PARENTAL PERMISSION FOR CHILD TO PARTICIPATE IN A RESEARCH STUDY

Title of Study: Play Study

Principal Investigators: Anjana Bhat, PT, PhD, University of Delaware (UD)

KEY INFORMATION

Important aspects of the study you should know about first:

- **Purpose:** The purpose of this study is to compare the effects of three types of play and/or movement interventions (i.e., play or move or create), on your child's brain activity, ability to move around, and their ability to interact with others.
- **Procedures**: If you choose to allow your child to participate, they will take part in 9 testing sessions and 16 expert-delivered training sessions over 18 weeks. During the testing sessions, your child will be asked to play movement and balance games. If you choose the face-to-face (F2F) mode of testing delivery completed in-lab or at-home, on day 3 of the pretest, posttest, and follow-up tests, your child will participate in a brain activity test by wearing a cap with sensors and small sensors on his/her arms, back, and legs. You and your child will also take part in 16 training sessions that will involve different types of play and movement games.
- You will complete 8 more training sessions on your own (1 per week).
- All sessions can be done F2F (in-lab or at-home) or through online videoconferencing **Duration:** The 9 testing sessions will last for 1-1.5 hours each and the 16 training sessions will last for around 45 minutes-1 hour each and will involve you and our child. Additionally, we will hold weekly preparatory web-meetings of 1 hour/week in the testing weeks and 30 minute-long weekly meetings during the 8 training weeks. The preparatory meetings will not involve your child.
- **Risks**: Your child may experience some fatigue due to the training activities. During web-conferencing meetings, it is possible that your identity is disclosed to others who may attend the meeting. But, meeting ids and passwords will be used to protect your identity.
- **Benefits:** There are no direct benefits from participation in this study.
- **Alternatives:** You could pay for your child to receive similar training sessions privately.
- **Costs and Compensation:** Your family will be mailed a $100 gift card for your and your child's participation after the last follow-up test session upon completing all testing sessions and at least 75% of the expert training sessions (12 out of 16 sessions).
- **Participation:** Allowing your child to take part or not in this research study is your decision. You can decide to allow your child to participate and then change your mind at any point. Even if you agree for your child to participate we will ask them if they want to participate and their wishes will be respected.

Please carefully read the entire document. You can ask any questions you may have before deciding If you agree for your child to participate.

Your child is being invited to participate in a research study. This form tells you about the study including its purpose, what your child will be asked to do if you decide for your child to take part, and the risks and benefits of being in the study. Please read the information below and ask us any questions you may have before you decide whether or not you want your child to participate.

PURPOSE OF THE STUDY

The purpose of this study is to compare the effects of three types of play or movement interventions on your child's motor and social communication skills. This study is being conducted at the University of Delaware (UD). A part of the data collected from this study will be used in the dissertation of a graduate student, Wan-Chun Su, who is in the Biomechanics and Movement Sciences program at the University of Delaware.

WHO IS BEING ASKED TO PARTICIPATE?

Your child will be one of approximately 45 children who will participate in this study.

Your child is being asked to participate because…

- He/she is between 5 and 15 years of age
- He/she has a diagnosis of Autism Spectrum Disorder (ASD).

PROCEDURES: WHAT WILL MY CHILD BE ASKED TO DO?

As part of this study your child will be asked to…….

- Screening and Eligibility: Your child's diagnosis will be confirmed through medical records or a letter from your child's physician, pediatrician, psychologist, or psychiatrist stating your child's diagnosis. We do not contact your doctors to obtain this information.
- Children will be excluded from the study if they have significant vision, hearing, behavioral, movement, or other impairments (e.g., history of seizures) that limit their ability to participate in the study. Children with severe mobility deficits who need to use a powered or manual wheelchair will be excluded from the study.
- Pre-testing sessions: Once we confirm your child's eligibility for the study, we will schedule three pre-testing sessions through videoconferencing..
- Face to face research will resume in the future per university guidelines; currently, telephonic, mailing and online videoconferencing research is permitted.
- Prior to testing, you will be asked to participate in a 1-hour videoconference to debrief you on the test activities and your role during the testing sessions.
- The testing sessions will last for 1-1.5 hours each.
- We will record each video conferencing session at our end on password-protected university computers.
- During the testing sessions, your child will be asked to participate in various games involving balancing, moving arms and legs, drumming, marching, swaying, or decision-making activities, and social interactions.

- During day 3 of the in-lab or at-home testing sessions in the pretest, posttest, and follow-up period, we will ask your child to wear a cap with sensors (to record brain activity levels) and small sensors on their arms, back, and legs (to track limb movements).
- The cap will hold multiple sensors that emit and receive infrared light, similar to small LED Christmas lights. This is a completely safe and non-invasive method of studying brain activity. As the light passes between the emitters and receivers it gives us information about changes in blood supply to different brain regions. It tells us about the parts of your child's brain that are active as they move their bodies.
- We will also place small and light wireless motion sensors on your child's wrists using elastic wrist bands and his/her shoes using velcro. These sensors will help us understand your child's ability to coordinate his/her arms and legs.
- During both testing sessions, we will also ask you to fill out multiple standardized questionnaires that will help us assess your child's sensori-motor, social communication, and behavioral skills.
- Training sessions: The training sessions will take place through video conferencing or F2F delivery (in-lab or at-home) at a time of your convenience twice a week for 8 weeks. Your child will be matched with other two children based on certain factors such as age, gender, and level of functioning and then will be randomly assigned to the play or move or create group. If your child is in the play group, you and your child will engage in music, dance, and yoga activities. If your child is in the move group, you and your child will engage in activities focusing on your child's flexibility, strength, and physical fitness. If your child is in the create group, you and your child will engage in reading, building, and art-craft activities. For both groups, training sessions will last from 45 minutes to 1 hour. We will video record each expert session on university-owned password-protected computers.
- Parent-led training: In addition, in all groups, at the start of the study, we will provide you with training supplies or a list of household supplies. You should use the supplies to practice play, move, or create group-related games with your child 1 additional time per week (on your own or with us guiding the session). We will request you to keep track of weekly play activities you practice with your child in a training diary that we will provide. Lastly, we will receive your and your child's input on the value and feasibility of the intervention provided.
- Post-testing sessions: Following the 8 weeks of training, we will complete three post-test sessions through video conferencing or F2F delivery (in-lab or at-home). The activities conducted during these sessions will be identical to those conducted during the pretest session. In addition, we will also ask you to fill out a few mailed questionnaires during the posttest to assess any changes in your child's abilities following the training activities.
- Follow-up testing sessions: Finally, we will conduct 3 follow-up tests sessions through video conferencing or F2F delivery (in-lab or at-home), 2 months after completion of training . Your child will do the same activities as they did during the pre- and posttest sessions. At the end of follow-up testing, we will share with you all training details from the group your child was not assigned to, so that you are able to implement the activities with your child in the future.

  Total Time Commitment: The total time commitment for the 9 testing sessions and 3 debriefing sessions is 16 hours. Over 8 weeks, expert training sessions will require a time commitment of 1.5-2 hours/week. In addition, you will need to dedicate 30 minutes to debriefing sessions each week. You will also spend 30

minutes to 1 hour/week to practice the activities with your child on your own. Therefore, the time commitment for intervention training and delivery is 28 hours over a period of 8 weeks. The overall time commitment for testing and intervention delivery is 40 hours over a period of 18 weeks.

WHAT ARE POSSIBLE RISKS AND DISCOMFORTS?

Possible risks of participating in this research study include ……

- The risks associated with the study are minimal. Your child may experience fatigue during testing and training activities. We will make sure to provide multiple breaks as desired by your child. If your child expresses discomfort verbally or through their behaviors or if you would like us to discontinue our session, we will immediately stop.
- You may experience some inconvenience in terms of multiple testing sessions. We will try our best to be flexible and accommodate your scheduling requests.
- Your child may experience some discomfort when wearing the brain cap and/or the sensors on their arms and legs. If this is bothering your child, we will remove the cap and/or sensors on your child's body.
- There is a small risk that your child may fall or hurt themselves while playing and moving during training activities as they normally would within their daily life. We will give you instructions to create a safe environment and remind you to be close to your child and guard appropriately to protect them from injury.
- You might feel uncomfortable and anxious when completing some questions within the screening questionnaire. You can skip items that bother you.
- During videoconferencing sessions, your identity may be disclosed to others who attempt to invade or inadvertently attend the session. But, meeting ids and passwords will be used to protect your identity.

WHAT ARE POTENTIAL BENEFITS FROM THE STUDY?

- Your child may not benefit directly from taking part in this research. However, the knowledge gained from this study will contribute to our understanding of the differential effects of play and movement interventions on the motor and social communication skills and brain activity patterns of children with ASD. This work may have implications for the development of novel movement interventions for children with ASD.

CONFIDENTIALITY: WHO MAY KNOW THAT YOUR CHILD PARTICIPATED IN THIS RESEARCH?

Your child's data will be handled confidentially by the researchers on this protocol and the student researchers working with them. If results of this study are published or presented, individual names and other personally identifiable information will not be used (see details below).

Your child's confidentiality will be maintained through the following methods:

- Study Records: All research records including data on tests, questionnaires, and videos belonging to your child will be assigned an identification number.
- Electronic study records will be stored on password-protected/encrypted, secure university computers in the Move to Learn Lab at the STAR Health Sciences Complex, University of Delaware, 540 S College Ave., Newark, DE.
- Hard copies of de-identified questionnaires will be kept in securely locked cabinets in the PI's lab.
- Access to study records will be restricted to research staff working on the project.
- All study records containing personally identifiable information and the master key linking your child's identity and their ID number will be maintained separately in a secured location in the PI's lab until the end is inactive after which identifiers about your child will be removed.
- Only de-identified data collected from your child will be retained indefinitely in the PI's lab for the purpose of analysis. However, your child's facial features will be seen in all video recordings to assess changes in behavior.
- Data Publication/Sharing: The findings of this research may be presented or published. If this happens, no information that gives your child's name or other details will be shared.
- If you give us permission to use your child's picture or videos for research or educational or public relations purposes (see last two optional consents), we could use them appropriately. Even in that case, we will reconnect with you to confirm your permission to use your child's picture or video.
- The confidentiality of your child's records will be protected to the extent permitted by law.
- Your child's research records may be viewed by the UD Institutional Review Board, which is a committee formally designated to approve, monitor, and review biomedical and behavioral research involving humans.
- We also must let you know that during your participation in this study if our research team was to observe or suspect, in good faith, child abuse or neglect, the Delaware state law obligates us to file a report to the appropriate officials.
- SPARK Study Participants: Additionally, for participants who also participate in the SPARK study, we are asking your consent for the SPARK study (https://sparkforautism.org/), hosted by the Simons Foundation, to share with University of Delaware the clinical, demographic, and genetic data collected during your participation in SPARK. Note that although we have access to shared genetic data, these data are not being used in this study. This information will be shared using your linked research ID number and using a secure transfer system. We are also asking for your consent to share some of your child's data we collect during this study here at University of Delaware with SPARK in order to add to the information that was collected during your participation in the SPARK study. Please note that because your child is a participant in both studies, SPARK and this study will be able to share and link your identifying information as well as any future data you may contribute to either project. The Simons Foundation funds innovative research and provides coded data access (data with your identifying information removed) to qualified researchers. Researchers can file an application with the Simons Foundation to obtain access to your study data for research purposes. Experts at the Simons Foundation who protect health and science information will look at every request carefully to minimize risks to your privacy. Only electronic data on standard questionnaires and assessments relating to your child (using their linked research ID number) will be shared with the SPARK study using a secure transfer system. Video data will not be shared.

- For participants who are not part of the SPARK study (https://sparkforautism.org/), hosted by the Simons Foundation, we are confirming that your demographic, health or research-related data will not be shared with SPARK researchers.
- We will protect your online/videoconferencing data by setting meeting passwords and ids, specific meeting times, and will record the video data captured on password-protected university computers.
- We will minimize the number of supplies we send to you by suggesting household supplies for testing/training. We will clean all supplies that we mail to you with disinfecting wipes.

USE OF DATA COLLECTED FROM YOUR CHILD IN FUTURE RESEARCH:

Identifiers about your child will be removed from the identifiable private information and after such removal, the collected information could be used for future research studies conducted in this lab.

COSTS AND COMPENSATION

- The study procedures will be provided to you and your child at no cost to you. Your family will receive a $100 gift card for your and your child's participation at the last follow-up session upon completing all testing sessions and at least 75% of the expert training sessions (12 out of 16 training sessions).

WHAT IF YOUR CHILD IS INJURED DURING PARTICIPATION IN THE STUDY?

- In the event of an injury, you will be responsible for offering any first aid to your child. If your child needs additional medical treatment, the cost of this treatment will be your responsibility or that of a third-party payer (for example, your child's health insurance). By signing this document, you are not waiving any rights that you and your child may have if injury was the result of negligence of the university or its investigators. In case of any questions or concerns (both during and after office hours) at the Delaware site, please contact PI, Dr. Anjana Bhat (Email: abhat@udel.edu, Phone: 443-523-8680).

DOES MY CHILD HAVE TO TAKE PART IN THIS STUDY?

- Taking part in this research study is your and your child's decision. Your child does not have to participate in this research. If you choose for your child to take part, you have the right to stop your child's participation at any time. If you decide later for your child not to participate, or if you decide for your child to stop taking part in the research, there will be no penalty/loss of benefits that your child and you are otherwise entitled.
- Your decision for your child to stop participation, or not to participate, will not influence current or future relationships with the UD.
- If, at any time, you decide to end your child's participation in this research study, please inform our research team or you can contact the PI to inform her of your decision. If you or your child stop participation in the study, we will keep any data collected of your child until that point. If your child does not complete all the required procedures listed in this form you will not be entitled to any compensation for the study.

INSTITUTIONAL REVIEW BOARD

This research study has been reviewed and approved by the University of Delaware Institutional Review Board (UD IRB). If you have any questions or concerns about your child's rights as a research participant, you may contact the UD IRB at hsrb-research@udel.edu or (302) 831-2137.

CONTACT INFORMATION

If you have any questions about the purpose, procedures, or any other issues/concerns related to this research study, you may contact the Principal Investigator: Anjana Bhat at (443) 523-8680 or abhat@udel.edu (at the UD site).

I have read and understood the information in this parental permission form. I agree for, and allow, my child to participate in the study. I understand that I will be given a copy of this form for my records.

_____	_____	_____
(Printed Name of Parent/Guardian)	(Signature of Parent/Guardian)	(Date)

_____	_____	_____
Person Obtaining Consent (PRINTED NAME)	Person Obtaining Consent (SIGNATURE)	Date

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OPTIONAL CONSENT FOR ADDITIONAL USES OF IDENTIFIABLE VIDEO RECORDINGS/PHOTOGRAPHS

I voluntarily give my permission to the researchers in this study to use videos and photographs of my child collected as part of this research study for publications, presentations, and/or educational purposes. I understand that no identifying information beyond that contained in the video recording will be provided to educational/scientific audiences; however, my child's facial features may be seen. Note: As mentioned earlier, video recording is done with all participants to assess changes in the child's behavior.

_____	_____	_____
(Printed Name of Participant OR Parent/Guardian)	(Signature)	(Date)

OPTIONAL CONSENT TO BE CONTACTED FOR FUTURE STUDIES:

Do we have your permission to contact you regarding your child's participation in future studies? If you agree to being contacted in the future, we will keep your contact information [Note: This does not apply to SPARK study families].

Please write your initials next to your preferred choice.

_____ YES _____ NO