Mass General Brigham

Research Consent Form

General Consent Form Template

Subject Identification

Official Title: Evaluation of a Resiliency Program for Fathers of Children and Youth with Special Health Care Needs
Document date: 08/4/2022

Protocol Title: Evaluation of a Resiliency Program for Fathers of Children and Youth with Special Health Care Needs

Principal Investigator: Karen Kuhlthau, PhD

Site Principal Investigator: N/A

Description of Subject Population: Fathers of Children with Special Health Care Needs

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

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 to pilot test and help evaluate the effectiveness of a resiliency program for fathers of children and youth with special health care needs (CYSHCN). We are doing the research to find out if this program is useful in decreasing stress and enhancing coping skills in fathers of CYSHCN. If you agree, you will participate in the SMART-3RP, a virtually-delivered psycho-educational resiliency program. You will participate in the program for 1-hr a week for 8-weeks, as well as complete surveys and an exit interview. You will be in the study for approximately 3 months if you decide to stay for the whole study.

The main risks of being in the study include: that the program does not work, and your stress either does not improve or worsens, and feeling uncomfortable participating in the SMART-3RP program.

You might benefit from being in the study because by observing a decrease in symptoms of parental stress. If you decide not to be in the study, some other things that might help your condition are father support groups or individual counseling.

You will be paid up to $115 for taking part in this research study. You will find more information about the payment amount for each visit and a plan if you do not complete all study visits later in this form.

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

Karen Kuhlthau is the person in charge of this research study. You can call her at 617-724-2842.

If you have questions about the scheduling of appointments or study visits, call Lucy Fell at 617-724-8546 M-F 9-5.

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?

The purpose of this research study is to pilot test and adapt a resiliency program for fathers of children and youth with special health care needs (CYSHCN). We want to use your feedback to help modify the program to suit the needs of fathers.

SMART-3RP is an eight-week psycho-educational resiliency program that is designed to help individuals build resiliency and coping strategies against stress and negative thoughts. In several studies in other populations, researchers have found that SMART-3RP is effective in helping individuals identify and cope with stressors. In this study, we will be closely examining how the SMART-3RP program effects stress in fathers of CYSHCN.

We plan to enroll up to 12 participants with the goal of conducting up to 2 intervention groups; each group will consist of approximately 3-8 participants.

All participants will be asked to complete multiple surveys: at study enrollment, following participation in the resiliency intervention, and a weekly feedback survey during the intervention. Following the last session of the intervention, you will be asked to participate in a group exit-interview, which will be recorded and transcribed.

Who will take part in this research?

We are asking you to take part in this research because you are the father of a child with special health care needs.

About 24 participants will take part in this research study, which will be conducted virtually using Zoom, a secure video-conferencing platform.

The US Health Resources and Services Administration is paying for this research to be done via the CYSHCNet : a collaborative research network for children and youth with special health care needs.

What will happen in this research study?

If you decide to take part in this research study, you will be assigned your own study identification number. This code is how you will be identified by study staff on study-related documents and samples. After enrolling in the study, you will be asked to fill out a baseline survey. The survey will ask you questions about demographic information and psychosocial factors. Surveys will be administered again after you have participated in the resiliency program.

Study Intervention: Of note, the SMART-3RP as delivered here is a **psycho-educational program** and is not being delivered as a clinical group.

The intervention may consist of eight SMART-3RP sessions once a week over the course of 8 weeks (1 hour each). The intervention will be conducted by an experienced instructor who has utilized this program before and is comfortable with the content. During the intervention, you will be asked to complete a brief weekly feedback survey, which may help us adapt the program to best suit the needs of fathers. We will ask you to participate in an individual or group exit-interview for approximately 30 mins to 1 hour during the week following the intervention, the conversation of which will be audio recorded and transcribed.

During the intervention, (and follow up period for those in the Immediate Group), you will be asked to practice what you've learned in the intervention. Additionally, you may be asked to keep track of your daily practice by filling out an online or paper log, which may be collected by study staff for data analysis following your completion in the program. During the 3RP session, the instructor will address any barriers or problems you may be having with daily practice and help to problem solve them with you.

The program is designed to improve your psychological resiliency, or ability to "bounce back," in response to difficult situations. The program teaches different "mind-body" approaches, such as breathing exercises and meditation, with the goal of increasing your ability to cope with stress. There are 3 core components into each session:

1. Elicitation of the Relaxation Response through mind-body techniques
2. Discussion about stress awareness to learn how to identify personal stressors and experiences of stress
3. Coping strategies and adaptive perspective-taking to promote positive well being

Videoconferencing Platform: All visits will take place virtually on Zoom, a secure, HIPAA-compliant videoconferencing platform. The platform will be set up so that when you are looking at the screen during each session, you will see other members of the group and the provider(s) and they will see you as well.

After completing the SMART-3RP program:

After completing the program, you will be asked to complete another set of surveys. The surveys will collect information similar to that collected at baseline, including demographic information and psychosocial factors. You will also be asked to participate in a 30 minute to1-hr group and/or individual exit interview to provide feedback on the program.

The study involves sending you text messages that are relevant to the research study. If you agree to send and receive text messages, you will be texted about scheduling sessions and for sessions and survey reminders. If the date/time of a session is changed for any reason, you will receive a text message. You will also be asked to text study staff on a designated number if you know that you will miss a session. When you are asked to complete a survey, you will be texted a reminder, that will prompt you to reference your email that includes the survey link. You will also be texted a reminder on the day of each session. Texting over mobile/cell phones carries security risks because text messages to mobile/cell phones are not encrypted. This means that information you send or receive by text message 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 in this research study.

- Text messages 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 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
- Text messages will only be read during regular business hours. Texts sent on nights or weekends will not be read until the following business day.
- Text messaging should not be used in case of an emergency. If you experience a medical emergency, call 911 or go to the nearest hospital emergency department.
- You may decide to not send or receive text messages with staff associated with this research study at any time. You can do this in person or by sending the research number a text message that says "Stop Research Text."
- Your agreement applies to this research study only. Agreeing to other texts from Mass General Brigham, for example appointment reminders, is a separate process. Opting out of other texts from Mass General Brigham is a separate process as well.
- It is your responsibility to update your mobile/cell phone number with this research study in the event of a change.

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

Possible Storing of Samples and Health Information at MGH for Future Use:

If we would like to store some of your samples and health information for future research. We will label your samples and health information with a code instead of your name. The key to the code connects your name to your samples and health information. The study doctor will keep the key to the code in a password protected computer.

Do you agree to let us store your health information for future research related to parental distress?

☐ Yes ☐ No Initials _____
If later you change your mind and want your information destroyed, contact the study investigator.

Will you get the results of this research study?

No. The research study we are doing is only a steppingstone in understanding in stress in fathers of CYSHCN**.** 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?

There is a possibility that the SMART-3RP program will not work, you may not improve, and your parental stress may worsen. As with any research study, there may be other risks that are currently unknown. It is possible that certain unknown risks could be serious.

Risks of Breach of Confidentiality of Study Information

Potential risks for all participants include...

1) Participants may feel distress from completing surveys or participating in the intervention.
2) In the event of a psychological emergency, confidentiality may be suspended if you are at risk for hurting yourself or someone else. Confidentiality may also be suspended in suspected cases of abuse or neglect of a child, elder, or person with a disability.

We will require every participant to agree to respect the confidentiality of other group members. We will ask you to wear headphones during the group and not to repeat group discussions to others or outside of the group. However, because this program will be delivered virtually, we cannot guarantee that other group members will not share the content of the groups.

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

We cannot guarantee that you will receive any benefits from this study, however participants in the current study may observe a decrease in symptoms of parental stress. It is hoped that the intervention will result in a statistically significant reduction of symptoms across these domains.

The current study may provide support to fathers of CYSHCN in developing new coping skills. This intervention may enhance our understanding of the role of mind-body interventions such as the SMART-3RP in fathers of CYSHCN/ This intervention may have widespread implications for types of resources available that may ultimately improve health and well-being of fathers.

What other treatments or procedures are available for your condition?

Other programs available for support and stress reduction in fathers of CYSHCN include independent counseling and father support groups.

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?

Yes. You will receive a check of which the amount is based on the number of surveys completed. You will receive $25 per survey completed (baseline, post intervention). If you complete both of these surveys, they will receive an additional $25. Additionally, you will receive $5 per each weekly feedback survey (8 surveys in total) and $25 for participating in an exit interview following the intervention. In total, participants may be able to receive a check of up to $115 upon completion of all surveys.

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

There are no costs to either or your insurance company for participating in 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 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
- 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: N/A

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. For example, we understand that the sponsor of this study may use your identifiable information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. 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. The sponsor has agreed that it will not contact you without your permission and will not use or share your identifiable information for any mailing or marketing list. 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.

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 health information to be used and shared as described above.

Subject	Date	Time (optional)

I agree to participate in text messaging as part of this research study in the manner 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.

Consent Form Version: 6/30/2022