

Title of Research Study: The Role of Social Partners in Buffering Physiological and Brain Indicators of Threat-Related Stress in Children and Adolescents: An MRI Study of Social Support

Investigator Team Contact Information: The primary investigators conducting this study are Kathleen M. Thomas, Ph.D. and Megan R. Gunnar, Ph.D., faculty members at the Institute of Child Development, University of Minnesota.

For questions about research appointments, the research study, research results, or other concerns, contact the study team at:

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Key Information About This Research Study

The following is a summary to help you decide whether or not to be a part of this research study.

What should my child and I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision to participate or not will not be held against you.
- You can ask all the questions you want before you decide whether to participate.

Why is my child being asked to take part in this research study?

We are asking you and your child to take part in this research study because your child is typically developing, between 10 and 15 years of age, and because you expressed interest in hearing about research opportunities for children and adolescents at some point in the past.

Why is this research being done?

The purpose of this study is to measure the body's response in unpleasant or threatening situations in children and adolescents, like seeing an unpleasant image or face. We are interested in whether the presence of a parent or friend can reduce the body's biological reaction to such stressors.

Previous research has shown that emotionally affective pictures or faces, especially unpleasant pictures, can have an effect on our bodies. These include slight increases in heart rate or breathing rate, sweating on the palms of our hands, and perhaps changes in stress hormones, which are chemicals naturally produced in the

brain and body, in both children and adults. Some of these hormones can be measured in body fluids like saliva around the time of the stress.

Sometimes, having a supportive person with us when we are stressed can reduce the levels of hormones that are produced during the stressor. This is called social buffering. However, few studies have looked at how the brain responds when in children and adolescents are managing and regulating their stress levels.

The current study will measure both the physiological responses of the body (hormones, heart rate and breathing, sweating) and the brain response to affective stimuli, and will test whether different people in a child's life (for example, a parent or a close friend) can serve as a social buffer against this type of stress.

This study will help scientists understand more about the biological responses to threat-related stress in children and adolescents and determine which brain systems may help youth regulate their stress. It will also help scientists understand how social relationships with family members and friends may support children and adolescents in managing their stress in challenging situations.

How long will the research last?

Participation in this study requires one online session lasting approximately 1 hour, and one visit to the University of Minnesota campus, which will last about 2.5 hours.

What will my child and I need to do to participate?

Visit 1: Online

At visit 1, we will ask you to do the following things:

- Review & sign this consent form
- Complete a questionnaire describing your family demographics, like the number of family members and parental income or education
- Complete questionnaires about your child's general health, pubertal development, behavior and development
- Complete a screening questionnaire about your child to be sure that they do not have any metal in or on their body that would be unsafe in the MRI scanner or have any health reasons why they should not be scanned

At visit 1, we will ask your child to do the following things:

- Review & sign an assent form
- Complete questionnaires to tell us about their social networks (family, friends, etc.), their self-concept, their pubertal development, and on their emotions and behaviors ("I feel nervous meeting new people").
- Complete a safety screening questionnaire to be sure that they do not have any metal in or on their body that would be unsafe in the MRI scanner or have any health reasons why they should not be scanned. For females who have started their menstrual cycle, we are required to ask whether they think they might be pregnant. If your daughter thinks she could be pregnant, we will not be able to scan her.

Visit 2: At the University

At visit 2, we will ask your child to do the following things:

- Leave you (although you will be nearby), put on hospital scrubs, and lie in an MRI scanner.

- Give up to 10 saliva samples throughout the 2.5-hour visit to measure stress hormones. Saliva is collected by having your child chew on a small sponge until it is soggy.
- Allow a hair sample: We will take a 3 mm wide section of hair from near the crown of your child's head, to determine stress, pubertal, and sleep hormone levels.
- Practice lying in a pretend MRI machine to make sure that they will feel comfortable in the actual MRI machine.
- Look at some aversive images that will be used in the MRI scanner to be sure that they are unpleasant, but not distressing or painful in any way.
- Perform two emotion tasks in the MRI scanner while we scan their brain. One task involves matching shapes or emotionally expressive faces from multiple choices. The other involves pressing a button for some letters but not others while emotionally charged images are present on the screen. The total time in the scanner is expected to be about 1 hour. Your child will do the following while being scanned in the MRI machine:
 - lie quietly and watch a movie for a few minutes
 - lie quietly with no audio or video for a few minutes
 - complete the emotion tasks
 - wear monitors to measure how physical responses such as heart rate, breathing rate, or sweating of the hands change during aversive learning
- Complete a questionnaire after the session to tell us how they felt during different tasks.
- Optional: Wear a device like a wristwatch or FitBit for several days to measure your child's general activity level both while they are awake and while they sleep.

At visit 2, we will ask you to do one of the following things:

- Sit next to your child at the MRI scanner. We will screen you to confirm that you do not have metal in your body or any health conditions that would be unsafe in the MRI environment. During the MRI, we will give you headphones to protect your hearing and a book to read while your child completes the scan.

OR

- Invite a close friend of your child to come to the scan and sit next to your child at the MRI scanner. We will screen your child's friend to ensure their safety in the MRI room, and secure permission from the friend's parent. During the MRI, we will give the friend headphones to protect their hearing and a book to read while your child completes the scan.

OR

- Neither of these things. Some participants in this study will not have anyone sitting in the room with them (typical MRI scan). In this case, you will be able to sit in the building lobby and simply wait for your child to complete the MRI scan.

Your child has been randomly (by flip of the coin) placed in the condition that is checked, below:

- Go through the MRI with you present in the room for support.
- Go through the MRI with a close friend present in the room for support, in which case you will be asked to bring one of your child's close same-sex friends to the second session.
- Go through task in the standard way, which is by themselves, without anyone else in the room.

Magnetic resonance imaging (MRI) is a procedure that allows us to take pictures of different body tissues. Unlike other imaging methods such as X-ray, MRI does not require any ionizing radiation (i.e., does not require exposure to radioactive materials), making it safer for use with children. The MRI machine contains a

strong magnetic field. Images of the brain are created by detecting the behavior of water or other naturally occurring molecules when they are in the presence of the magnetic field. Your child will not be able to feel the images being taken. Our MRI studies do not use any invasive procedures like injections, radioactivity, or X-rays.

If you and your child decide to participate, your child will lie on a bed with their head and shoulders inside the MRI tunnel. Your child will have a video screen and headphones inside the tunnel so that they can watch a movie, perform a computer task, or see the buffer while we take images of their brain. During the MRI scan, the machine makes a number of loud noises. Your child will wear earplugs and headphones for hearing protection and communication with the researchers, and additional foam cushions will be placed over your child's ears to further dampen the sound and help your child lie still. We will place a sensor on the tip of one finger and, 3 sticky electrodes over your child's heart to measure heart rate, and some electrodes on the hand or foot, since heart rate and other physiological activity can affect the measured brain activity and are good indicators of stress.

Your child will be able to communicate with the investigators at all times during the scan and will be free to get out of the scanner at any time should they desire. Your child should experience no physical discomfort, except that associated with remaining still for the scanning period. Occasionally children report that the pressure of the cushions around their head becomes annoying by the end of the scanning session.

Is there any way that being in this study could be bad for me or my child?

This study is designed to measure reactions to emotions. The images we will use are part of a standard set that has been used for years, including with children. However, each child is different, and your child may find this situation more or less stressful than another child does. We will give you a chance to preview a representative sample of images so that you are well informed and can determine if they are appropriate for your child.

Some people may not feel comfortable in the MRI scanner. The scan requires youth to lie with their head and shoulders inside a tunnel. For people who do not like small spaces, this can be uncomfortable. To get clear pictures of the brain, we also need people to lie very still in the scanner. This can be challenging. Finally, the scanner makes a lot of loud noises during the session that some people may find unpleasant or annoying. We provide hearing protection to make sure the sounds cannot damage your child's hearing.

People who have metal in or on their bodies should not have an MRI scan. The MRI machine uses a strong magnetic field that we cannot feel, but that may cause metal objects to heat up or move. This could cause an injury. We carefully screen all participants for possible metal objects before allowing them to go to the MRI scanner.

This study includes children and adolescents between 10 and 15 years of age. This is a period of time when many physical changes are occurring in a child's body with the onset of adolescence or puberty. We ask each child or teen to complete a questionnaire to determine their level of physical and pubertal development. Some children may find this embarrassing or uncomfortable.

We will ask you and your child to complete some questionnaires. These surveys ask about topics that may be sensitive or private, like your family income or your child's emotions and behaviors. We work carefully to protect your privacy and always keep the information that you provide confidential. However, some people find such private questions uncomfortable.

For females who have started their menstrual cycle, we are required to ask whether they think they might be pregnant. If your child thinks they could be pregnant, we will not be able to scan them. By Minnesota Statute, we are not allowed to break confidentiality to inform parents of a teen pregnancy. If your child tells us that they might be pregnant, we will offer them a urine pregnancy test to give her more information. If the test is positive, we will encourage them to tell you, including offering to sit with both of you while they inform you. If your child thinks they may be pregnant or has a positive pregnancy test, we will provide them with information on services that they can access to receive pre-natal care and counseling.

Your child will need to chew on a collection sponge several different times to provide measures of stress hormones in their saliva. Some children or adolescents find the saliva measures embarrassing or gross.

More detailed information about the risks of this study can be found under "***What are the risks of this study? Is there any way being in this study could be bad for me? (Detailed Risks)***"

Will being in this study help me in any way?

There are no benefits to you or your child from your taking part in this research. We hope that this research will help us identify the brain systems that children and adolescents use to manage stress and determine whether social partners like parents or friends can help reduce the biological reactions to aversive stimuli.

Detailed Information About This Research Study

The following is more detailed information about this study in addition to the information listed above.

How many people will be studied?

This study will include 150 children and adolescents from 11 to 15 years of age.

This study includes random assignment to one of three types of social buffering (presence of a parent, close friend, or no one). The type of buffering that your child gets will be chosen by chance, like flipping a coin. You will not get to choose which type of buffering your child gets.

What happens if I say “Yes”, but I change my mind later?

You and/or your child can leave the research study at any time, even if you have already started, and no one will be upset by your decision.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you. This means that your choice not to be in this study will not negatively affect your right to any medical care, your academic standing as a student, or your present or future employment through the University of Minnesota.

You or your child may choose to stop any measurement that you do not want to complete or to skip measures that you do not want to complete. If you or your child decide to skip a measure or stop in the middle of a measure, we will move on to the next measure. If you or your child decide to stop the study all together and not finish the remaining measures, we will keep the already collected data unless you tell us to destroy it.

We may choose to stop the study at any time if we learn new information that would put your child at risk (for example, a forgotten piece of metal, like a permanent retainer). In addition, we may choose to stop the study if we believe that your child has become too distressed by the study measures.

What are the risks of being in this study? Is there any way being in this study could be bad

for me? (Detailed Risks)

Viewing unpleasant images is stressful for children and adults. We will definitely tell children that they are going to watch some unpleasant pictures of faces or scenes.

MRI machines use a strong magnet and radiofrequency magnetic fields to take images of your body. The scanning process is similar to an x-ray or CT scan, but MRI does not use ionizing radiation (high-energy radiation that can potentially cause damage to DNA) like x-rays or CT scans. The risks associated with MRI scans are:

Projectiles: Objects with magnetic properties can be pulled into the magnet and turn into projectiles. To minimize this risk, we ask that subjects remove all metallic items (watches, cell phones, hair pins, etc.) prior to entering the scanner and by controlling access to the scanner.

Claustrophobia: The scanner is a long narrow tube that may cause some people to feel claustrophobic (i.e., anxious in small spaces).

Hearing Damage: The noise generated by the operation of the scanner during a study is loud enough to cause hearing damage if people do not wear hearing protection. Hearing protection is required and is provided by the investigator.

Nerve Stimulation: Some people experience localized tingling, twitching, or muscle contractions during MRI scans. This is expected, but your child will be told to notify the investigator if it occurs and is uncomfortable.

Disruption of Devices: Some devices can be damaged by magnetic fields and should not be brought into the scanner room. This includes some implanted devices such as pacemakers, cochlear implants, insulin pumps, nerve stimulators, etc. If your child has any implanted device, be sure to notify the investigator.

Heating of Devices: The radiofrequency waves used in MRI can heat conductive materials such as metal implants (screws, plates, rods, wires, artificial joints, etc.), certain tattoo inks, certain clothing fabrics, jewelry, medication patches, wigs, etc. You and your child will be asked to remove these items. If they cannot be removed, your child will not be allowed to proceed with the scan.

A thorough pre-scan questionnaire will allow us to minimize the risk of device disruption and heating. Your child will be in constant contact with the investigator and will be able to notify the investigator immediately, via a squeeze ball, if they experience anything unusual, become claustrophobic, think that their hearing protection is not adequate, or experience nerve stimulation that is uncomfortable. If your child is randomized to the parent present condition or friend present condition, we will also screen you or your child's friend for metal in or on your body to ensure safety when sitting next to the MRI scanner.

In addition, there is a risk of unknown effects related to participation in MRI research. Long-term effects of exposure to high magnetic fields are unknown. Most people experience no short-term ill effects from the strong magnetic field, but some people report dizziness, mild nausea, headache, a metallic taste in their mouth, or sensations of flashing lights. These symptoms, if present, subside shortly after leaving the magnet. Your child will be told to notify that researcher right away if they experience any discomfort or pain, and the researcher will stop the scan and take your child out of the magnetic field if needed.

Will I receive any imaging results after my child's MRI scan?

The images or pictures created during this study are for research purposes only and are not intended to provide health care to your child. However, if the results from the magnetic resonance imaging show something unusual in the pictures, a radiologist trained in reading the pictures will look at them. The pictures will not contain any personal information except your child's age and sex. There will be no charge to you for

having the radiologist look at your child's pictures. An investigator will contact you if the recommendation of the radiologist is to further investigate the unusual results of the pictures with your child's own physician. However, further medical follow up is not a part of this study and the study does not have funds set aside for this purpose. Therefore, if the results do show something unusual, any medical follow up cost will be your responsibility and/or the responsibility of your health insurance carrier.

What do I need to know about reproductive health if my child and I are in this study?

The risks of exposure to high magnetic fields are unknown for fetuses. Therefore, females who are capable of becoming pregnant, and have any reason to believe that they might be pregnant, should not participate in this MRI study. We are required to ask about pregnancy for any female participant who has experienced their first menstrual cycle.

Will I learn about any new information about the effects of MRIs on human health?

You will be told of any important new information that is learned during the course of this research study which might affect your willingness to continue participation.

Will it cost me anything to participate in this research study?

Taking part in this research study will not lead to any costs to you.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study records, to people who have a need to review this information. We cannot promise complete confidentiality.

Organizations that may inspect and copy your information include the representatives of the National Institutes of Health, the Institutional Review Board (IRB), the committee that provides ethical and regulatory oversight of research, and other representatives of this institution, including those that have responsibilities for monitoring or ensuring compliance.

All personnel at the University of Minnesota are mandated reporters. We will not ask you or your child about child abuse, but if you or your child tell us about child abuse or neglect, we may be required both by law and by University policy to report this information to appropriate authorities.

Your child's biological samples (saliva, hair) that are collected as part of this research will not be used or distributed for future research studies, even if all identifiers are removed.

A description of this clinical trial will be available at <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you or your child. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Certificate of Confidentiality

To help protect your privacy, the National Institutes of Health has granted a Certificate of Confidentiality. The researchers can use this Certificate legally to refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. It is unclear if the Certificate will work in foreign countries.

The Certificate does not prevent a researcher from reporting information learned in research when required by

other state or federal laws, such as mandatory reports to local health authorities for abuse or neglect of children/vulnerable adults, or information to the Food and Drug Administration (FDA) when required in an FDA audit. However, the Certificate limits the researcher from disclosing such information in follow up civil, criminal, legislative or administrative legal proceedings if the information was created or compiled for purposes of the research.

You also should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

Will I receive my child's research test results?

Most tests done in research studies are only for research and have no clear meaning for health care or education. The investigator(s) will not contact you or share your child's individual test results with you in this study except in the case of an anomalous brain scan. If we notice anything concerning in the physical exam or in the MRI scans, we will let you know. However, our MRI scans are not clinically diagnostic, and we are not medical radiologists. It is possible that your child could have a brain anomaly that we would not recognize as atypical.

Whom do I contact if I have questions, concerns or feedback about my experience of my child's experience?

This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Will I have a chance to provide feedback after the study is over?

The study investigators would welcome your feedback at the end of the study.

In addition, the HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

What happens if I am injured while participating in this research?

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary

manner, to you or your insurance company. If you think that you have suffered a research related injury let the study staff know right away.

Will I be compensated for my participation?

If you agree to take part in this research study, we will compensate both you and your child for your time and effort. Compensation will be given in the following amounts:

Visit 1: Child/Adolescent: \$40 debit or gift card
Parent: \$25 debit or gift card

Visit 2: Child/Adolescent: \$60 debit or gift card plus \$30 for optional wearable device
Parent: \$25 debit or gift card
Friend: \$40 debit or gift card *[If your child's friend is part of the study]*

If you or your child decide to stop the study prior to the end of visit 2, you will both receive partial compensation based on the portion you have completed. For example, if you complete Visit 1, but do not attend Visit 2, you will receive a \$25 debit or gift card and your child will receive a \$40 debit or gift card.

Payments will be made using a pre-paid card called Greenphire ClinCard. It can work as a pre-paid credit card or like a bank debit card. We will give each participant (you, your child, your child's friend) a debit card, and money will be added to the card after each completed visit.

You may use this card at any store that accepts MasterCard or you can use a bank machine to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals (ATM use) and inactivity (no use for 6 months). We will give you the ClinCard Frequently Asked Questions information sheet that answers common questions about the debit card. You will also receive letters with additional information on how you can use this card and who to call if you have any questions. Be sure to read these letters, including the cardholder agreement, for details about fees.

The debit card system is administered by an outside company. The company, Greenphire, will be given your name. They will use this information only as part of the payment system. Your information will not be used for any other purposes and will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study in which you are participating.

Any demographic information collected and provided to Greenphire is stored in a secure fashion and will be kept confidential, except as required by law.

Payments that you receive as compensation for participation in research are considered taxable income. If payment to any individual equals or exceeds \$600 in any one calendar year, the University of Minnesota is required to report this information to the Internal Revenue Service (IRS). Research payments to study participants that equal or exceed \$600 during any calendar year will result in a FORM 1099 (Miscellaneous Income) being issued to you and a copy sent to the IRS.

If you object to the terms and conditions of the ClinCard, you may choose to receive your payment or your child's payment as a gift card. Gift cards are limited to use at a specific store or with a particular vendor.

Use of Identifiable Health Information

We are committed to respecting your privacy and your child's privacy, and to keeping any personal

information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information and your child's personal health information that includes information that can identify you. For example, personal health information may include your name, address, phone number or social security number. We will not share your personal health information with anyone outside of our study, except in the case of regulatory agencies or bodies that provide oversight for our research, including the University of Minnesota IRB and regulators at the National Institutes of Health.

We respect your child's privacy as well. Therefore, we will not share your child's answers or responses on any measure with you. However, if your child volunteers that they are thinking of hurting themself or someone else, we may be required to tell you and/or a medical professional. As mandated reporters, any report of child maltreatment must be reported to Child Protective Services.

The results of this study may be used for teaching, publications, or for presentation at scientific meetings. No names or identifying information from participants will be used in these presentations.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

Yes, No,
I agree I disagree

My child will wear a device like a wristwatch or FitBit to record their activity for several days, after which I will return the device to the research team.

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

Signature Block for Child/Teen Consent

Printed Name of Parent or Guardian

Date

Signature of Parent or Guardian

Printed Name of Child/Teen Participant

Printed Name of Researcher Obtaining Consent

Date

Signature of Researcher Obtaining Consent