ALBERT EINSTEIN COLLEGE OF MEDICINE
MONTEFIORE MEDICAL CENTER
YESHIVA UNIVERSITY

DOCUMENTATION OF INFORMED CONSENT AND HIPAA AUTHORIZATION

Introduction

You are being asked to participate in a research study called **Clinical Decision Support for Patient Migraine Management (CDST).** 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 #: 646-592-4368
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, by e-mail at irb@einstein.yu.edu, or by mail:

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

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Concise Summary

Little is known about how people with migraine manage their migraine throughout the day. This study will evaluate factors associated with how people with migraine manage migraine, and will evaluate whether different types of education change how people manage migraine.

If you choose to participate you will be asked to enter information into an electronic headache diary (an "app") three times a day for up to six months and complete several on-line surveys. If you meet criteria, you will be randomized to receive one of two types of education about migraine after three months. The possible benefits to you personally include knowledge about your migraine patterns and improvement in your migraine management. Study risks are minimal; there is the possibility of loss of confidentiality and you may feel uncomfortable answering questions about your migraine attacks or changing how you manage migraine.

Why is this study being done?

Migraine is a common, painful and disabling disorder. Some people with migraine use more effective day-to-day strategies to manage migraine than other people. This study seeks to understand how people manage their migraines, what factors impact patient migraine management, and whether education about migraine can change patient migraine management.

Why am I being asked to participate?

You were identified to participate in this study because you were prescribed a certain type of migraine medication (triptan) within the past year and are between the ages of 18 and 65. You are being asked to participate in this study because you also have a diagnosis of migraine, reported having between 6-14 headache days each month, have not made any changes to your acute or preventive migraine treatment plan for at least one month, read English, and have capacity to consent. You do not have probable or confirmed medication overuse headache, a plan to change preventive or acute migraine medication during study participation, are not pregnant or are planning to become pregnant during study involvement, and do not have psychiatric illness or cognitive difficulties that would interfere with participation in the study. This is a single-site study.

How many people will take part in the research study?

You will be one of about 144 people who will be participating in this study.

How long will I take part in this research?

It will take you up to 6 months to complete this research study. During this time, we will not ask you to make any in-person study visits.

What will happen if I participate in the study?

You will be sent an internet link to provide informed consent and complete baseline surveys. The surveys will include questions about:

- your general health
- your demographics
- your headache symptoms
- any disability you experience due to your headaches
- thoughts, feelings and beliefs related to headaches
- your emotional health

You will be sent instructions to initialize the study app for diary data collection. The app will alert you to fill out the diary three times a day for 30 days. If you continue to meet criteria for the study, you will continue to fill out the diary three times per day for an additional two months, and you will receive links for additional surveys each month.

If you continue to meet criteria after three months, you will have the opportunity to continue in the study and be randomized to receive one of two kinds of education about migraine through your headache diary. You will continue to complete the headache

diary three times a day and receive additional surveys each month for an additional three months. Thus, the total potential length of study participation is 6 months.

Information Banking (Future Use and Storage)

We will destroy the data within 6 months of the completion of the study. Information about you will be kept as long as required by regulations and institutional policy, but will not be used for future studies. We would like to keep your contact information so that we can contact you to inform you about new studies. Please indicate your choice below.

INITIAL YOUR CHOICE BELOW

_____ I consent to be contacted in the future to learn about:
_____ New research protocols that I may wish to join.
_____ General information about research findings.
_____ I do not want to be contacted at all.

Will I be paid for being in this research study?

Total possible compensation is $190. You will receive gift cards after completing month 3 of recording, with a possible compensation of $105 ($10-20 for each survey, and $0.50 for each diary entry). If you continue the study past month 3, you will receive additional gift cards after completing month 6 of recording with a possible compensation of $85 ($10-20 for each survey, and $0.50 for each diary entry). If you choose to withdraw from the study before your participation is completed, you will be paid only for what 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 Elizabeth Seng, PhD at 646-592-4368.

What else do I have to do?

- If you do not feel well at any time, call your doctor or the research study doctor immediately.
- If you think you have become pregnant, contact your research study doctor immediately.
- If any other doctor recommends that you take any medicine, please inform him/her that you are taking part in a research study. You should give the other doctor the research study doctor's name and phone number.
- You may carry out all your normal daily activities.

Confidentiality

We will keep your information confidential. 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 secure manner 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
- the organization that funded the research
- 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.

Certificate of Confidentiality
As a way to protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health, which is funding this study. If information from this study were requested or subpoenaed by government agencies or the courts, we would use the Certificate to attempt to legally refuse to provide that information. These requests are rare – in only a few cases did researchers have to use the Certificate, and it was honored most of the time, but not every time. There are several kinds of situations to which the Certificate does not apply. For example, we are still required to report child abuse and some diseases, and we must make data available to the government for review or evaluation of our research. The Certificate does not prevent you or a member of your family from voluntarily sharing information. Similarly, if an

insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Are there any risks to me?

A risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Loss of privacy means having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your privacy – see the Confidentiality section above for details.

Surveys

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, and your mood, stress, and lifestyle (e.g., sleep, diet, exercise). You can choose not to answer questions that make you feel uncomfortable. You may feel uncomfortable learning new things about your migraine disease.

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 increased knowledge about your migraine attacks and possible improvement in migraine management.

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 change your preventive or acute migraine treatment plan 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. The researchers and the sponsor may continue to use and share the information they have already collected.

To revoke (take back) your consent and authorization, you must contact the Principal Investigator in writing at the address on page 1 of this form. However, you may first call or speak to the Principal Investigator and she will stop collecting new information about you. If you take back your consent and authorization, you will not be allowed to continue to participate in this research study.

Can the study end my participation early?

We will not let you participate in the study any more if you no longer meet the 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