ALBERT EINSTEIN COLLEGE OF MEDICINE
MONTEFIORE MEDICAL CENTER

DOCUMENTATION OF INFORMED CONSENT AND HIPAA AUTHORIZATION

Introduction

You are being asked to participate in a research study called the Bronx Mindfulness-Based Cognitive Therapy for Migraine: a Randomized Clinical Trial. Your participation is voluntary -- it is up to you whether you would like to participate. It is fine to say "no" now or at any time after you have started the study. If you say "no," your decision will not affect any of your rights or benefits or your access to care.

The researcher in charge of this project is called the "Principal Investigator." Her name is Elizabeth K. Seng, Ph.D. You can reach Dr. Seng at:
Office Address: 1165 Morris Park Ave
City, State Zip: Bronx, NY 10461
Telephone #: 718-430-3850
For questions about the research study, or if you believe you have an injury, contact the Principal Investigator or the IRB.

The Institutional Review Board (IRB) of the Albert Einstein College of Medicine and Montefiore Medical Center has approved this research study. The IRB # is in the stamp in the upper right hand corner. If you have questions regarding your rights as a research subject you may contact the IRB office at 718-430-2253 or by mail:

Einstein IRB
Albert Einstein College of Medicine
1300 Morris Park Ave., Belfer Bldg #1002
Bronx, New York 10461

Support for this research study is provided by start-up funds provided to Dr. Seng by the Ferkauf Graduate School of Psychology

Why is this study being done?

The goal of this study is to see whether a new type of behavioral treatment, Mindfulness-Based Cognitive Therapy, can help decrease disability in people with migraine. This individual treatment teaches new ways to think about migraine and other stresses in life. Many previous studies have found that Mindfulness-Based Cognitive Therapy reduces disability in people with depression and other mental health disorders; however, only one small pilot study in a rural area has found that Mindfulness-based Cognitive Therapy decreases disability in people with migraine. This study aims to examine whether Mindfulness-Based Cognitive Therapy can decrease disability in a larger group of people with migraine, in the Bronx.

Why am I being asked to participate?

You are being asked to participate in this study because you responded to an advertisement about this study from a flyer, your doctor's office, or online. You are also being asked to participate because you have a diagnosis of migraine, you report that you have six or more headache days per month, you are between the ages of 18-65, you can read English, and you have the capacity to consent to participate in the study; you also have NOT used new preventive pain treatments in the last four weeks, and do not plan to use new preventive pain treatments for the duration of the study, and you do NOT have a severe psychiatric illness that would interfere with participation in the treatment. This study aims to recruit 80 people with migraine. This is a single-site study.

How many people will take part in the research study?

You will be one of about 150 people who will be participating in this study.

How long will I take part in this research?

It will take you up to 9 months to complete this research study. During this time, we will ask you to make up to 9 study visits to the **Montefiore Headache Center or Yeshiva University.**

What will happen if I participate in the study?

The Screening Visit will occur at the Montefiore Headache Center or Yeshiva University and will take about 2 hours. During this visit, we will ask you some questions to see if you are eligible to take part in this research study. The research assistant will review the results of these tests and procedures. If you aren't eligible, the research assistant will tell you why. At this visit we will:

- Ask you about your medical history
- Give you some questionnaires to fill out about your demographics, your headache symptoms, disability you experience due to your headaches, thoughts, feelings and beliefs related to headaches, and your emotional health.

If you are eligible for the study, we will ask you to refrain from taking any new preventive treatments for pain. It is possible that over the course of the study, your migraines may get worse. If this happens, please call the principal investigator at the number provided in this consent form.

If you are eligible for the study, you will complete an electronic daily headache diary for 4 weeks, which includes questions about headache symptoms and disability, stress, mood, and lifestyle impact (e.g., sleep, exercise). You will be provided with a mobile device for the diary, or you may download the diary to your own device if compatible. At the end of the four week period, you will complete online questionnaires about headaches, thoughts, feelings and beliefs related to headaches, and your emotional health.

If you remain eligible for the study, we will assign you by chance (like a coin toss) to the Mindfulness-Based Cognitive Therapy group or the Waitlist/Treatment As Usual group. You and the research assistant cannot choose your study group. You will have an equal chance of being assigned to the Mindfulness-Based Cognitive Therapy group.

If you are assigned to the Waitlist/Treatment As Usual group, you will have no study obligations for eight weeks. You will then be asked to complete another 4 weeks of the electronic daily headache diary, and a final set of online questionnaires about headaches, thoughts, feelings and beliefs related to headaches, and your emotional health.

If you are assigned to the Mindfulness-Based Cognitive Therapy group, you will be assigned to a Mindfulness-Based Cognitive Therapy therapist. The therapist will meet with you for 90 minutes every week for 8 weeks. At each treatment visit, you will:

- Discuss a topic related to mindfulness
- Practice mindfulness meditation
- Discuss homework from the previous week, and assign homework for the following week
- At sessions 1, 4 and 8, we will complete paper-and-pencil surveys examining how you feel about the group, the therapist, and expectations about the treatment.

If you are assigned to Mindfulness-Based Cognitive Therapy, you will complete an electronic daily headache diary for the 8 weeks of the treatment, and for 4 weeks following the treatment. At the conclusion of this 4-week of headache recording, you will complete a set of online questionnaires about headaches, thoughts, feelings and beliefs related to headaches, and your emotional health. You will be contacted 6 months after completing treatment to complete follow-up questionnaires about headaches, thoughts, feelings and beliefs related to headaches, and your emotional health.

A description of this clinical trial will be available on 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.

Will there be audio and/or video recording?

The 8 sessions of Mindfulness-Based Cognitive Therapy will be audio-recorded to ensure that facilitators are providing the treatment faithfully. Recordings will be transcribed and coded for treatment fidelity. Recordings will be destroyed immediately upon transcription, no more than 6 months after the conclusion of data collection.

Will I be paid for being in this research study?

You will receive a total of $60 in Amazon gift cards for completing three sets of questionnaires and two four-week periods of headache diaries. If you are randomized to receive Mindfulness-Based Cognitive Therapy, you will receive an additional $20 Amazon gift card for completing the 6-month follow-up questionnaires. If you choose to withdraw from the study before all questionnaires, diaries, and clinic visits are completed, you will be paid only for the visits you completed.

Will it cost me anything to participate in this study?

There will be no cost to you to participate in the study.

What will happen if I am injured because I took part in this study?

If you are injured as a result of this research, only immediate, essential, short-term medical treatment as determined by the participating hospital, will be available for the injury without charge to you personally.

- No monetary compensation will be offered.
- You are not waiving any of your legal rights by signing this informed consent document.
- If additional treatment is required as a result of a physical injury related to the research, necessary medical treatment will be provided to you and billed to your insurance company or to you as part of your medical expenses.

Immediately report any discomforts, problems or injuries you experience during the course of your participation in the study to Dr. Elizabeth Seng, 718-430-3850.

What else do I have to do?

- You must tell the research assistant about all medications you are taking including "over-the-counter" remedies and nutritional supplements or herbs.
- If you do not feel well at any time, call your doctor or the principal investigator
- If a doctor recommends that you take any preventive medicine for pain, please inform him/her that you are taking part in a research study. You should give the other doctor the principal investigator's name and phone number.
- You may carry out all your normal daily activities.

Are there any risks to me?

Confidentiality
We will keep your information confidential, however, a risk of taking part in this study is that your confidential information might be shared accidentally with someone who is not on the study team and is not supposed to see or know about your information. This is very unlikely, because the study team takes confidentiality of your information seriously. Your research records will be kept confidential and your name will not be used in any written or verbal reports. Your information will be given a code number and separated from your name or any other information that could identify you. The form that links your name to the code number will be kept in a locked file cabinet and only the investigator and study staff will have access to the file. All information will be kept in a secure manner and computer records will be password protected. Your study information will be kept as long as they are useful for this research.

The only people who can see your research records are:

- the research team and staff who work with them
- clinicians and staff at Montefiore who review your records for your care
- groups that review research (the Einstein IRB, and the Office for Human Research Protections)

These people who receive your health information, may not be required by privacy laws to protect it and may share your information with others without your permission, if permitted by laws governing them. All of these groups have been asked to keep your information confidential.

Are there any times you would not keep my data confidential?
If you give us information that you may hurt yourself, we may have to break confidentiality and report this information to the authorities to ensure that you remain safe.

If you give us information that you may hurt someone else, we may have to break confidentiality and report this information to the authorities to ensure that both you and others remain safe.

Questionnaires
You may feel uncomfortable answering questions about your headache symptoms, how your headaches impact your daily life, your thoughts and beliefs as they relate to headaches, your mood, stress, and lifestyle (e.g., sleep, diet, exercise), and your perceptions about the Mindfulness-Based Cognitive Therapy group and facilitators. You can choose not to answer questions that make you feel uncomfortable.

Risks of Participating in Mindfulness-Based Cognitive Therapy
This study involves the practice of mindfulness. If you are randomized to the Mindfulness-Based Cognitive Therapy group, you will be asked to attend to sensations, thoughts and feelings that you might not ordinarily experience in as much clarity or depth. This type of internal exposure may cause discomfort. There is a small possibility that the level of discomfort will increase to an intolerable degree. If this occurs, you may stop the procedure immediately.

Are there possible benefits to me?

You may or may not receive personal, direct benefit from taking part in this study. The possible benefits of taking part in this study include reduction in headache-related disability if Mindfulness-Based Cognitive Therapy is shown to be effective, better understanding of your headaches and the behavioral factors (such as stress, mood, and lifestyle factors) that might influence your headaches.

What choices do I have other than participating in this study?

You can refuse to participate in the study. If you decide not to participate, the medical care providers at this facility will still give you all of the standard care and treatment that is appropriate for you. If you choose to participate in this study, you will not be able to add new preventive pain treatments during the course of the study.

Are there any consequences to me if I decide to stop participating in this study?

No. If you decide to take part, you are free to stop participating at any time without giving a reason. This will not affect your care and you will continue to be treated at this facility. However, some of the information may have already been entered into the study and that will not be removed.

Can the study end my participation early?

We will not let you participate in the study any more if during the first 4-week headache diary recording you do not meet study inclusion criteria. In addition, your participation will end if the investigator or study sponsor stops the study earlier than expected.

CONSENT TO PARTICIPATE

I have read the consent form and I understand that it is up to me whether or not I participate. I know enough about the purpose, methods, risks and benefits of the research study to decide that I want to take part in it. I understand that I am not waiving any of my legal rights by signing this informed consent document. I will be given a signed copy of this consent form.

Printed name of participant	Signature of participant	Date	Time
Printed name of the person conducting the consent process	Signature	Date	Time

USE OF IDENTIFIED INFORMATION FOR FUTURE RESEARCH

In addition to the research you are consenting to under this research study, Dr. Elizabeth Seng or other researchers at this or other institutions may wish to contact you to participate in future research. This requires that your name, contact information, and information relevant to study participation be collected at this time. This information will never be linked to the current study's research records. This information will be added to a database to recruit participants for future research studies. This information about you may be shared with other researchers who will keep the information confidential. However, it is possible that information about you may become known to people other than the researchers. Please note that ONLY the information contained below on this form will be retained, solely for the use of contacting you for future research opportunities; your information collected for the current study will only be kept as long as they are useful for the current study, and will subsequently be destroyed.

At this time, the researcher does not know what the future studies will be. You have the right to withdraw consent to be contacted for future research and have your name removed from the database at any time by contacting the supervisor of the study named on the first page of the consent.

PARTICIPANT:
PLEASE INDICATE YOUR CHOICE BY INITIALING ONE (1) OF THE FOLLOWING OPTIONS

___ I consent to be contacted to participate in future research.

___ I do NOT consent to be contacted to participate in future research.

Your wish does not constitute a guarantee that you will be contacted

PARTICIPANT:
FOR FUTURE CONTACT, PLEASE FILL IN THE FOLLOWING INFORMATION

Name:

Age:

Gender:

Mailing Address:

Email Address:

Phone Number:

On about how many days during the past month were you unable to perform the normal tasks of your day because of your headache?

PARTICIPANT:
FOR FUTURE CONTACT, PLEASE INITIAL YOUR CHOICES BELOW

_____ Contact me for any study.

_____ I am willing to participate in an online study.

_____ I am willing to participate in an on-site study.

_____ I am willing to participate in a one-time study.

_____ I am willing to participate in a daily diary study.