Toward Understanding Drivers of Patient Engagement With Digital Mental Health Interventions – Part I

NCT05360901

Date: 8/8/2022

Mass General Brigham

Research Consent Form
Certificate of Confidentiality Template
Version Date: February 2021

Subject Identification

Protocol Title: Toward Optimizing Digital Mental Health Interventions: A Clinical Trial Aimed at Understanding What Drives Patient Engagement - Part 1

Principal Investigator: Jessica M Lipschitz, PhD

Site Principal Investigator:

Description of Subject Population: Adults with depression and/or anxiety

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

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. Your decision won't change the medical care you get within Mass General Brigham now or in the future.

The following key information is to help you decide whether or not to take part in this research study. We have included more details about the research in the Detailed Information section that follows the key information.

Why is this research study being done?

In this research study we want to learn more about what kinds of messages may help motivate patients with depression and/or anxiety to stay engaged in mobile app interventions.

How long will you take part in this research study?

If you decide to join this research study, we will ask you to complete a brief enrollment call, utilize a mobile app for three weeks, complete a brief survey on days when you receive a push notification, complete a brief weekly survey, and take part in 1, 90-minute study visit**.**

What will happen if you take part in this research study?

If you decide to join this research study, the following things will happen you will interact with a mobile application, take part in a study interview, and complete questionnaires.

Why might you choose to take part in this study?

You may not benefit from taking part in this research study. Others with depression and/or anxiety may benefit in the future from what we learn in this study.

Why might you choose NOT to take part in this study?

Taking part in this research study has some risks and requirements that you should consider carefully.

Important risks and possible discomforts to know about include possible fatigue from the study visits, and potential discomfort from the nature of questions asked. There is also a potential for loss of confidentiality. Additionally, if data you provide indicates that you may be at risk of hurting yourself or someone else, we will call you and may need to notify authorities.

A detailed description of side effects, risks, and possible discomforts can be found later in this consent form in the section called “What are the risks and possible discomforts from being in this research study?”

What other treatments or procedures are available for your condition?

Other treatments or procedures that are available to depression and/or anxiety include medications along with psychotherapy.

If you have questions or concerns about this research study, whom can you call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Jessica Lipschitz, PhD is the person in charge of this research study. You can call her at 617-732-6548 M-F 9-5. You can also call Meg Shanahan at 617-732-5790 M-F 9-5 with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call Rachel Van Boxtel at 617-732-9116.

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

Why is this research study being done?

We are doing this research to better understand what kinds of messages may help motivate patients with depression and/or anxiety to stay engaged in mobile app interventions.

Who will take part in this research?

We are asking you to take part in this research study because you experience depression and/or anxiety.

Up to 40 people will take part in this research study.

The National Institute of Mental Health is paying for this research to be done.

What will happen in this research study?

This study will involve one enrollment call, a three-week study period, and a 90-minute follow-up study visit. This study visit will be audio recorded so we can go back and review the feedback you provide afterwards.

Enrollment Call/Zoom & Survey – 15 minutes

- You will complete questionnaires on demographics, depression severity (Patient Health Questionaire-8), anxiety severity (Generalized Anxiety Disorder-7), a brief enrollment survey on messaging preferences, and comfort with mobile technology (Technology Adoption Propensity Scale).
- We will help you download the study intervention app (IntelliCare) and the push notification delivery/survey app (MyDataHelps or Catalyst by MetricWire) on your personal smartphone.

Study Period – 3 weeks

- We will ask you to utilize IntelliCare and respond to push notifications from MyDataHelps or Catalyst by MetricWire for three weeks. Note that these apps use cellular data when opened without a wireless internet connection and you will not be reimbursed for any data charges.
- We will ask you to complete brief self-report measures on depression severity and anxiety severity after week 1 and week 2.

Follow-up study visit – 90 minutes

- We will ask you to complete some self-report measures on messaging preferences, depression severity and anxiety severity. We will also ask you to answer open-ended questions on your experiences with mental illness and your experiences with technology.
- We will ask you for feedback about your experiences with the IntelliCare app and push notification messages received. We will also present you with low-fidelity prototypes of additional messages.

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 data in other research. It won't be possible to link the information or samples back to you. Information 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?

No. The research study we are doing is only a stepping stone in understanding what drives patient engagement with digital interventions. Therefore, no information about the results of this research study or the results of your individual participation in the research study will be given to you or your doctor. Tests done for the research using your samples will not be useful in directing your medical treatment. The results of the tests will not be placed in your medical record.

What are the risks and possible discomforts from being in this research study?

The main risk of allowing us to store and use your data and certain limited health information for research is a potential loss of privacy. We will protect your privacy by labeling your information only with a code, and keeping the key to the code in a password protected database.

As is always the case with electronic data, there is a possibility that databases may be hacked. Data entered into the IntelliCare will be anonymous and is encrypted in transit and at rest. This means that, while the company that hosts IntelliCare (Adaptive Health, Inc.) will have access to a detailed log of how you use the app, they will not have access to any of your personal

information that allows them to tie this app use back to you. The MyDataHelps and Catalyst by MetricWire apps that we use for push notifications and the associated surveys are HIPAA compliant. All data collected will be stored on secure servers at either Brigham and Women's Hospital, Adaptive Health, Inc., Metricwire Inc., or CareEvolution, LLC.

It is important to know that none of the apps used provide in-the-moment crisis support. If your symptoms get worse, you should contact a medical provider such as your primary care provider or a mental health clinic. If you begin having thoughts of death or suicide, you should call 911 or go to the nearest emergency room. You can also call the National Suicide Prevention Lifeline at 1-800-273-8255. It is also important to know that your Brigham and Women's doctors will not be receiving or reviewing data you enter into the IntelliCare or study questionnaires. These data are not monitored in real-time.

Additionally, some of the questions that you will be asked in the study interview may be unsettling, but most will not be. You may ask to see the questions before deciding whether or not to participate in the study. You may decline to answer any question that you are not comfortable answering. You may also become fatigued during the study visit. At your request, this visit may be split into several shorter sessions.

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

There may be no immediate benefits to you from participation in this research study; however, the results may allow researchers to design effective ways to better engage patients with digital mental health interventions. Subjects engaged in this type of participatory design research, sometimes report a sense of accomplishment from participation.

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?

You will be paid up to $102 for participating in this study. We will also reimburse parking at BWH for study visits, up to $15 per visit.

We may be using an approved, outside vendor (Advarra) make these payments to you via a reloadable credit card-based system, called Advarra Participant Payments. This secure system is similar to a gift card or credit card.

If you are paid by this system, you will be given a Participant Payments Visa card when you enroll in the study. Once the card is activated, the study team will add a payment after each paid visit you complete. The payment should be available to you within a day. You may use the card anywhere Visa cards are accepted, such as at a grocery store.

We will need to collect your Social Security number in order to make these payments, and it will be shared securely with the company that runs the card-based system. Payments like this are considered taxable income. If you receive more than $600, the payment will be reported to the IRS as income by the hospital.

If you provide a receipt for something like travel expenses and we can cover that, that is not considered taxable income. Reimbursement of expenses will not be made using the Participant Payments card.

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

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. There are no routine items or services associated with this study.

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:

- 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 researchers within or outside Mass General Brigham, for use in other research as allowed by law.

Certificate of Confidentiality

A federal Certificate of Confidentiality (Certificate) has been issued for this research to add special protection for information and specimens that may identify you. With a Certificate, unless you give permission (such as in this form) and except as described above, the researchers are not allowed to share your identifiable information or identifiable specimens, including for a court order or subpoena.

Certain information from the research will be put into your medical record and will not be covered by the Certificate. This includes records of medical tests or procedures done at the hospitals and clinics, and information that treating health care providers may need to care for you. Please ask your study doctor if you have any questions about what information will be included in your medical record. Other researchers receiving your identifiable information or specimens are expected to comply with the privacy protections of the Certificate. The Certificate does not stop you from voluntarily releasing information about yourself or your participation in this study.

Even with these measures to protect your privacy, 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 completely 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 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 identifiable information to be used and shared as described above.

Subject	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.

Study Doctor or Person Obtaining Consent	Date	Time (optional)

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