BOSTON MEDICAL CENTER AND THE
BOSTON UNIVERSITY SCHOOLS OF
MEDICINE, PUBLIC HEALTH AND DENTAL
MEDICINE

RESEARCH CONSENT FORM

Basic Information

Title of Project: Optimizing a Family Partner Navigation Model for Children

NCT03569449

IRB Number: H-37634

Sponsor: National Institute of Mental Health (NIMH)

Principal Investigator:
Dr. Emily Feinberg
801 Albany Street, room 2034
Boston, MA 02118
617-414-7440
emfeinbe@bu.edu

Overview

We are asking you to agree for you and your child to be in a research study. A research study is an organized way of collecting information about scientific questions. I would like to tell you what you and your child should expect if you agree for you and your child to be in the study. There are programs in place to make sure that investigators fulfill their obligations that we should discuss.

It is your decision whether or not to agree for you and your child to join the study. We are doing the research to better understand how Family Partners can be most helpful to families whose children have mental health needs. If you agree, you and your child will be randomized to one of 16 different ways that a Family Partner can work with families in getting to mental health services. If more than one child in your family is enrolled in the study, all children will be assigned the same condition and you will complete a consent form for each child in your family that participates. You and your child/children will be in the study for 12 months if you and your child/children decide to stay for the whole study. You will find more information about what will happen in this study later in this form.

The main risks of being in the study are loss of confidentiality (privacy). We will do our best to protect your privacy if you decide to be in the study. You will find more information about risks later in this form.

You and your child/children might benefit from being in the study because you may be helped to get mental health and other services your child/children needs with the help of the Family Partner. You will find more information about benefits later in this form.

Your child's doctor may also be an investigator in this research study. Being an investigator means your child's doctor is interested in both your child and the study. You may want to get a second opinion about you and your child being in the study. You can do so now or at any time during the study. Another doctor who is not an investigator can give you a second opinion about you and your child being in the study. You do not have to agree for you and your child to be in this study even though it is offered by your child's doctor.

Purpose

The purpose of the study is to learn the best ways that Family Partners can help children and families find and receive mental health services that they need.

What Will Happen in This Research Study

Who is a Family Partner?

Family Partners are parents with lived experience that are trained to help other parents access services they need. We have included Family Partners in this study who are bilingual. That means they speak English and also either Spanish or Vietnamese.

Why and how we are doing the study?

We think Family Partners can help children and families by working with them to find and receive the services the child needs and the family prefers. We think that having a parent who has had experience seeking mental services can make it easier for families. This help that the Family Partner provides is called "family navigation". There are different ways that the Family Partner can help. There are different plans and tools that they can use. We don't really know which parts of family navigation are the most helpful.

For that reason, we are conducting a study in which families who are working with a Family Partner are randomized. Randomize means to assign the research participant to one of the groups in the research study. It is like using a flip of a coin to choose where the assignment is based on chance. If your child is in the study he or she will be randomized to one of 16 different ways that a Family Partner can work with families. If more than one child in your family is participating in the study, we will assign all children the same random condition.

What does participating in the study mean?

If you agree to take part, you and your child will meet with a Family Partner who will work with you in choosing the type of mental health services you prefer for your child. Then the Family Partner will help you with appointments and help you manage your child's care. The mental health services you choose can be offered to you here at DotHouse with a mental health provider working with your doctor. The mental health services can also be outside of DotHouse –at school or at your home. You may decide that it is important to include your child's school and others in

order to help with your child's needs. If more than one child in your family is eligible and participates in the study, we will follow the same study procedure with all children. Family Partners will support each child's service goals individually according to the parent's goals.

After choosing your plan, there are different ways that the Family Partner may work with you. How the Family Partner works with you depends on how you are randomized. If more than one child in your family is enrolled in the study, you will remain in the same random condition for each child. The things that may be different are:

1) The Family Partner may be located at DotHouse and meet with you in-person, by phone or through MY CHART, the electronic health record patient portal. Alternatively, the Family Partner may be available to meet with you in the community or your home, and, for example, attend school meetings.
2) Together you may use a special computer program called Act.MD that can be used on your phone to help you, the Family Partner and other providers that you choose (like school) share information OR you may communicate as usual and not use the phone program Act. MD.
3) The Family Partner may follow your child's progress and symptoms at routine visits OR more frequently, like every 3 months. If more than one child in your family is enrolled, we may follow all your children's progress and symptoms more frequently, like every 3 months.
4) The family partner may follow a schedule of programmed visits (for example, monthly visits for 6 months) or she may schedule visits with you depending on your need.

It all depends on the type of family navigation you are randomized to. Some of the ways that Family Partners do their work may work better. We are not sure what will work best and that is why we are doing the study. We want to know what ways of doing family navigation are better for helping children and families find and receive child mental health services.

You and your child or children will be in the study for 12 months. During 6 months, the Family Partner will follow to see if your child received care, how often and when he or she received the care. The Family Partner will enter information about this in your child's medical record as well as information about what they do to try to help. You will also receive questionnaires asking you about how you and your child are feeling and doing. These questions may be sent to you through MyChart, REDCap, or someone from the research team will call you about three times over 12 months. It's possible that these questionnaires will also be administered via a video conference software, Zoom. MyChart is a medical record program through which we can send questions to you by computer and REDCap is a secure database system that can be used to complete questionnaires. If you choose to complete the questionnaires by mail, we will also send you a pre-stamped, addressed envelope for you to mail them back. Your answers can then be included in your child's health record to help document your child's progress. Also, a research staff person will check to see how satisfied you are with the work the Family Partner has offered to you and your child. After the 6 months of working with your family partner, you may be contacted via phone about an optional interview regarding your experience with a Family Partner. This interview is expected to last approximately 60 minutes. If you decide to participate in this optional interview you will receive $20 as a way to thank you for your time.

The researchers will be able to use all of this information to study what is working best using family navigation.

Principal Investigator: Dr. Emily Feinberg

We are doing this study as part of providing regular care so there are no special visits or tests.

It is important for you to know that this is a research study and not treatment or therapy.

If at any point you decide you do not want to be in the research and work with a Family Partner that is fine. You will always have access to all services and care at DotHouse. You can get help for your child to receive mental health services without participating in this study.

You and your child will be one of approximately 715 subjects (304 children and one of his or her parents/guardians and additional eligible siblings) who will be asked to be in the study.

Risks and Discomforts

A risk of participating in the study includes that you or your child may become upset in talking about problems or mental health. You can skip any questions that make you feel uncomfortable during the study or you can take a break from answering those questions. If you or your child become upset we can get you immediate care if you desire that.

If you or your child decides that your child should stop being in the study, we ask that you or your child lets us know. You and your child are free to stop at any time.

Potential Benefits

The benefits of being in this study may be: Family Partners may help you better access help for your child and including finding and receiving mental health services for your child. However, you and your child may not receive any benefit. You and your child being in the study may help the investigators learn how Family Partners can best be helpful to families.

Alternatives

The following alternative procedures or treatments are available if you choose not to have your child be in this study: you can get mental health services directly without working with a Family Partner. You can also get help from a care manager at the health center to help you without being part of the study.

Costs

Items and services done only for study purposes will be provided at no cost to you or your child. They won't be billed to your child's health insurance either. With greater access to mental health services you may have costs related to getting that care. You or your child's health insurance will be billed for all costs that are part of your child's normal medical care. These costs include co-payments and deductibles. You can ask any questions now about insurance coverage for this study or about the research activities paid for by the sponsor. You can also ask the investigator later, using the number on the first page of this form.

Payment

You and your child will not be paid for being in this study.

After the 6 months of working with your Family Partner, if you decide to participate in an optional interview, you will receive $20 to thank you for your time.

Confidentiality

We will try to protect your and your child's privacy and confidentiality.
We must use information that shows your and your child's identity to do this research.
Information already collected about you and your child will remain in the study record even if

you and your child later withdraw. We will store your and your child's information in ways we think are secure. We will store electronic files in computer systems with password protection and encryption. Act.MD and REDCap also use password protection and encryption. However, we cannot guarantee complete confidentiality of information stored in computer files or Act.MD or REDCap. Audio recordings from qualitative interview and recorded FN sessions will be stored in BOX, a HIPAA compliant web storage tool. All stored recordings will be de-identified.

This study is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. All studies funded by the National Institutes of Health that involve identifiable information. The CoC provides how we can share research information. Because we have a CoC, we cannot give out research information that may identify you or your child to anyone that is not involved in the research except as we describe below. Even if someone tries to get your or your child's information in connection with a legal proceeding, we cannot give it to them. The CoC does not prevent you or your child from sharing your or your child's own research information. We will record information from this study in your child's medical record, such as information related to your child's medical care. Please ask us if you have any questions about what information will be included in your child's medical records. You should know that once information has been put into your child's medical records, it is not covered by the CoC. However, information in your child's medical records is protected in other ways.

If you agree for you and your child to be in the study, we will share information that may show your and your child's identity with the following groups of people:

- People who do the research or help oversee the research, including safety monitoring.
- People from Federal and state agencies who audit or review the research, as required by law. Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and the Massachusetts Department of Public Health.
- People who see your child's medical records. Please ask us if you have any questions about what information will be included in your child's medical records.
- Any people who you give us separate permission to share your or your child's information.

You should know that we are required to report information about child abuse or neglect; elder abuse; harm to self or others.

We will share research data where we have removed anything that we think would show your or your child's identity. There still may be a small chance that someone could figure out that the information is about you or your child. Such sharing includes:

- Publishing results in a medical book or journal.
- Adding results to a Federal government database.
- Using research data in future studies, done by us or by other scientists.

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.

Use and Disclosure of Your Child's Health Information

The research team has to use and share your child's health information to do this study, including information that may identify you or your child. By agreeing to allow your child to be in this study and signing this form, you are giving us your permission where needed to use and share your child's health information as described in this form.

Health information that might be used or given out during this research includes:

- Information that is in your child's hospital or office health records. The records we will use or give out are those related to the aims, conduct, and monitoring of the research study.
- Health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.
- The health information specifically includes:
  - Mental health communications (with a psychiatrist, psychologist, clinical nurse specialist, marriage-, family-, rehabilitation-, or mental-health-counselor, or educational psychologist)
  - Domestic violence counseling
  - Social work communications

The reasons that your child's health information might be used or given out to others are:

- To do the research described here/ research you are participating in
- To make sure we do the research according to certain standards set by ethics, law, and quality groups.
- To comply with laws and regulations. This includes safety-related information.
- As we explained above, we also have to give out any information from your child about child abuse or neglect; elder abuse; harm to self or others.

The people and groups that may use or give out your child's health information are:

- Researchers involved in this research study from Boston Medical Center, Boston University, and/or other organizations
- Individuals included in the Act.MD care coordination App and REDCap.
- Other people within Boston Medical Center and Boston University who may need to access your child's health information to do their jobs such as for treatment, research administration, payment, billing, or health care operations
- People or groups that the researchers use to help conduct the study or to provide oversight for the study
- The Institutional Review Board that oversees the research and other people or groups that are part of the Human Research Protection Program that oversees the research
- Research monitors, reviewers, or accreditation agencies and other people or groups that oversee research information and the safety of the study.

We ask anyone who gets your child's health information from us to protect the privacy of your child's information. However, we cannot control how they may use or share your child's health information. We cannot promise that they will keep it completely private.

The time period for using or giving out your child's health information:

- Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

Your privacy rights are:

- You have the right not to sign this form that allows us to use and give out your child's health information for research. If you do not sign this form, your child cannot be in the research. This is because we need to use the health information to do the research. Your decision not to sign the form will not affect any treatment, health care, enrollment in health plans, or eligibility for benefits for you or your child.
- You have the right to withdraw your permission to use or share your child's health information in this research study. If you want to withdraw your permission, you must write a letter to the Principal Investigator at the address listed on the first page of this form. If you withdraw your permission, you will not be able to take back information that has already been used or shared with others. This includes information used or shared to do the research study or to be sure the research is safe and of high quality. If you withdraw your permission, your child cannot continue to be in the study.
- When the study has been completed for everyone, you have the right to request access to the health information that we used or shared to make your child's treatment or payment decisions. If you ask for research information that is not in your child's medical record, we might not give it to you, but we will explain why not. You may use the contact information on the first page of this form to find out how to get your child's health information. You may also contact the HIPAA Privacy Officer at Boston Medical Center at DG- privacyofficer@bmc.org or at Boston University at HIPAA@BU.EDU.

Compensation for Injury

If you think that your child has been injured by being in this study, please let the investigator know right away. Use the phone number on the first page of this form. Your child can get treatment for the injury at Boston Medical Center, at DotHouse or at any healthcare facility you choose. There is no program to provide compensation for the cost of care for research related injury or for other expenses. Other expenses might be lost wages, disability, pain, or discomfort. You or your child's insurance will be billed for the medical care your child receives for a research injury. You are not giving up any of your legal rights by signing this form.

Re-Contact

We would like to ask your permission to contact you and your child again in the future. This

contact would be after the study has ended. Please initial your choice below:

_____Yes You may contact me and my child again to ask for additional information related to this study

_____No You may not contact me and my child again to ask for additional information related to this study

Permission to share information with your child's school

Depending on your child's needs, it is possible that we may need to share information from his/her medical record with the school to help you access services in the school. Some of the information we may need to share may include information about diagnoses and recommended services. We would like your permission to share this information with your child's school.

_____I DO give permission to share information with my child's school.

_____I DO NOT give permission to share information with my child's school.

Permission to audio record

We would like to ask your permission to audiotape a session of Family Navigation so that we can understand better what people discuss in these sessions and how the family partner works with you. You can still participate in the study even if you don't want to be audiotaped.

_____I DO give permission to be audio taped.

_____I DO NOT give permission to be audio taped.

Permission to audio record an optional interview

You may be contacted to participate in an optional interview after working with your Family Partner for 6 months. We would like to ask for your permission to audiotape the optional interview if you decide to participate.

This interview will ask you questions about your experience with your Family Partner. We will record this interview for data analysis purposes. The interview recording will be stored in BOX a HIPAA compliant web storage platform. You can still participate in the study even if you don't want to participate in an optional interview.

_____ I DO give permission to be audiotaped during the optional interview

_____ I DO NOT give permission to be audiotaped during the optional interview

Permission to share data with NIMH Data Archive

Data from this study may be submitted to the National Institute of Mental Health Data Archive (NDA). The NDA is a data repository run by the National Institute of Mental Health (NIMH)

that allows researchers studying child mental health and behavioral health to collect and share deidentified information with each other. A data repository is a large database where information from many studies is stored and managed. Deidentified information means that all personal information about research participants such as name, address, and phone number is removed and replaced with a code number. With an easier way to share, researchers hope to learn new and important things about child mental health and behavior more quickly than before.

During and after the study, the researchers will send deidentified information about your and your child's health and behavior to NDA. Other researchers nationwide can then file an application with the NIMH to obtain access to your deidentified study data for research purposes. Experts at the NIMH who know how to protect health and science information will look at every request carefully to minimize risks to you and your child's privacy.

You may not benefit directly from allowing your information to be shared with NDA. The information provided to NDA may help researchers find better treatments and outcomes for children's mental health and behavior. NIMH will also report to Congress and on its web site about the different studies that researchers are conducting using NDA data. However, you and your child will not be contacted directly about the data you contributed to NDA.

You may decide now or later that you do not want to share your and your child's information using NDA. If so, contact the researchers who conducted this study, and they will tell NDA, which can stop sharing the research information. However, NDA cannot take back information that was shared before you changed your mind. If you would like more information about NDA, this is available on-line at https://nda.nih.gov.

____I DO give permission to share information with NDA

____I DO NOT give permission to share information with NDA.

Subject's Rights

By consenting for you and your child to be in this study, you do not waive any of your or your child's legal rights. Consenting means that you have been given information about this study and that you agree to participate and to have your child participate in the study. You will be given a copy of this form to keep.

If you or your child do not agree for you and your child to be in this study or if at any time you or your child withdraws from this study, you or your child will not suffer any penalty or lose any benefits to which you or your child are entitled. Your and your child's participation is completely up to you and your child. Your decision and your child's decision will not affect your or your child's ability to get health care or payment for your or your child's health care. It will not affect your or your child's enrollment in any health plan or benefits you or your child can get.

Principal Investigator: Dr. Emily Feinberg

We may decide to have you or your child stop being in the study even if you and your child want to stay. Some reasons this could happen are if staying in the study may be bad for you or your child, or if the study is stopped.

Questions

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, contact Dr. Emily Feinberg at 617-414-7440. Also call if you need to report an injury to your child during this research.

You may also call 617-358-5372 or email medirb@bu.edu. You will be talking to someone at the Boston Medical Center and Boston University Medical Campus IRB. The IRB is a group

that helps monitor research. You should call or email the IRB if you want to find out about your child's rights as a research subject. You should also call or email if you want to talk to someone who is not part of the study about your questions, concerns, or problems.

Child Subject: _____

Printed name of subject

By signing this permission form, you are indicating that

- you have been read this form
- your questions have been answered to your satisfaction
- you voluntarily agree participate and to have your child participate in this research study
- you permit the use and release of information that may identify you or your child as described

Printed name of parent/legal guardian

_____ _____

Signature of parent/legal guardian Date

Researcher: _____

Printed name of person conducting consent discussion

I have personally explained the research to the above-named child and to the parent/legal guardian (who has been read this permission form) and answered all questions. I believe that they understand what is involved in the study and freely agree to participate.

I believe that the parent/legal guardian understands what is involved in the study and freely

Principal Investigator: Dr. Emily Feinberg
agrees to participate and to have their child participate.

I consider that the above-named child (check one):

- ☐ is capable of understanding what is involved in the study and freely agrees to participate.
- ☐ is not capable of understanding what is involved in the study.

_____ _____

Signature of person conducting consent discussion Date