Evaluation of Organizational Skills Training (OST)
Program for Upper Elementary Students

NCT03443323

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Children's Hospital of Philadelphia

Informed Consent Form and HIPAA Authorization

Study Title: **Evaluation of Organization Skills Training (OST) Program for Upper Elementary Students**

Consent Name: **Organizational Skills Training School Based (OST-S): Parent Consent**

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You and your child may be eligible to take part in a research study. This form gives you and your child important information about the study. It describes the purpose of this research study and the risks and possible benefits of participating.

If there is anything in this form you do not understand, please ask questions. Please take your time. You and your child do not have to take part in this study if you or your child do not want to. If you and your child take part, you and your child can leave the study at any time.

In the sections that follow, the word "we" means the study investigators and other research team members.

Why are you and your child being asked to take part in this study?

You and your child have been asked to join this research study because your child has trouble with organization, time management and/or planning skills. Children in 3rd through 5th grade with this trouble are being asked to join.

What is the purpose of this research study?

The goal of this research study is to learn about a small group skills training program called Organizational Skills Training (OST). We hope to help children use new organizational skills along with the help of their parents and teachers. We plan to partner with parents and schools to help children to be more organized and successful in school.

How many people will take part?

About 280 student-parent pairs will take part in this research study. These students will be from over 20 schools in Pennsylvania and New Jersey and the study will take place over at least 5 years.

What is involved in the study?

If you and your child agree to take part in this study, you and your child will participate in one of two groups, which is determined randomly (like the flip of a coin). The two groups are Organizational Skills Training - School Based (OST-S) and a waitlist group. Both groups will receive OST-S. If you and your child are assigned to the OST-S group, you and your child will receive OST-S during this school year and complete questionnaires at 3 time points this school year and 1-time next school year. If you and your child are assigned to the waitlist group, you

and your child will still complete questionnaires at 3 time points this school year (and 1 time-point next school year) and then receive OST-S the next school year. OST-S small group sessions will take place at your child's school.

OST-S will teach you how to help your child with organization, time management and planning skills. Students, parents, and teachers in both groups will be asked to answer questions. We will ask you how well your child is doing. We will also ask you questions about your child's organization, time management, and planning skills.

How long will you and your child be in this study?

If you and your child agree to join, the OST-S groups will last for at least 8 weeks. The groups will happen either this school year or next school year depending on which group you and your child are assigned to. When you and your child receive OST-S it will most often include 16 total small group sessions. Each small group session will occur most often 2 times a week and each session will last about 40 minutes during the school day. You and your child will be in this research study for a total of 12 months (1 year).

What are the study procedures?

This research study involves the following procedures:

OST-S Sessions (OST-S Group): Participation in OST-S will most often include 16 total sessions. Sessions will be held each week at your child's school (by a trained school staff member) and each session will last about 40 minutes. The sessions will be held when it does not interfere with your child's main subjects. In the case that learning needs to occur virtually, the software typically used by your child's school to engage with students/families would be utilized.

Each session that your child participates in will be audio and video-recorded. The sessions are being recorded so that the research team can be sure that OST-S is being done in the correct way. The video recording will be stored in a locked file cabinet at CHOP. They will later be stored electronically (or uploaded) on a secured web space. Only our research team can access locked file cabinets and secure web spaces which are protected with a username and password. The videos will not be shown to you and your child or your child's teachers or used to evaluate your child's performance. The videos are for research purposes only.

Finally, we may observe your child's backpack and school binders to support his/her improvement in organizing these materials and to determine if there has been an improvement in organization skills.

Parents and teachers of participating students will also be asked to participate in two brief consultation sessions with the school staff member running your child's OST-S small group sessions. In the case that learning needs to occur virtually, the software typically used by your child's school to engage with students/families would be utilized. These sessions will also be audio recorded and stored the same way your child's recordings will be stored.

OST-S Sessions (Waitlist Group): Participation in OST-S next school year will most often include 16 total sessions. Sessions will be held each week at your child's school (by a trained school staff member or a CHOP staff member) and each session will last about 40 minutes. The sessions will be held when it does not interfere with your child's main subjects. In the case that learning needs to occur virtually, the software typically used by your child's school to engage with students/families would be utilized.

Parents and teachers of participating students will also be asked to participate in two brief consultation sessions with the person running your child's OST-S small group sessions. In the case that learning needs to occur virtually, the software typically used by your child's school to engage with students/families would be utilized. No intervention/consultation sessions (student, parent or teacher) will be recorded.

Questionnaires & Collection of Information (Both OST-S and Waitlist Groups): We will ask you questions about your child's organizational skills and how your child is doing in school. **We will ask you these questions 4 different times. These times will be at the time you and your child agree to participate in the study (baseline), approximately 8-weeks after baseline, approximately 5-months after baseline, and approximately 1-year after baseline**. We will also ask your child's teachers to answer questions about your child's organizational skills and how your child is doing in school. We will also collect information about your child such as report card grades.

We may communicate with you via phone and e-mail (if provided) and text message (with your permission).

You will be asked to complete all questionnaires through a secure web-based link that will be sent to your e-mail or phone via text-message (with your permission). If you prefer, you many also request to complete the questionnaires on paper.

What are the risks of this study?

Taking part in a research study involves inconveniences and risks. If you and your child have any questions about any of the possible risks listed below, you and your child should talk to your child's study doctor, teacher or school counselor.

While in this research study, you and your child are at risk for the following:

Risks associated with OST-S Sessions:

There are no known physical or legal risks of participating in OST-S sessions.

- As is the case with all therapeutic interventions, one risk of joining this research study is that OST-S might not be helpful for you and your child. If your child is still having trouble with skills at school after OST-S and you and your child want other therapies, we will work with you to find providers in your community.

Risks associated with Questionnaires:

- There are no physical risks, but you and your child might feel some embarrassment or discomfort. You and your child do not have to answer any questions that make you or your child too uncomfortable. One questionnaire that you will be asked to complete (BASC-3) will be administered directly from the publisher (Pearson). It requires all questions to be completed. However, if you are not comfortable answering any of these questions, you can either not complete the questionnaire or not submit your answers.
- If members of the study team notice a change in your child's mood or emotions, they will tell the study team and may remove you and your child from the study, so that they may assist your child in getting the right treatment. They will work with you and your child to be sure your child receives the right kind of help.

Risks associated with Audio/Video Recording:

- The student intervention sessions and parent/teacher sessions will be audio and/or video recorded. No one other than the research team will see/hear the recordings. If someone's name is mentioned, it will not be included on any notes made by the researchers. The main risk to you is that there is the possibility that your video might be seen by someone outside of the study team and someone could find out you were in this study. But we will do our best to keep your information confidential, so we think this risk is very low. To prevent this the recordings will be kept on password-protected computers and on devices that will be kept in locked cabinets.

Are there any benefits to taking part in this study?

Your child may benefit from this study by learning skills to improve organization, time management, and planning skills. These skills may also help your child do better in school. What we learn from this study may help schools find better ways to help students who have trouble with organization, time management, and planning. However, we cannot promise that you or your child will get any direct benefit by joining this study.

Do you need to give your consent in order to participate?

Yes, if you decide to allow your child to participate in this study, you must sign this form (either on a paper copy or electronically). A paper copy will be given to you (or if signed electronically - an electronic version will be emailed to you) to keep as a record. Please consider the study time commitments and responsibilities as a research participant when making your decision about you and your child participating in this study.

What happens if you decide not to take part in this study?

Participation in this study is voluntary. You or your child do not have to take part if you or your child choose not to. If you or your child decide not to take part or if you or your child change your mind later, there will be no penalties or loss of any benefits to which you or your child are otherwise entitled. If your child changes his/her mind and no longer wants to participate in small group sessions, he/she can make a separate decision to still complete the questionnaires for the study.

Can you stop your participation in the study early?
Yes, you and your child can stop being in the study at any time. You and your child do not have to give a reason.

Can the study doctor take you out of the study early?
Yes, the study team may take you and your child off of the study if:

- The study is stopped.
- New information suggests taking part in the study may not be in you and your child's best interest.

What choices do you have other than this study?
There are options for you and your child other than this study including:

- Receiving care in your community or your child's school outside this study.
- You may discuss other options available to your child with your child's doctor or teacher.

What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?
As part of this research, private information about you and your child will be collected and your child's participation in the treatment sessions may (depending on group assignment) be video-recorded. This will include information such as age, grade level, gender, race/ethnicity, and socioeconomic status, as well as your child's use of medication. We will also collect information about your child's academic performance and organizational/planning skills. We will do our best to keep you and your child's personal information private and confidential. However, we cannot guarantee absolute confidentiality. You and your child's personal information may be disclosed if required by law.

The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. We will keep you and your child's identity private in any publication or presentation.

Several people and organizations may review or receive you and your child's identifiable information. They will need this information to conduct the research, to assure the quality of the data, or to analyze the data or records. These groups include:

- Members of the research team at CHOP, New York University (NYU), and University of Pennsylvania;
- CHOP staff who are directly or indirectly involved in your care;
- School staff who are involved in your child's education and the conduct of this study;
- People who oversee or evaluate research and care activities at CHOP;
- People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections.
- Institute of Educational Sciences who is sponsoring this research;

- Pearson Q-Global (a web-based system for test administration, scoring and reporting) for the BASC-3 measure

By law, CHOP is required to protect your child's private information. The research team will only allow access to your child's private information to the groups listed above. By signing this document, you are authorizing CHOP to use and/or release you and your child's private information for this research. Some of the organizations listed above may not be required to protect your information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

There is no set time for destroying the information that will be collected for this study. Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.

Can you change your mind about the use of personal information?

Yes, you and your child may change your mind and withdraw you and your child's permission to use and disclose your child's health information at any time. To take back you and your child's permission, it is preferred that you tell the investigator in writing.

Thomas Power, Ph.D.
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Roberts Center for Pediatric Research
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In the letter, state that you and/or your child changed your mind and do not want any more of you and your child's private information collected/recorded. The personal information that has been collected already will be used if necessary, for the research. No new information will be collected. If you and your child withdraw your permission to use you and your child's personal information, you and your child will be withdrawn from the study.

Financial Information

The Organizational Skills Training School-based (OST-S) will be provided at no cost to you and your family.

Will you and your child be paid for taking part in this study?

Your child will not be paid for participating, but your child will be given a small gift or prize as a thank you for taking the time in completing the questionnaires. Your child will also receive small gifts (e.g., pencils, notebooks, small toys) for participating and reaching certain goals in OST-S sessions.

You will receive $30 for your time and effort in completing the questionnaires at each of the 4 times points. Payments to you will be loaded onto an electronic bankcard that works like a debit card. If you receive payment using a bankcard, the bank will have access to identifiable information. The bank will not have access to any medical information or any information provided as part of this study.

If you agree to be contacted by text message, standard text messaging rates apply.

Who is funding this research study?

The Institute of Educational Sciences is providing funding for this study.

Financial Disclosure

If your child is assigned to the OST-S Group, Dr. Richard Gallagher and Dr. Howard Abikoff at the NYU School of Medicine will observe recordings of your child to help support the CHOP Team in conducting the program.

The NYU School of Medicine maintains a financial disclosure process by which researchers must disclose any personal financial interests that may be related to the research.

Dr. Richard Gallagher and Dr. Howard Abikoff, researchers involved in this study, each receive royalty payments from Multi-Health Systems and Guilford Press for co-authorship of rating instruments and a book used in this research. NYU also receives royalty payments for the intellectual property. If the research is successful, Dr. Gallagher,

Dr. Abikoff, Multi Health Systems, Guildford Press, and NYU may benefit from the outcomes.

The NYU Langone Conflicts of Interest Office (CIMU) has reviewed the researchers' financial interests and approved a written plan to monitor these interests for the duration of the study.

The NYU Conflicts of Interest Management Unit (CIMU) has reviewed the financial interests and approved a written plan to monitor these interests for the duration of the study. The Institutional Review Board that reviewed this study was informed of this decision. If you would like more information, please ask the researchers, the study coordinators, or the CIMU at 212-263-4489.

What if you and your child have questions about the study?

If you or your child have questions about the study, call the study team at **267-425-1933**. You may also talk to your child's teacher or principal if you have questions or concerns.
The Institutional Review Board (IRB) at The Children's Hospital of Philadelphia (CHOP) has reviewed and approved this study. The IRB looks at research studies like these and makes sure research subjects' rights and welfare are protected. If you have

questions about your rights or if you have a complaint, you can call the CHOP IRB Office at 215-590-2830.

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

Consent to Take Part in this Research Study and Authorization to Use and Disclose Health Information for the Research

The research study and consent form have been explained to you by:

Person Obtaining Consent	Signature of Person Obtaining Consent
	Date:

By signing this form, you are indicating that you have had your questions answered, you agree to take part in this research study and you are legally authorized to consent to your child's participation. You are also agreeing to let CHOP use and share your child's personal information as explained above. If you don't agree to the collection, use and sharing of your child's personal information, your child cannot participate in this study. **NOTE:** *A foster parent is not legally authorized to consent for a foster child's participation.*

Name of Child

Name of Authorized Representative	Relation to child: ☐ Parent ☐ Legal Guardian
Signature of Authorized Representative	Date

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ONLY if applicable:

I also give my permission for _____ (list adult caregiver name) to participate in the study with my child. I understand that his/her participation will involve completing questionnaires about my child and participating in the parent meetings.

Signature of Authorized Representative	Date

A second parent/legal guardian may also agree to take part in this research study. Participation of a second parent/legal guardian is optional and NOT required for the child to participate in the study.

By signing this form, you are indicating that you have had your questions answered, you agree to take part in this research study and you are legally authorized to consent to your child's participation. You are also agreeing to let CHOP use and share your child's personal information as explained above. If you don't agree to the collection, use and sharing of your child's personal information, your child cannot participate in this study. **NOTE:** *A foster parent is not legally authorized to consent for a foster child's participation.*

Name of Child

Name of Authorized Representative

Relation to child:
☐ Parent ☐ Legal Guardian

Signature of Authorized Representative

Date

☐ A second parent/legal guardian was NOT interested in participating. (For administrative purposes only and to be utilized for tracking.)