

Partners HealthCare System Research Consent Form

Subject Identification

General Template
Version Date: August 2016

Protocol Title: Evaluation of a resiliency intervention for parents of children with learning disabilities

Principal Investigator: Elyse Park, PhD, MPH

Site Principal Investigator: N/A

Description of Subject Population: Parents of children with learning disabilities

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.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as “Partners.”

If you have any questions about the research or about this form, please ask us. Taking part in this research study is up to you. 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.

Consent: After you receive this consent form, you will be asked to review it with a study staff member on the phone. If you decide to participate in the study, we will ask you to scan, email, fax or mail it to us. After we receive your signed copy of this consent form, you will be enrolled in the study.

Why is this research study being done?

The purpose of this research study is to evaluate the effectiveness of a resiliency program for parents who have children with learning disabilities. We want to find out if this program is useful in decreasing stress and enhancing coping skills in parents of children with learning disabilities.

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

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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 parents of children with learning disabilities.

In total, we will run approximately 6-8 groups in this study in its entirety.

All participants will be asked to complete a survey at 3 separate points in time: at study enrollment, at 3 months post enrollment, and at 6 months post enrollment. At 6 months post enrollment, you may also be asked to give a hair sample to measure cortisol.

How long will I take part in this research study?

It will take you about 6 months to complete this research study. During this time, you will be asked to complete a survey at 3 points in time (now, at 3 months post enrollment, and at 6 months post enrollment). You will also participate in an 8-session, 1 hour a week virtual SMART-3RP program within the 6 months you are in the study.

What will happen in this research study?

What will happen after you enroll...

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 at 3 months and at 6 months post enrollment.

Randomization: In order to measure the effects of the intervention, you will be “randomized” into one of the study groups after enrollment into the study: *Immediate Group* or *Waitlist Control*. The Immediate Group will receive the study intervention within two weeks after enrollment into the study (baseline). Randomization means that you are put into a group by chance. It is like flipping a coin. You will have an equal chance of being placed in either group. Both groups will receive the same intervention during the course of the study, but at different time points.

If you are assigned to the Waitlist Control group, enrollment in the study (baseline) will be followed by approximately 3 months of waiting for the intervention. You would then be administered a second set of questionnaires (3 months post enrollment), followed by the

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intervention and then have your final data collection (questionnaires and hair cortisol) at 6 months post enrollment.

If you are assigned to the Immediate Group, enrollment (baseline) will be followed by the intervention (3 months). You would then be administered 3 month post enrollment questionnaires, followed by 3 months of continuing to practice what you learned during the intervention, and then by your final data collection (questionnaires and hair cortisol) at 6 months post enrollment.

After you sign this consent form, you will be given your group assignment and a calendar of your intervention schedule.

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 one intake with (either individually or in a group), and 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. We may also offer optional booster sessions after the completion of the group.

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 will 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 a multimodal mind-body resiliency program that incorporates 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 (meaning through a videoconferencing platform, similar to Skype or FaceTime) using 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.

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At 3 months after joining the study:

Surveys: At 3 months post enrollment, 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.

At 6 months after joining the study:

Surveys: At 6 months post enrollment, you will be asked to complete a third set of surveys. The surveys will collect information similar to that collected at baseline and 3 months post enrollment.

Hair Sample Collection: Additionally, you may be asked to provide a hair sample (approximately 150 strands), which is about the diameter of a small paperclip after completion of the SMART-3RP program. You will be provided with a stamped envelope to mail us your hair sample.

Why hair sample? Hair cortisol is the most accurate, non-invasive form of cortisol collection. This single hair sample will allow us to look at cortisol over the course of the study.

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 samples and health information for future research related to parental distress?

Yes No Initials _____

If later you change your mind and want your samples destroyed, contact the study investigator.

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. It is unlikely that participation in the current study would lead to worsening of stress.

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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 parents of children with learning disabilities in developing new coping skills. This intervention may enhance our understanding of the role of mind-body interventions such as the SMART-3RP in parents of children with learning disabilities. This intervention may have widespread implications for types of resources available that may ultimately improve health and well being of parents and children with learning disabilities.

Can I still get medical care within Partners if I don't take part in this research study, or if I stop taking part?

Yes. Your decision won't change the medical care you get within Partners 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.

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Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. 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 I do if I 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.

Even if you decide to stop participating in the SMART-3RP, we would encourage you to complete the study surveys.

Will I be paid to take part in this research study?

Yes. You will be paid in two \$20.00 gift cards: one after completing the second and another after completing the third survey.

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

There are no costs to either you or your insurance company for participating in this study.

What happens if I am injured as a result of taking part in this research study?

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.

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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 next section of this consent form.

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

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 during business hours of Monday-Friday 9:00am-5:00pm. You can also call Emma Chad-Freidman at 617-643-6036 during business hours of Monday-Friday 9:00am-5:00pm with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call Emma Chad-Freidman at 617-643-6036.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. 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

Also, if you feel pressured to take part in this research study, or to continue with it, they want to know and can help.

If I take part in this research study, how will you protect my privacy?

During this research, identifiable information about your health will be collected. In the rest of this section, we refer to this information simply as “health information.” In general, under federal law, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use, and share your health information for research and why they may need to do so.

In this study, we may collect health information about you from:

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- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable health information and why they may need to do so:

- Partners research staff involved in this study
- The sponsor(s) of this study, and the people or groups it hires to help perform this research
- Other researchers and medical centers that are part of this study and their ethics boards
- A group that oversees the data (study information) and safety of this research
- Non-research staff within Partners who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- The Partners ethics board that oversees the research and the Partners research quality improvement programs.
- People from organizations that provide independent accreditation and oversight of hospitals and research
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other US or foreign government bodies that oversee or review research)
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)
- Other:

Some people or groups who get your health information might not have to follow the same privacy rules that we follow and might use or share your health 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 health 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 health 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 information for any mailing or marketing list. However, once your information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

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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.

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 identifying 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 health 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 health 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.

You have the right to see and get a copy of your health 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.

