDFULNESS-BASED TRAINING PROGRAM s20-01911 |
| **Principal Investigator:** | Amanda J. Shallcross<br>Department of Population health<br>NYU Langone Health<br>180 Madison Avenue<br>Floor 7, Office 711<br>New York, NY 10026<br>646-501-3426 |
| **Emergency Contact:** | Amanda J. Shallcross<br>646-501-3426 |

## 1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “subjects” or “research subjects”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

## 2. What is the purpose of this study?

The purpose of this research study is to develop and test an intervention designed to improve mood and reduce pain associated with migraine headaches.

## 3. How long will I be in the study? How many other people will be in the study?

This study will last about 2 months. About 16 study subjects over the age of 18 are to be entered into this study. This study will be an out-patient study. Your study visits will be entirely online or over the phone.

## 4. What will I be asked to do in the study?

If you choose to take part in the study, we will ask you to sign this consent form before you have any procedures with the study staff that are part of the study.

- **Screening**: To confirm that you meet the requirements to take part in this study, we will ask you questions about your mood, mental health history, and treatment. This will be conducted via a telephone or video-conferencing call with the study team to confirm final eligibility. If you do not meet the requirements, we will tell you why.

- **8-week intervention program**: You will participate in a skills-based psychological intervention that will be delivered remotely. You will be assigned to receive this intervention either over the telephone or via WebEx video-conferencing with a group of up to 8 people who have migraines and who report elevated depressive symptoms. The intervention program involves a commitment of 1 hour per week for 8 weeks. During the sessions, you will learn cognitive and mindfulness skills to help manage and cope with depression. Each weekly session consists of: check-in, instruction, skill building, discussion, and a home-based practice assignment. The sessions will be audio recorded to ensure that the facilitator is following the training protocol. If you do not wish to be recorded, you cannot participate in this study. A separate consent form will be presented to you for all audio-recording. Even if you participate in the video-conferencing intervention, only your audio will be recorded.

- **Assessments**: Before, during, and after the intervention program, you will be asked to complete some questionnaires online (or on paper if you prefer – we will mail you the questionnaires) about your mood, medications, and how you felt about the program (after you have completed the sessions). Each questionnaire will take roughly 30-45 minutes. You may skip over any questions that you find uncomfortable. After the intervention, we may invite you to provide some verbal feedback about your experience in the study over the phone, which would take around 10-15 minutes.

Any identifiable data collected and/or used for the purposes of this research will not be used or distributed for future research studies.

## 5. What are the possible risks or discomforts?

Participation in this study may involve some added risks or discomforts and may involve risks that are currently unforeseeable. These may include those directly related to study procedures as well as uneasiness related to the subject of this study. You may contact the study doctor if you are concerned about anything during the course of your participation in this study.

You will be asked questions about your current mood and experience of pain. Some of these questions could make you feel uncomfortable. You should discuss any concerns about discomfort with the research personnel.

Any time information is collected; there is a potential risk for loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

## 6. What if new information becomes available?

During the course of this study we may find more information that could be important to you. This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

## 7. What are the possible benefits of the study?

You may benefit from participation in this study by learning about strategies to improve migraine management and depressive symptoms.

## 8. What other choices do I have if I do not participate?

You may choose not to take part in the study. Deciding not to participate will not result in any penalty or loss of benefits to which you are entitled, and will not affect your relationship with NYU Langone Health.

## 9. Will I be paid for being in this study?

You will be paid to take part in this study. We will pay you by Amazon gift card.

You will be compensated $15 for the baseline assessment and $15 for the follow-up post-intervention assessment.

If you chose to leave or are withdrawn from the study for any reason before finishing the entire study, you will be paid for each completed assessment.

If you complete all the study visits, you will receive $30 for being in this study.

## 10. Will I have to pay for anything?

There will be no costs to you for participating in this research study. While you participate in this study, you may have costs which include such things as transportation, child care, and time from work (if you are employed) that are not reimbursed.

You and/or your health insurance may be billed for the costs of medical care during this study if these expenses would have happened even if you were not in the study, or if your insurance agrees in advance to pay. If you have health insurance, the cost of these services will be billed to your insurance company. If your insurance does not cover these costs or you do not have insurance, these costs will be your responsibility.

## 11. What happens if I am injured from being in the study?

If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of page 1 of this consent form.

There are no plans for the NYU School of Medicine or Medical Center to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

## 12. When is the study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped or your participation ended at any time by your physician, the study sponsor, or the Food and Drug Administration (FDA) without your consent because:

- The principal investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The study sponsor, the principal investigator, the Food and Drug Administration (FDA) or other body responsible for monitoring the safety of the study has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits.

## 13. How will you protect my confidentiality?

Your medical information is protected health information, or "PHI", and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record as well as information in your medical record at NYU Langone Health. In compliance with NYU Langone Health policies and procedures and with HIPAA, only those individuals with a job purpose can access this information.

Medical information created by this research study may become part of your medical record. We may include your research information in your medical record for several reasons, including for the billing of services provided in connection with the study, to securely document any medical services you receive, and so that other members of the NYU Langone Health community who may treat you have access to important information about your health.

You have a right to access information in your medical record. In some cases, when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Health policies and applicable law.

**Certificate of Confidentiality**
To help us further protect your confidentiality, this research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The NIH has issued a Certificate of Confidentiality for this research. This adds special protection for the research information (data, documents, or biospecimens) that may identify you.

Research information protected by this Certificate of Confidentiality cannot be disclosed to anyone else who is not connected with the research, without your consent. With this Certificate of Confidentiality, the researchers may not disclose or use research information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, without your consent. However, disclosure, without your consent, is still necessary if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases).
The Certificate of Confidentiality cannot be used to refuse a request for information from appropriate government agencies responsible for project oversight.

The Certificate of Confidentiality does not prevent you from releasing information about yourself and your involvement in this research, including for your medical treatment. Federal regulations may also allow for the use or sharing of information for other scientific research.

By agreeing to be in this research and signing below, you are giving your consent to share research information with others at NYU Langone Health. This means that your research information, including lab results, x-rays, MRIs, information about the investigational drug used in this study, may be included in your NYU Langone Health electronic medical record.

## 15. HIPAA Authorization

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with others in connection with this study- in other words, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

**What information may be used or shared with others in connection with this study?**
All information in your research record for this study may be used and shared with those individuals listed in this section. Additionally, information in your medical record that the research team believes may be important to the study may be accessed by those listed here. This includes, for example, results from your physical examinations, laboratory tests, procedures, questionnaires, and diaries.

**Who may use and share information in connection with this study?**
The following individuals may use, share, or receive your information for this research study:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study

- The study sponsor: National Center for Complementary and Alternative Medicine (NCCAM)
- Governmental agencies responsible for research oversight (e.g., the Food and Drug Administration or FDA).
- Health care providers, including your doctors and others who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

**What if I do not want to give permission to use and share my information for this study?**
Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

**Can I change my mind and withdraw permission to use or share my information?**
Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

**How long may my information be used or shared?**
Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

## 16. Permission to contact you about future research

We would like to contact you about future research. We will only contact you about future research that is approved by the IRB. If you agree, then the research team member who contacts you will tell you about a research study. At that time, you are free to decide whether or not you are interested in participating in that study. You will then have the opportunity to contact the researcher to schedule an appointment to be fully informed about that future research project. You have the right to take back this additional permission at any time.

Your permission to allow us to contact you about future research would be greatly appreciated, but it is completely up to you. If you choose not to allow us to contact you, you can still take part in this study. Please understand that giving your permission to do this is only for the purpose of helping us identify subjects who may qualify for one of our future research studies. It does not mean that you must join any study.

*You will have the opportunity to opt-out of this at the end of the consent form.

## 17. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research

studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU IRB Office number is (212) 263-4110. The NYU School of Medicine's IRB is made up of doctors, nurses, non-scientists, and people from the Community.

## 18. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website site at any time.

## 19. Option to decline participation in portion of the study

**Contacting you about future research**

☐ **NO,** I **do NOT** want to be contacted about any future research.

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Subject Initials

**When you sign this form**, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

| Name of Subject (Print) | Signature of Subject | Date |
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| | | |

| Name of Person Obtaining Consent (Print) | Signature of Person Obtaining Consent | Date |
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