STANFORD UNIVERSITY Research Consent Form

Protocol Director:
Pardis Miri, PhD

IRB Use Only
Approval Date: August 11, 2022
Expiration Date: Does Not Expire

Protocol Title: Facilitating Affect Regulation in Youth with Autism Spectrum Disorder

Please check all that are applicable:

☐ I am an adult participant in this study.

Print your name here:

_____

☐ I am the parent or guardian granting permission for a child in this study

Print child's name here:

_____

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FOR QUESTIONS ABOUT THE STUDY, CONTACT:
Pardis Miri, PhD. Phone number: 650 736-1235
Address: 450 Jane Stanford Way, Department of Psychology, Mail Code 2130, Stanford, CA, 94305-2130

DESCRIPTION: You are invited to participate in a research study to investigate the calming effect of a vibrating device that guides your child through slow-paced breathing. We are at early prototyping stages of developing this device. The goal of this study is to seek your and your child's thoughts, feelings, feedback, advice, and experience to improve our device design, user experience, and functionalities. To give you a more tangible example, imagine your cell phone vibrating for consecutive intervals of 10 seconds during which four seconds of it is perceived as being fast and six seconds of it as being slow. When you perceive such patterns, you need to pace your breathing to inhale for about four seconds, recognize when the frequency of vibration is changed, and then exhale for about 6 seconds. We are also interested in how the exposure to a vibrating breathing pacer may influence your child behaviorally and emotionally. We have found that attending to this vibrating device resulted in anxiety reduction in the college students population. We are also interested in investigating placement, pattern, and personalization of this device tailored to the needs of your child. However, before this stage, we would like to receive feedback on the user-friendliness of our companion app. In this process we will show you and your child prototypes of the companion app as sketched papers (low-fidelity prototypes) or digital images (medium fidelity prototypes). These sketches show the User Interface and some design features we intend to change or add in the companion app.

If you and your child choose to participate, Dr. Pardis Miri and her research study staff will perform the following procedures after signing the informed consent and authorization form regarding the confidentiality of your child's personal health information.

You and your child will be in the study for one hour. We will show you paper or digital sketches of the App we are developing and we will engage you and your child to provide feedback on what you think the app is supposed to do, how you would navigate the app, and your overall thoughts and feelings about the app.

Women of Childbearing Potential

If your child is pregnant or currently breastfeeding, she may not participate in this study. You understand that if your child is pregnant, if she becomes pregnant, or if she is breast-feeding during this study, your child may be exposed to an unknown risk.
You agree to notify the investigator as soon as possible of any failure of proper use of your child's birth control method, or if your child becomes pregnant, either of which may result in your child being withdrawn from the study.

Video and Audio Recordings

Video and/or audio recording will occur during all telehealth sessions. Recorded data will be analyzed for reliability of our team assessments for the purposes of improving our device design and user experience. Recordings will be kept in a secure password protected repository (Stanford medicine BOX) and will be securely disposed of seven years after the completion of the study. This is required as part of this study.

1. I give consent for my child and I to be videotaped during this study.

2. Audio and/or video recording(s) can be analyzed for research and the results of these analyses can be shared for scientific purposes.

3. The recording(s) can be shown in classrooms to students for educational purposes.

4. The recording(s) can be shown in public presentations to scientific and non-scientific groups that may be videotaped and publicly distributed (e.g., posted on a website, made available for purchase on DVD).

Before using the video at the scientific meetings, we will show the video to you and ask for your permission to use it either as is or with voice distorted and faces blurred.

Participants Responsibilities

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.

- Keep your study appointments. If it is necessary to miss an appointment, please contact the Protocol Director or research study staff to reschedule as soon as you know you will miss the appointment.
- Tell the Protocol Director or research staff if you believe your child might be pregnant or gotten your partner pregnant.
- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.

RISKS AND BENEFITS:
The risks associated with this study are minimal discomfort to your child. There is also the possibility of minor risk of performing cognitive tasks. We do not anticipate any political, economic, or social well-being risks. If any of the above is experienced, you/your child may choose to continue participation or not at that time.

Another risk of research studies is a breach of confidentiality.

It is possible that researchers may learn information from this study that may make them concerned about your child's health and/or safety or the health and/or safety of others; in such a case, the researchers may tell you or someone else about it.
There may be no direct benefits to your child nor are there any costs or payments to participate in this research study. It is possible that there will be an improvement in your child's behavioral deficits but we cannot guarantee this outcome. Additionally, it is likely that the knowledge that may be gained from this study will contribute to better therapy for Autism and its related behavioral issues in the future.

Your decision whether or not to participate in this study will not affect your employment/medical care. We cannot and do not guarantee or promise that you will receive any benefits from this study.

TIME INVOLVEMENT: Your participation in this experiment will take approximately one hour through Stanford Zoom video sessions.

PAYMENTS/REIMBURSEMENTS:
You will receive 15 dollars as payment for your participation, upon completion of the study. Payments may only be made to U.S. citizens, legal resident aliens, and those who have a work eligible visa. You may need to provide your social security number to receive payment.

COST:
If you participate in this study, the study will pay for those services, supplies, procedures, and care associated with the study that are not a part of your routine medical care. However, there may be additional costs to you. These include basic expenses like transportation and the personal time it will take to come to send the device back to us. You and/or your health

insurance must pay for services, supplies, procedures, and care that are required during this study for routine medical care. You will also be responsible for any co-payments and/or deductibles as required by your insurance. Participation in this study is not a substitute for health insurance.

COMPENSATIONS FOR RESEARCH RELATED INJURIES:
All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. You will be responsible for any associated co-payments or deductibles as required by your insurance.
If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.
You do not waive any liability rights for personal injury by signing this form.

PARTICIPANT'S RIGHTS: If you have read this form and have decided to participate in this project, please understand your participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.
The results of this research study may be presented at scientific or professional meetings or published in scientific journals. However, your identity will not be disclosed**.**

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. You have the right to refuse to answer particular questions. If you decide to withdraw your consent to participate in this study, you should notify Dr. Pardis Miri at (650) 736-1235.

STANFORD DATA SHARING
If you have previously participated in other research studies at Stanford University that used the same cognitive and behavioral tests as this study, we would like access to your testing data in order to avoid having you and your child repeat these assessments.

Can we access your child's research data and past behavioral testing from those other studies at Stanford University?
Please initial: _____ Yes _____No

We may also want to share your child's research data and behavioral testing data from this study with other research studies at Stanford University. This may help your child avoid repeating assessments if you and your child choose to participate in other future studies.

Can we share your child's research data and behavioral testing data with other Stanford studies that you are participating in?
Please initial: _____ Yes _____No

Authorization To Use Your Health Information For Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?

The purpose of the study is to test the efficacy of vibrotactile-based technologies for affect regulation in youth diagnosed with Autism Spectrum Disorder (ASD). We have been successful in developing such technology to assist with anxiety reduction in healthy college students population and have preliminary findings that suggest our approaches should also apply to an ASD population. We hope that by studying the effects of this system tailored to the needs of children diagnosed with ASD, we can design better ways to empower these children to manage their problem behaviors. Your child's health information may be used in scientific publications and discussed at scientific meetings.

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study. Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write

to: Dr. Pardis Miri at 450 Jane Stanford Way, Department of Psychology, Mail Code 2130, Stanford, CA, 94305.

What Personal Information Will Be Obtained, Used or Disclosed?
Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to, name, date of birth, social security number (for payment purposes only), telephone number, e-mail address, and mailing address. The records that will be collected, used, and shared for this study may include your child's research record, supporting information from your child's medical record number, medical records, results of laboratory, diagnostic or other tests, and clinical and research observations and video recordings made during your child's participation in the research study.

Who May Use or Disclose the Information?
The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director Dr. Pardis Miri
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff

Who May Receive or Use the Information?
The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- Stanford Wearable Electronics Initiative (eWear)

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?

Your authorization for the use and/or disclosure of your health information will end on December 31, 2050 or when the research project ends, whichever is earlier.

Will access to my medical record be limited during the study?
To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it was used to make a medical or billing decision about you (e.g., if included in your official medical record).

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

_____ _____
Signature of Legally Authorized Representative (LAR) Date
(e.g., parent, guardian or conservator)

_____
Print Name of LAR

_____
LAR's Authority to Act for Participant
(e.g., parent, guardian or conservator)

WITHDRAWAL FROM STUDY
The Protocol Director may also withdraw you from the study, without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- Your child pregnancy
- Your child breastfeeding
- You child needs treatment not allowed in the study.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

CONTACT INFORMATION:
Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Dr. Pardis Miri. You may contact her now or later at 650-736-1235.

Injury Notification: If you feel you have been hurt by being a part of this study, please contact the Protocol Director, Dr. Pardis Miri at 650-736-1235.
Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at 650-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.
Appointment Contact: If you need to change your appointment, please contact the research study staff at 650-736-1235.
Alternate Contact: If you cannot reach the Protocol Director, please contact the outpatient clinic of the Child Psychiatry Division at 650-723-5511 at any time of the day or night and ask to speak to the physician on call.

EXPERIMENTAL SUBJECTS BILL OF RIGHTS: As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;

- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

The extra copy of this signed and dated consent form is for you to keep.

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

_____ _____
Signature of Legally Authorized Representative (LAR) Date
(e.g., parent, guardian or conservator)

_____
Print Name of LAR

_____
LAR's Authority to Act for Participant
(e.g., parent, guardian or conservator)

_____ _____
(If available) Signature of Other Parent or Guardian Date

_____
Print Name of Other Parent or Guardian

_____
Authority to Act for Participant

The IRB determined that the permission of one parent is sufficient in accordance with 45 CFR 46.408(b).

_____ _____
Signature of Person Obtaining Consent Date

_____
Print Name of Person Obtaining Consent