Document:
Informed Consent Form - English

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Parenting STAIR: Adapting a Trauma-Focused Parenting Intervention for Military-Connected Mothers and Their Children

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NYU IRB No: FY2024-8459

RESEARCH INFORMED CONSENT FORM

Parenting STAIR: Adapting a Trauma-Focused Parenting Intervention for Military-Connected Mothers and Their Children (FY2024-8459)

Principal Investigator: Kathrine Sullivan, Ph.D.

Funding Sponsor: The National Institute of Child Health and Human Development (NICHD)

INVITATION TO BE A PART OF A RESEARCH STUDY

You are invited to participate in a research study. This form has information to help you decide whether or not you wish to participate — please review it carefully. Your participation is voluntary. Please ask any questions you have about the study or about this form before deciding to participate.

PURPOSE OF THE STUDY

The purpose of this study is to assess Parenting STAIR, or PSTAIR, a promising and innovative intervention for military-connected mothers (MCM) who have experienced trauma and their young children (ages 2-10). The treatment aims to help mothers manage the strong feelings that sometimes happen after experiencing something scary or stressful, as well as to better connect with their children and manage their behavior effectively. PSTAIR includes three phases, which focus on 1) developing coping skills, 2) decreasing distress, and 3) improving your relationship with your child. As a part of the study, you will participate in mental health and/or parenting services provided by a Cohen Veterans Network (CVN) clinic.

ELIGIBILITY TO PARTICIPATE

You are eligible to participate in this study if you 1) are a service member/veteran or the spouse of a service member/veteran, 2) are eligible to receive services at a CVN clinic, 3) have a child ages 2-10, 4) speak and understand English or Spanish, 5) have difficulties related to stressful life experiences in your past, 6) screen positive for symptoms of PTSD or depression, or have lower confidence in your parenting.

You should not participate if you 1) are currently experiencing psychotic symptoms, 2) are at high risk for suicide defined as having intent, means, and a plan, 3) have a communication disability, such as complete hearing loss, and/or 4) have a severe substance or alcohol use disorder.

You should also not participate if the child who would participate with you has been diagnosed with a severe developmental disability.

To determine if you are eligible, we will conduct a virtual assessment with you over NYU HIPAA compliant Zoom comprised of several questionnaires. We anticipate that this assessment will take about 1 hour. If we determine that you are not eligible, we will work

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with CVN to offer an appropriate treatment plan to meet your needs and the needs of your family.

DESCRIPTION OF STUDY PROCEDURES

If you agree to participate in this study, you will:

1. Complete three online assessments administered by research staff, which we anticipate will take about 1 hour each. In these assessments, we will ask you about your mental health and parenting experiences. In the first assessment, we will also gather some information about you (e.g., your race/ethnicity, marital status, employment status, etc.).
2. Engage with your child in three online, observed play sessions, which will take about 15 to 30 minutes each. Therefore, you will be asked to consent for your child to participate in the study.
3. Have your assessments and observed play sessions audio and video recorded with your permission using NYU HIPAA compliant Zoom.
4. Attend about 12-16 weekly treatment sessions with your clinician, which will take about one hour each.
5. Consent for research staff to share assessment findings with your clinician to help guide their treatment decision making.

Once we have confirmed your eligibility for treatment with a clinic, you will be randomly assigned (like the flip of a coin) to receive either the PSTAIR treatment or another evidence-based treatment offered by your clinician. If you are not chosen to receive the PSTAIR treatment, the evidence-based treatment you do receive will be determined through shared decision making between you and the clinical staff at your CVN clinic. Depending on how you originally presented for treatment, usual care may be a treatment for you, such as Prolonged Exposure (PE) or Eye Movement Desensitization and Reprocessing (EMDR), a treatment for your child, such play therapy or sand tray therapy, or family therapy.

If you are assigned to receive the PSTAIR treatment, you will also be asked to attend some treatment sessions with one of your children present. During these sessions, you will be asked to play with your child while your clinician offers you coaching in the moment. Additionally, because the PSTAIR treatment is modular, the number of treatment sessions that you will be asked to attend may vary based on your individual needs. The total number of sessions will be determined through shared decision making between you, your clinician, and research staff.

RISKS OR DISCOMFORTS

There are no known serious risks to participating in this study beyond those of everyday life. However, minor risks or discomforts that may arise include:

- Emotional discomfort from being asked sensitive questions.
- Emotional discomfort from talking about trauma during sessions.
- Stress or frustration related to practicing parenting skills.
- Breach of confidentiality.

We understand that some of the questions we may ask might make you feel uncomfortable. You may end study treatment sessions at any time. You can also stop answering the questions or end study assessment sessions at any time. If you are unable or unwilling to complete assessments, you will no longer be able to participate in the study.

To minimize emotional discomfort and stress, your clinician will regularly check in with you about your emotional state and work with you to anticipate possible parenting challenges that you may experience from week to week.

Any time personally identifiable information is collected, there is a risk of a breach of confidentiality. However, we have processes in place to protect your data, which we will discuss in the Privacy and Data Confidentiality section.

Although we have stated the potential risks that we are aware of, unforeseeable risks may arise during the course of the study. We will inform you of any new risks that arise as we become aware of them.

Please tell the research staff if you believe you are harmed from your participation in the study.

BENEFITS

Because this is a research study, we cannot be sure that our intervention will help you and your child. However, participation in this study has the potential to reduce your trauma-related mental health symptoms. It may also improve your parenting skills and strengthen your relationship with your children.

While military-connected families experience high levels of trauma, as well as mental health and parenting challenges, there are currently very few treatments that focus on their unique needs. We hope that this study will contribute to our understanding of how to effectively treat military-connected mothers who have experienced trauma. It may also help us improve mental health services for mothers of young children exposed to trauma in other contexts.

COMPENSATION

Participating in this study will have no impact on the cost of treatment you would receive at CVN. CVN can and does bill insurance for your treatment if available. However, you will not incur any additional cost outside of the standard cost of treatment if you choose to participate in the study. This study is paid for with money from the National Institute of Child Health and Human Development (NICHD). You will be compensated in Amazon gift cards for completing study assessments and observed play sessions at three timepoints: once before starting treatment, once during treatment, and once after treatment has ended. You will receive:

- $25 for completing the pre-treatment assessment and $10 for completing the pre-treatment observed play session.
- $35 for completing the mid-treatment assessment and $10 for completing the mid-treatment observed play session.

- $45 for completing the post-treatment assessment and $15 for completing the post-treatment observed play session.

Compensation for assessments and observed play sessions will be emailed to you within five business days of completion.

VOLUNTARY PARTICIPATION

Participating in this study is completely voluntary. You may choose not to take part in the study or to stop participating at any time, for any reason, without penalty or negative consequences. Nonparticipation or withdrawal will not affect you or the services you or your family receive at a CVN clinic.

We may end your participation in the study if you do not follow the study procedures, if you experience a serious adverse event, if you relocate to another location where your clinician is not authorized to provide treatment, or if we determine that you are at significant risk due to a worsening health condition.

We will also inform you of any new discoveries made during the course of the study that might influence your decision to participate.

Every eligible, consented participant in the study will be counted, even if things do not go according to plan. If you withdraw or are withdrawn from the study early, we will keep information about you that is already collected.

Additionally, if you withdraw or are withdrawn from the study early and you are receiving the PSTAIR treatment, you will no longer be able to receive PSTAIR. Instead, you will be reassigned to receive the standard of care available to you at your CVN clinic. Clinical staff will determine the potential services and/or evidence-based treatments that they believe will be the most helpful for you going forward. If you withdraw or are withdrawn from the study early and are receiving treatment-as-usual, withdrawal will not affect the treatment that you are receiving.

Even if you end treatment early, it is helpful for us to compare your assessment results to those who continued to receive treatment. Therefore, we may contact you about completing study assessments. You will still be compensated for completing the assessments.

Inclusion of one of your children in the intervention does not prevent any other children in your family from receiving additional services at a CVN clinic. Other children in your family will continue to be eligible to receive the full range of usual treatments and services provided by CVN clinics, and will also be referred for additional clinical services as needed.

ALTERNATIVES TO PARTICIPATING IN THE STUDY

If you choose not to participate in the study, you will still be offered the standard of care available to you at a CVN clinic, should you be interested in receiving mental health services. Clinical staff will contact you to discuss the potential services and/or evidence-based treatments that they believe will be the most helpful for you.

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PRIVACY & DATA CONFIDENTIALITY

In this study, you may be asked to provide information that could be used to identify you personally. This information will be kept confidential. Only researchers and others that will keep the information confidential (e.g., regulatory agencies or oversight groups) may access information that could personally identify you. Confidentiality of your research records will be strictly maintained by the following procedures:

1. The researchers will keep all physical study records locked in the office of Dr. Kathrine Sullivan (Principal Investigator) at NYU.
2. Electronic study records will be stored on a secure server, NYU Box. Any computer hosting electronic records will also have password protection to prevent access by unauthorized users. Only members of the research staff will have access to the passwords. Electronic records will be kept indefinitely.
3. Data will be collected on password protected devices using REDCap. REDCap is a secure, web-based, and HIPAA-compliant application. Only research staff are able to log-on to REDCap, and all project changes and user rights are monitored by the Principal Investigator. NYU REDCap Administration monitors server security.
4. Assessments will be audio and video recorded using NYU HIPAA compliant Zoom.
    a. Parent-child assessments will be recorded for coding purposes only. Recordings will be shared securely via NYU Box with our co-investigators at the University of California Davis. They will not be shared for any other purposes unless you authorize us to do so.
5. All study records and audio-video recordings will be labeled with a number code and will not show your name.
6. All study records and audio-video recordings will be kept for up to six years. At the end of six years, recordings will be destroyed.
7. At the end of the study, the researchers may publish their findings. Information will be presented in summary format, and you will not be identified in any publications or presentations.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. Researchers with this Certificate will not disclose or use information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, even if there is a court subpoena. Exceptions include:

- A federal, state, or local law requires disclosure.
- Your explicit approval for the researchers to release your name and/or personally identifiable information.

If your clinician determines that you are at risk of harming yourself or others, they will consult with their supervisor at their CVN clinic, as well as with research staff as needed, to ensure that you receive necessary crisis intervention services.

Additionally, we are required by law to record instances of reportable child maltreatment and report these instances to proper authorities.

We may wish to use information about you collected for this study for future research, share it with other researchers, or place it in a data repository. These studies may be similar to this

study or completely different. All information that could identify you will be removed before sharing the data or using it for other research studies. We will not ask you for additional permission before sharing this information. Please indicate below your permissions regarding this use of your information:

- ◯ I do not give permission to use my de-identified data for future research or to share it with other researchers. Use it only for this research study.
- ◯ I give permission to use my de-identified data for future research, share it with other researchers, or place it in a data repository.

You may change your decision by notifying the researchers at any time during your participation in the research study.

PERMISSION TO CONTACT YOU ABOUT FUTURE RESEARCH

We may wish to contact you about future research at New York University. Your permission to allow us to contact you about future research is voluntary. If you choose not to allow us to contact you, it will not affect your treatment in any way. Giving us permission to contact you may help us find people who may qualify for future research studies. It does not mean that you or your child must join any study. You can decide at that time whether you are interested in participating in that specific study. If you are interested, you will have the opportunity to schedule an appointment to be fully informed about the research project. The future research must be approved by the original IRB of record. The Principal Investigator, Dr. Kathrine Sullivan, and her research staff must be affiliated with the research protocol. Please indicate below your permissions regarding future research:

- ◯ I do not authorize the Dr. Sullivan and her research staff to contact me about future research at New York University.
- ◯ I authorize the Dr. Sullivan and her research staff to contact me about future research at New York University.

ACCESS TO YOUR STUDY INFORMATION

During the study, you will be able to request information from your research record at any time by contacting the research staff directly at silver.PSTAIR@nyu.edu.

Following your first assessment, research staff will prepare a report to share with your CVN clinician that summarizes your results. Your clinician will then discuss with you whether your results indicate:

1. If you are experiencing elevated PTSD and/or Depression symptoms.
2. If your child may be experiencing emotional or behavioral difficulties.

You will be provided an opportunity to ask your clinician questions regarding these assessment findings. You may also request that your clinician provide you a summary of your results. These assessments will not be used for formal diagnostic purposes.

CONTACT INFORMATION

You are encouraged to ask questions at any time during this study. For information about the study, you may contact the Principal Investigator, Dr. Kathrine Sullivan, at (915) 213-6653 or silver.PSTAIR@nyu.edu.

If you have questions about your rights as a research participant or if you believe you have been harmed from the research, please contact the NYU Human Research Protection Program at (212) 998-4808 or ask.humansubjects@nyu.edu.

AGREEMENT TO PARTICIPATE

By signing this document, you are agreeing to participate in this study. Make sure you understand what the study involves before you sign. If you have any questions about the study after you agree to participate, you can contact the research staff using the information provided above. You are entitled to and will be given a copy of this signed consent form.

☐ I certify that all the information in the document above is correct, and I understand that signing this form electronically is the equivalent of signing a physical document.

Name of Participant or Legal Representative*	Signature of Participant or Legal Representative*	Date

**For subjects who may not be capable of giving informed consent, the signature of a legal representative is required.*