Open Pilot Trial of a Resiliency Group Program for Caregivers of Children with Learning and Attentional Difficulties

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Research Informed Consent Form (English-language Version)

Version Date: 9/25/24

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Mass General Brigham

Research Consent Form
Certificate of Confidentiality Template
Version Date: November 2022

Subject Name:

MRN or DOB:

Subject Identification

Protocol Title: Open Pilot Trial of a Resiliency Group Program for Caregivers of Children with Learning and Attentional Difficulties

Principal Investigator: Elyse Park, PhD, MPH

Description of Subject Population: Caregivers of Children with Learning and Attentional Difficulties

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 because you are a primary caregiver of a child with a learning and attentional difficulties (LAD). We are doing the research to guide the development of a resiliency program for parents of children with LAD. If you agree, you will complete a brief screening process to determine your eligibility and then you will be assigned according to availability to receive one of two supportive group programs designed for people who take care of children with LAD. You will be in the study for about three months if you decide to stay for the whole study.

The main risks of being in the study are related to experiencing emotional discomfort related to discussing your experience of parenting a child with LAD.

You might benefit from being in the study by learning new strategies for building resiliency while parenting a child with LAD.

If you decide not to be in the study, some other things that might help your condition are pursuing counseling or health-related services from your personal medical providers.

You will be paid up to $180 via gift cards 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.

Elyse Park, PhD, MPH is the person in charge of this research study. You can call her at 617-724-6836. You can also call the study research coordinator at 617-726-6992 or mghsparkstudy@mgb.org on Monday-Friday between 9am-5pm with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call the study research coordinator at 617-726-6992.

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?

In this research study we want to learn more about how to develop two virtual supportive group programs for parents of children with learning and attentional difficulties (LAD). Parents of children with LAD often experience increased stress related to navigating the educational system, social isolation, familial concerns, and financial and professional sacrifices. The goal of this study is to complete an initial test of two programs that we are developing, called the Stress Management and Resiliency Training- Relaxation Response Resiliency Program (SMART-3RP) and Health Education Program (HEP) with parents from diverse backgrounds. As part of this initial test, we hope to gather feedback on intervention delivery and timing, intervention content and questionnaires, and Spanish cultural and language modifications. This feedback will help us to refine and improve our study programs to best fit parents' needs.

Who will take part in this research?

We are asking you to take part in this research study because you are a primary caregiver of a child with a learning and attentional disorder and we received your contact information from the Massachusetts Federation for Children with Special Needs (the Federation), where you may be connected with services. You may also have reached out to us directly to indicate your interest in the study after learning about it from another group that you are connected to.

About 40 people will take part in this research study.

This is a multisite, collaborative study conducted by researchers at MGB, the Federation, and Stony Brook University.

The National Institutes of Health are paying for this research study to be done.

What will happen in this research study?

If you choose to take part in this study, we will ask you to sign this consent form before we do any study procedures. If you decide to join this study, we will ask you for the following:

- **Sociodemographic information** including age, how many children you have, race, ethnicity, highest level of education, employment status, marital status, health insurance coverage, and gender.

- **Self-report measures of stress, coping, and emotional well-being.** We will ask you to answer a set of questions about different aspects of stress, coping, and emotional well-being to better understand your concerns and how your experience may change over the course of the study. This can be done online or via phone/videoconference with a member of the study team, whichever is easier for you. Answering these questions should take no more than approximately 30 minutes. You do not have to answer any questions that make you uncomfortable. We will ask you to fill out this survey at two timepoints during the study: when you first join the study and at the end. You can stop completing the surveys and come back to them at any time; we may contact you to remind you to complete the surveys.

Participants who have completed this survey will be assigned to Group A (SMART-3RP) or Group B (HEP) according to availability. Each group will have approximately up to 10 people. Group A includes mind-body practices, such as relaxation response, and Group B focuses on health behavior education.

If you are assigned to Group A, the following things will happen:

- **Videoconferencing-based Intervention Sessions (SMART-3RP).** The study will arrange 8 group meetings that will occur every week over approximately 2 months. The sessions will be 1 hour long and will be delivered through Zoom (a web-based application used by Massachusetts General Hospital). This will allow you to take part in the sessions on a device of your choosing (smartphone, tablet, laptop, desktop computer, etc.). These sessions will be audio-recorded. You may opt out of the sessions at any time. The groups will focus on topics including stress awareness, relaxation, health behaviors, and coping strategies for managing stress. Study staff will provide you information on how to access the video conferencing platform. We will launch the video conferencing in a private and secure area. To protect your privacy we ask that you do not take screenshots, photographs, or recordings of any kind with any electronic equipment. We would like to remind you that a video meeting is similar to us visiting you at home. We may learn more about your home and the people living with you than we would during a visit at the hospital. For example, we may learn information from you that must be reported to public health or public safety authorities. We are required by law to report known or suspected child or elder abuse. If we make such report, the public health and safety authorities can use the information as they see fit and may end up sharing it with other government agencies. Please ask the research staff if you have any questions about this prior to your video visit.

- **Post-Treatment Survey.** After the approximately 8 week program, you will complete a post-treatment survey. Just like the surveys you will be invited to complete at the start of the study, you can stop completing the surveys and come back to them at any time; we may contact you to remind you to complete the surveys.

If you are assigned to Group B, the following things will happen:

- **Videoconferencing-based Intervention Sessions (HEP).** The study will arrange 8 session group meetings that will occur every week over approximately 2 months. The sessions will be 1 hour long and will be delivered through Zoom (a web-based application used by Massachusetts General Hospital). This will allow you to take part in the sessions on a device of you choosing (smartphone, tablet, laptop, desktop computer, etc.). These sessions will be audio-recorded. You may opt out of the sessions at any time. The groups will focus on topics like stress, daily health behaviors, and strategies to maintain emotional well-being. Study staff will provide you information on how to access the video conferencing platform. We will launch the video conferencing in a private and secure area. To protect your privacy we ask that you do not take screenshots, photographs, or recordings of any kind with any electronic equipment. We would like to remind you that a video meeting is similar to us visiting you at home. We may learn more about your home and the people living with you than we would during a visit at the hospital. For example, we may learn information from you that must be reported to public health or public safety authorities. We are required by law to report known or suspected child or elder abuse. If we make such report, the public health and safety authorities can use the information as they see fit and may end up sharing it with other government agencies. Please ask the research staff if you have any questions about this prior to your video visit.
- **Post-Treatment Survey.** After the approximately 8 week program, you will complete a post-treatment survey. Just like the surveys you will be invited to complete at the start of the study, you can stop completing the surveys and come back to them at any time; we may contact you to remind you to complete the surveys.

We will send your information to researchers working with us at Stony Brook University to help us interpret the findings of the study. We will label all your study information with a code number instead of your name. The key to the code connects your name to your study information. We will keep the key to the code here at MGB. No one outside MGB will know which information is yours.

You can withdraw from the group intervention program at any point during your participation. If you decide to stop taking part in the study for any reason, we may invite you to continue completing study surveys. If you agree to complete the study baseline and post-treatment surveys, we anticipate that each will take about 30 minutes of your time.

How may we use and share your 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 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.

At the completion of this research study, we would like to store and be able to use and share your identifiable health information with researchers at Mass General Brigham for other research related to developing a resiliency program for parents of children with learning and attentional difficulties. If we share your health information with other researchers outside of Mass General Brigham, we will label the information with a code instead of your name or other directly identifying information. The key to the code connects your name or other identifiers to your information. We will keep the code in password protected computers and secure file folders that are only accessible to trained study staff.

Because this health information is identifiable, we are asking your permission to store, use and share it for other research. You can still take part in the research study whether or not you give permission for the storage, use, and sharing health information for other research.

Do you agree to let us store and use your health information for other research related to developing a resiliency program for parents of children with learning and attentional difficulties?

☐ YES ☐ NO Initial _____

Future Contact:

With your permission, we may contact you about similar studies led by researchers on our team that you may be eligible for in the future. Your decision about being contacted for future studies will not impact your ability to participate in the present research, nor will it impact the types of services you receive from MGH/Partners or the Federation.

Do you agree to be contacted about future research studies that you may be eligible for?

☐ YES ☐ NO Initial _____

With your permission, we may also contact you in the future about an opportunity to participate on an advisory board to provide feedback to our research team about future efforts to develop supportive programs for parents of children with LAD. Your decision about being contacted about participating on a future advisory board will not impact your ability to participate in the present research, nor will it impact the types of services you receive from MGH/Partners or the Federation.

Do you agree to be contacted about possible participation on a future advisory board?
☐ YES ☐ NO Initial _____

Will you get the results of this research study?

No. The research study we are doing is only a stepping stone in understanding the experiences of caregivers of children with LAD**.** 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 information will not be useful in directing your medical treatment. The results of this research will not be placed in your medical record.

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

There are some risks related to taking part in this study. Questions and discussion of parenting a child with learning and attentional difficulties can be emotionally challenging. As a reminder, you may choose not to answer or discuss any questions that you do not want to and may decide to drop out of the study at any time.

Additionally, it is rare, but possible, that personal information that you have provided for the study could be accessed by accident. To prevent this from happening, electronic data is stored on password protected computers, and only study team members work with the data. Audio recordings will be saved on a secure server accessed only by qualified team members. Study results are only reported on the whole group, never identifying one individual in reports. We expect minimal risk related to surveys and group participation. Please note that your identity will be known by the other focus group participants, and the researcher(s) cannot control what participants repeat about others outside the group.

During this study, we may learn information from you that must be reported to public health or public safety authorities. We are required by law to report known or suspected abuse of a child, elderly person, or disabled person. If we make such a report, the public health and safety

authorities can use the information as they see fit and may end up sharing it with other government agencies.

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

You may learn from the exchange of information with other parents and the knowledge that by contributing your story and experience to this project, care for parents of children with learning and attentional difficulties will be improved. You may also benefit from receiving information about strategies to build resiliency and manage stress related to parenting a child with LAD. We hope that other caregivers of children with learning and attentional difficulties may benefit in the future from what we learn in this study,

What other treatments or procedures are available for your condition?

You may also choose to pursue different types of resiliency, stress management, or health-promoting program through your current medical providers.

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. If you enroll in the study and agree to participate in the group program, you may receive $20 per group session attended (up to $160 for 8 sessions) and $20 for completing a post-group survey. Participants who complete all of these parts of the study can receive up to a total of $180. At the end of the study, a single-time payment will be made according to parts of the study procedure that were completed (i.e. attendance at each study session and post-treatment survey). You will receive your payment in the form of gift cards.

We may use your information to develop a new product or medical test to be sold. The Sponsor, hospital, and researchers may benefit if this happens. There are no plans to pay you if your information is used for this purpose.

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.

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.

_____

Print Name

_____ _____ _____

Subject Signature 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 Form Version Date: 9/25/24