KEY INFORMATION FOR Telehealth Behavioral Migraine Management

We are asking you to choose whether or not to volunteer for a research study about remote behavioral treatments to reduce headache frequency in people with migraine. Remote treatments are methods for enhancing health care, public health and health education delivery and support using telecommunications technologies.

This page is designed to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

This study is evaluating whether a 2-3 month remotely delivered behavioral treatment for migraine will help to reduce the number of days you experience headaches and migraine-related disability.

By doing this study, we hope to learn whether a remote behavioral migraine treatments are feasible (whether patients engage in the various treatment components) and acceptable (whether patients are satisfied with the treatment). Your participation in this research will last about 12 weeks.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You may experience a reduction in headache days and migraine-related disability from participating in this study. For a complete description of benefits, refer to the Consent Document below.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You may have an intense emotional experience while engaging in certain components of the treatment.
For a complete description of risks, refer to the Consent Document below.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights or access to care you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Elizabeth Seng, Ph.D. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: Elizabeth.Seng@einsteinmed.edu.

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact staff in the Einstein Institutional Review Board (IRB) between the business hours of 9am and 5pm EST, Monday-Friday at 718-430-2253 or irb@einsteinmed.edu

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MONTEFIORE MEDICAL CENTER
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DOCUMENTATION OF INFORMED CONSENT AND HIPAA AUTHORIZATION

Introduction

You are being asked to participate in a research study called **Telehealth Behavioral Migraine Management.** 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.

"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@einsteinmed.edu, 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 a **National Center for Advancing Translational Sciences (NCATS) Clinical and Translational Science Award (CTSA).**

Dr. Seng has a relationship with GlaxoSmithKlein, a company that manufactures medication for the treatment of Migraine Headache

Why is this study being done?

Migraine is common and disabling. Behavioral Migraine Management can reduce migraine frequency and migraine-related disability. This study is evaluating the feasibility and acceptability of a telehealth adaptation of Behavioral Migraine Management including online education modules and telephone sessions.

Why am I being asked to participate?

You are being asked to participate in this study because you are an adult with migraine who experiences headaches more than 4 days per month. You were recommended for the study by your provider at the Montefiore Headache Center.

How many people will take part in the research study?

You will be one of about **60** people who will be participating in this study.

How long will I take part in this research?

It will take you about 12 weeks to complete this research study. During this time, we will ask you to keep a daily headache diary and participant in one of three remotely delivered behavioral migraine interventions, and to complete questionnaires at the beginning and end of the study.

What will happen if I participate in the study?

If you are eligible to participate in this study, you will complete a daily headache diary. At the beginning and end of the study you will also be asked to take a brief survey. You may choose one of the three remote-delivered intervention options below:

Online Behavioral Migraine Education Modules: You will receive eight weekly online educational modules about migraine that will take approximately 15 minutes to complete each week.

Behavioral Treatment with a Therapist: You will receive six hour-long individual behavioral intervention sessions via phone call to treat migraine approximately every other week over the course of 12 weeks.

A Combination of Online Modules and Behavioral Treatment with a Therapist: You will receive weekly online modules over the course of 12 weeks. You will also receive four hour-long individual behavioral intervention sessions via phone call to treat migraine and three check-in phone calls.

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 I be paid for being in this research study?

You will receive a total of $42 for 3 months of daily headache diary entries (84 diary entries). If you choose to withdraw from the study before all visits are completed, you will be paid only for the visits you completed.

Some researchers may develop tests, treatments or products that are worth money. You will not receive payment of any kind for your information or for any tests, treatments, products or other things of value that may result from the research.

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?

Taking part in this research study may result in injury or harm to you. In the event of an injury resulting from your participation in this study, you should seek appropriate medical care and inform the study doctor. In the event of an emergency you should go to an emergency room.

If you are injured or harmed as a result of participating in the study and receive medical care through the Montefiore Medical Center, a Montefiore doctor, or any other health provider, you will be sent a bill for whatever medical care you receive. All or part of your bill may be paid by your health insurance.

Albert Einstein College of Medicine and Montefiore Medical Center are not offering to pay you for pain, worry, lost income, the cost of your medical care or non-medical care costs that might occur as a result of your taking part in this study. However, you do not waive any of your legal rights in signing this form.

Immediately report any discomforts, problems or injuries you experience during the course of your participation in the study to **Elizabeth K. Seng, Ph.D. at 646-592-4368.**

What else do I have to do?

- You must tell the research study doctor about any past and present diseases or allergies you are aware of and 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 research study doctor immediately.
- If you think you have become pregnant, contact your research study doctor immediately.
- You may carry out all your normal daily activities.

Confidentiality

The researchers and study staff follow federal and state laws to protect your privacy. This part of the consent form tells you what information about you may be used and shared in the research described in this form. You do not have to sign this form but, if you do not, you may not participate in the research.

Your information and research records will be kept confidential. Your study information will be kept as long as they are useful for the research described in this form.

The only people who can see your research records are:

- Researchers and other individuals who work with the researchers
- Organizations and institutions involved in this research, including those that fund the research.
- Groups that review research such as central reviewers, Institutional Review Boards, the Office for Human Research Protections, data coordinating centers, and domestic and foreign agencies that regulate research.

The purposes of these uses and disclosures are to (1) conduct the study and (2) make sure the study is being done correctly. The information covered under this form may no longer be protected by federal privacy laws (such as HIPAA) once disclosed, and those persons who receive your health information may share your information with others without your additional permission. All of these groups have been asked to keep your information confidential.

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?

You may have an intense emotional experience while engaging in certain components of the treatment.

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.

Questionnaire
You may feel uncomfortable answering questions about how your migraine impacts your life. You can choose not to answer questions that make you feel uncomfortable.

New Findings
If we learn any significant new findings during the study that might influence your decision to participate, we will contact you and explain them.

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 this study include experiencing a reduction in headache days and migraine-related disability.

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.

Your other choices are to receive behavioral treatment for headache through the Behavioral Medicine Sub-clinic at Parnes Clinic, Ferkauf Graduate School of Psychology, 1225 Morris Park Ave, Bronx, NY (718-430-3850).

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 have a serious adverse event that is deemed to be study-related. In addition, your participation will end if the investigator or study sponsor stops the study earlier than expected.

E-Consent signature field:

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.