Mass General Brigham

Research Consent Form
General Consent Form Template
Version Date: November 2022

Subject Name:

MRN or DOB:

Subject Identification

Protocol Title: Behavioral Health Home Hospital: A Pilot Randomized Controlled Trial

Principal Investigator: Dr. David Levine, MD, MPH

Site Principal Investigator

Description of Subject Population: Highly selected lower-risk patients with acute psychiatric illness that require inpatient care.

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.

Some of the people who are eligible to take part in this study may not be able to give consent to take part because of their medical condition. Instead, we will ask the person's authorized representative to give consent. Throughout the consent form, "you" always refers to the person who is receiving treatment as part of the study.

Key Information

We are asking you to be in a research study. This form will tell you what you should expect if you agree to be in the study. You will find more information about each of the following points later in this form.

It is your decision whether or not to join the study. We are asking you to be in this study because you require inpatient acute behavioral health care but are not a harm to yourself or others and therefore may not require care in a locked psychiatric unit if a home hospital team were available to help care for you. We are doing this research to find out if providing acute behavioral health

care at home is feasible and acceptable to a subset of lower-risk patients with behavioral health concerns. For the BHH , a clinical team will come to your home and provide hospital-level care at home to treat your behavioral health illness instead of staying in the hospital for your treatment. You will be in the study for the length of your treatment and then 30 days after if you decide to stay for the whole study.

The main risks of being in the study are emotional distress and discomfort and potential physical impairment and death.

You might benefit from being in the study because you are able to receive care in your own home and eat your own food, sleep in your own bed and spend time with family and friends. T These potential benefits are under investigation and may not be a benefit.

If you decide not to be in the study you will receive regular inpatient behavioral health care.

You will not be paid for taking part in this research study.

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

Dr. David Levine MD MPH MA is the person in charge of this research study. You can call him at 617-732-7063, M-F from 9am-5pm with questions about this research study.

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

A description of this clinical trial will be available on *http://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.

Why is this research study being done?

Normally when a person becomes very sick, they may need to go to the hospital. We have been successful in caring for adults in their homes who would normally be in the hospital because of an illness. Our work has so far excluded patients with any active psychiatric condition. We now want to see if we can give the same care to a highly selected lower-risk group of people with psychiatric illness. We are doing this work to see if providing hospital care at home ("home hospitalization") is reasonable and acceptable to patients.

We are asking you to take part in this study because you are an adult with a behavioral health diagnosis that the research doctors consider safe to take care of at home and agree to home hospitalization.

In addition to expert clinical staff, we will be using state-of- the-art technology during the home hospitalization: remote vital-sign monitoring (checking things like heart rate with an arm band), video visits with doctors, and virtual reality.

Other technology that will be used includes:

- We may track your location to ensure your safety with the AngelSense wearable device. The device is HIPAA compliant. It can be unsafe if you leave unexpectedly, and this device might help reduce the risk. When you wear this device, the care team will be able to track your location, and the team will be notified if you leave your home. Only your care team will have access to your location, and in an emergency, it may be shared with Emergency Medical Services if needed.

- We will monitor your physical activity using the Actigraph wearable device that has a built-in activity tracker. Only your care team will have access to the data. Benefits include helping us see how well you are moving. The risks are not yet determined to be different in BHH compared to in the traditional brick-and-mortar.

- You may have the option to use a MetaQuest virtual reality headset for group and individual therapy or individual activities. All headsets will be managed by the BHH team and none of your personal information will be used. Benefits include being able to engage in immersive activities and therapy anonymously. Risks include possible discomfort, headaches or nausea from using the headset.

- We may use an automatic pill dispenser, MedaCube 2.0, to deliver your medications. The dispenser will be connected to a hot spot provided by the BHH team for internet connectivity. Benefits include automatic dispensing and reminders to take your medicines. Risks include possible challenges with medication administration.

- You may have the option to use virtual reality (VR) and tablet apps, such as Innerworld, Tripp, Insight Timer, and Mindfulness.com. The apps will be accessed through study-provided VR headsets and encrypted tablets. Benefits include engaging in mental health resources that may support your treatment and participating anonymously. Risks include possible discomfort, headaches or nausea if using the VR headset.

Who will take part in this research?

- About 20 patients will take part in this study. You will not receive payment for taking part in this study.
- This study is funded by the Thompson Family Foundation. None of the vendors involved are funding this study.

What will happen in this research study?

Behavioral Health Home hospital: your care will be in your home with a set of services tailored to your medical needs:

- Virtual visit by a Mass General Brigham physician or advanced practice provider at least once a day
  - Available 24 hours every day by video or phone if your condition requires it
- In-home and virtual nurse at least twice a day to provide care, including checking vital signs.
  - Available more often if your condition requires it

- The BHH team can provide in-home, in-person clinical coverage and monitoring as needed for up to 8 hours a day
- Group or individual therapy
- In-home and virtual visits by other members of your care team as needed (e.g. mental health specialist, care coordinator)
- Remote wireless vital signs (such as heart rate), activity, and sleep monitoring with alarms that notify our team if something is not right
- Medical tests and treatments if needed. These may include:
  - In-home intravenous infusions (for IV fluids or medications) as needed
  - In-home testing as needed: blood tests
  - If required by the physician, the health care proxy can consent to the patient receiving an intramuscular medication

We will collect information from your medical record so that we can measure the quality and safety of the care you received. We will also ask you some questions at the beginning, during, and end of the hospitalization and 30 days after discharge to learn more about your experience of the care you received. You will be asked to complete a brief survey at admission, discharge and 30 days after discharge to assess your outcomes. Additionally, you will be asked to complete a brief interview when you are discharged to learn more about your experiences while hospitalized. All of this information will remain confidential (see below).

At any time, you can choose to stop taking part in this study and return to the hospital. The study team may choose to end your participation in the study if you become too ill for behavioral health home hospital and need to go to the hospital for further care.

This may happen because:

- Your condition does not respond to standard treatments
- Your initially diagnosed condition was incorrect
- You have an adverse reaction to treatment

If you decline to follow the care plan, you will be returned to the hospital.

A record of your admission may be made in your electronic medical record. Information from the research that relates to your general medical care may be included in the record (for example, list of allergies, results of standard blood tests done at the hospital labs). Please ask your study doctor if you have any questions about what information will be included in your electronic medical record.

We will collect information about what happens to you during and for 30 days after your hospitalization. For example, we will determine the cost of your hospitalization, how long your

hospitalization lasted, if you used an emergency room after your hospitalization, the quality of care you received, your quality of life, and how satisfied you were with your hospitalization. We want to make sure the study doctors know about any possible problems or side effects you experience while you are in the study.

By consenting to this study, you agree to the expectations of BHH. The expectations are similar to if you were in the hospital. Please ask the BHH team if you have any questions:

- You agree to communicate with your care team through visits at home by care team members or virtual communication through a tablet or phone.
- You agree to stay in your house for the duration of your hospitalization. As you progress with your treatment, you may eventually be able to go on small outings with a care team member or caregiver, but this will be up to your care provider's discretion.
- You agree to wear an arm band that will monitor your vital signs and agree to keep it on unless you are in the shower.
- To participate in the study, you must agree to the level of in-home support and monitoring determined by the study doctor and clinical team. This could include the possibility of asking you to agree to be in the same home with your caregiver 24/7, unless another member of the BHH care team is present. If the study doctor determines you require additional caregiver support, participation will only be possible if you agree to that plan and an appropriate caregiver is available

Patient interaction monitoring:

There will be an optional audio and video recording of a patient visit as part of the research study. The video recording will be used by the study team for quality assurance purposes and to ensure that BHH protocols are followed. The recording will not be shared or published. The recording will be securely stored and labeled with an ID number. The recording will not be used for anything other than what is stated in the consent form without your written permission. Your signature on this consent form gives the study staff permission to record you as described above during participation in this study.

By consenting to this study, you agree to the expectations of BHH. The expectations are similar to if you were in the hospital. Please ask the BHH team if you have any questions:

- You agree to wear a wrist monitor that will monitor your daily activity and agree to keep it on unless you are in the shower.

- You agree to participate in your care and pause other responsibilities, such as school and/or work. This is at the discretion of the care provider.
- You agree not to take any substances that are not prescribed, such as alcohol, drugs, marijuana, and non-prescribed medication, and secure these substances in a locked box until you are discharged from BHH.

We will collect information about what happens to you during and for 30 days after your hospitalization. For example, we will determine how long your hospitalization lasted, if you used an emergency room after your hospitalization, the quality of care you received, your quality of life, and how satisfied you were with your hospitalization.

Text message and email reminders may be used to remind you to complete the discharge and post-discharge surveys electronically in REDCap. These communications carry security risks because they are not encrypted. This means that information you receive by text message and email could be intercepted or viewed by an unintended recipient, or by your mobile/cell phone provider or carrier. Below are some important points about texting and email in this research study(Mass General Brigham Human Research Affairs 2024).

- Text messages and emails are not encrypted and therefore carry security risks.
- This research study and Mass General Brigham are not responsible for any interception of messages sent through unencrypted text message or email communications.
- You will be responsible for all fees charged by your carrier's service plan for text messaging. This research study and Mass General Brigham are not responsible for any increased charges, data usage against plan limits or changes to data fees from the research texts.
- You may decide to not receive text messages or email reminders with this research study at any time. You can do this by contacting the BHH team or respond to the texts directly to opt out.
- Your agreement applies to this research study only. Agreeing to other texts or emails from Mass General Brigham, for example appointment reminders, is a separate process. Opting out of other texts or emails from Mass General Brigham is a separate process as well.
- It is your responsibility to update your mobile/cell phone number or email with this research study in the event of a change.

How may we use and share your samples and health information for other research?

Your samples or health information collected for this study will NOT be used or shared for other research, even if we remove identifiable information like your name, medical record number, or date of birth.

Will you get the results of this research study?

You and your doctor should not expect to get information about the results of the research study or the results of your individual participation in the research study. We and the researchers involved in this study will study data from many people. It could take many years before anyone knows whether the results have any meaning. There is a small chance that we could find out something from the study that might be important to your health. If this happens, we may contact you to find out if you would like to learn more. However, even if we find something important to your health, we cannot guarantee that you will be contacted.

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

Any time a person is admitted to the hospital, there are risks of physical impairment and death, emotional distress, costs, and discomfort from both the disease as well as procedures during the admission. Any of these same risks apply when being hospitalized at home. An additional risk of being hospitalized at home is that in the case of an acute emergency, your physician and nurse are further from you than in traditional hospital care. However, you can reach our study clinical team 24 hours a day by video or phone. If there is an emergency (such as increased agitation), we will call our urgent team to your home. Clinical staff will make sure you are comfortable using the study devices to reach the clinical staff at any time. We will also explain to you what our plan is for handling any unexpected problems or events. In addition to the risks listed above, other previously unknown risks may occur. Additionally, there is a small risk of loss of confidentiality. There is the unlikely possibility of a breach of confidentiality. We only use encrypted hospital systems to store your information. We use coding systems and de-identify your information. All data is stored on password-protected computers with antivirus software. If we learn information from you during this study that indicates intent to seriously harm others or yourself, we may be required by law to share that information with third parties, including public safety or law enforcement authorities, and may take other precautions to protect against such harm.

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

Some of the possible benefits are included below and are under investigation, so there may be no benefit:

- Remain in your home during your acute psychiatric illness
- Spend more time with your family and friends
- Experience an alternative psychiatric admission that may be less troubling than the traditional experience

We hope this research may have future benefits such as:

- If behavioral home hospital is shown to benefit patients, then this may become a common alternative to traditional psychiatric hospitalization for many adults.
- This model may also reduce future health care costs in the U.S.

What other treatments or procedures are available for your condition?

You do not have to take part in this study to be treated for your medical condition. Taking part in this study is voluntary. If you do not want to take part in the study, you will be admitted to the hospital as an inpatient and you will be treated according to standard of care for your condition.

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 not be paid for taking part in this research study.

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.

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 they may need to do so:

- 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
- 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: None

Some people or groups who get your identifiable information might not have to follow the same privacy rules that we follow and might use or share your identifiable information without your permission in ways that are not described in this form. We share your identifiable information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. However, 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 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 study 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 health information to be used and shared as described above.

_____

Print Name

_____ _____ _____

Subject Signature Date Time (optional)

Signature of Guardian or Authorized Representative for Adult:

I give my consent for the person I am authorized to represent to take part in this research study and agree to allow his/her health information to be used and shared as described above.

_____

Print Name (check applicable box below)

- ☐ Court-appointed Guardian
- ☐ Health Care Proxy
- ☐ Durable Power of Attorney
- ☐ Family Member/Next-of-Kin

Signature	Date	Time (optional)

Relationship to Subject:_____

Assent

Statement of Person Giving Assent

- 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, and my questions have been answered.

Signature of Adult:

I agree to take part in this research study and agree to allow my health information to be used and shared as described above.

Print Name

Signature of Adult | 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.

Print Name

Signature of Study Doctor or Person Obtaining Consent | Date | Time (optional)

Consent of Non-English Speaking Subjects Using the "Short Form" in the Subject's Spoken Language

Statement of Witness

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

Print Name

Witness Signature | Date | Time (optional)

Consent of Subjects Who Cannot Read or Write or are Physically Unable to Talk or Write

The consent form was presented orally to the subject in the subject's own language, the subject was given the opportunity to ask questions, and the subject has indicated his/her consent and authorization for participation by (check one box as applicable):

☐ Making his/her mark above

☐ Other means _____

(fill in above)

Consent Form Version: 04/1/06, Version 4