

Partners HealthCare System Research Consent Form

Parent Template
Version Date: January 2019
NCT04121650

Subject Identification

Protocol Title: Executive Functions and Symptom Reduction in Youth
Receiving Homebased Treatment with Collaborative Problem Solving

Principal Investigator: Alisha R. Pollastri, Ph.D.

Site Principal Investigator: N/A

Description of Subject Population: Youth aged 7 to 14 who receive homebased
services from Youth Villages

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about giving permission for your child to take part in this research study. People who agree to take part in research studies are called “subjects.” This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as “Partners.”

If you decide to give permission for your child to take part in this research study, you must sign this form to show that you want him/her to take part. We will give you a signed copy of this form to keep.

Key Information

Taking part in this research study is up to you. You can decide not to give permission for your child to take part. If you decide to give permission for your child to take part now, you can change your mind and s/he can drop out later. Your decision won’t change the medical care your child gets within Partners now or in the future.

The following key information is to help you decide whether or not to give permission for your child to take part in this research study. We have included more details about the research in the Detailed Information section that follows the key information.

Partners HealthCare System Research Consent Form

Parent Template
Version Date: January 2019

Subject Identification

Why is this research study being done?

In this research study we want to learn more about changes in youths' symptoms and thinking skills when they receive in-home services from Youth Villages.

How long will your child take part in this research study?

If you decide to give permission for your child to join this research study, the total length of participation will be from now until approximately 12 months after services end.

What will happen if your child takes part in this research study?

If you decide to allow your child to be a part of this study, the following will happen:

- (1) Your child will complete a series of tasks on an electronic tablet to assess particular areas of his or her thinking skills. Each computer task is like a game and lasts approximately 2 to 20 minutes. Your child should be able to finish all tasks within about one hour.
- (2) While your child is completing these tasks, we will ask you to complete surveys regarding your child's behavior, your parent-child relationship, and your child's treatment.
- (3) Your Youth Villages clinical specialist will complete one survey regarding your child's behavior and treatment at three timepoints: within the first month of services, around 4 months of services, and when services end.
- (4) You will be contacted when you complete Youth Villages in-home services, and then 6 and 12 months after services end, to complete a phone survey about how your child is doing.
- (5) Other information from your child's records at Youth Villages will be used in the research, including demographic information (e.g., sex, age, racial/ethnic background) and clinical information (e.g., problems being treated, how many sessions were received).

Why might you choose to have your child take part in this study?

There will be no direct benefit to you or your child for participating. However, we hope that information derived from this research might lead to greater understanding of treatment effects in a homebased setting. Information from this study may be helpful to other parents/guardians and children in the future by contributing to improved mental health services for children and families.

Why might you choose NOT to have your child take part in this study?

Taking part in this research study has some minor risks that you should consider carefully. Important risks and possible discomforts to know about include discomfort from sitting still for a

Partners HealthCare System Research Consent Form

Parent Template
Version Date: January 2019

Subject Identification

period of time, boredom from completing tasks and questionnaires, or risks to privacy if your information were not kept secure. A detailed description of side effects, risks, and possible discomforts can be found later in this consent form in the section called “What are the risks and possible discomforts from being in this research study?” Other things to consider are the time commitments of about one hour to complete tasks and questionnaires.

What other treatments or procedures are available for your child’s condition?

Your child does not have to take part in this study to receive the services from Youth Villages. You are free to decline participation and your child will receive the same clinical services offered by Youth Villages.

If you have questions or concerns about this research study, whom can you call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Alisha Pollastri, Ph.D. is the person in charge of this research study at Think:Kids at Massachusetts General Hospital. You can call her at 617-643-6030 M-F 9am to 5pm Eastern Time. You can also Jocelyn Sisson, Assistant Director of Research at Youth Villages, with questions about this research study at 901-251-4955, M-F 9am to 5pm Central Time.

If you have questions about the scheduling of appointments or study visits, call Sammy Stoll at 617-643-7037.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research
- Any pressure to take part in, or to continue in the research study

Detailed Information

Why is this research study being done?

Youth Villages has partnered with Think:Kids at Massachusetts General Hospital (which is part of Partners Healthcare), to study the effects homebased treatment delivered to approximately 80 children and families through Youth Villages. Youth Villages uses a particular treatment approach called Collaborative Problem Solving (CPS), and this study will evaluate the effect that treatment with CPS may have on youths' *executive functioning skills*, which is a term for thinking skills like being flexible, solving problems, and paying attention. Your child's participation will help us gain knowledge about how executive functioning skills change over time due to homebased treatment with CPS.

Who will take part in this research?

- Study population: Children between 7-14 years old and receiving homebased services from Youth Villages.
- Number of Participants: About 80 youth will be recruited for this study.
- Sponsor/funding information: This research is paid for by funds awarded to the Principal Investigator, Dr. Alisha Pollastri, by the Louis V. Gerstner III Research Scholar Award.

What will happen in this research study?

If you decide to allow your child to be a part of this study, the following will happen:

- 1) Your child will complete a series of tasks on an electronic tablet to assess particular areas of his or her thinking skills. Each computer task is like a game and lasts approximately 2 to 20 minutes. Your child should be able to finish all tasks within about one hour.
- 2) While your child is completing these tasks, we will ask you to complete surveys regarding your child's behavior, your parent-child relationship, and your child's treatment. You should be able to finish all surveys within about one hour.
- 3) Your Youth Villages clinical specialist will complete one survey regarding your child's behavior and treatment at three timepoints: within the first month of services, around 4 months of services, and when services end.
- 4) You will be contacted around discharge and 6 and 12 months after your Youth Villages services end, to complete a brief phone survey about how your child is doing.
- 5) Other information from your child's records at Youth Villages will be used as part of the research study, including information about the specialist who saw your child (e.g., their educational background) and clinical information (e.g., problems being treated, number of sessions held).

Partners HealthCare System Research Consent Form

Parent Template
Version Date: January 2019

Subject Identification

How may we use and share your child's samples and health information for other research?

The information we collect in this study may help advance other research. If your child joins this study, we may remove all information that identifies your child (for example, your name, medical record number, and date of birth) and use the de-identified information in other research. It won't be possible to link the information back to your child. Information may be shared with investigators at our hospitals, at other academic institutions or at for-profit, commercial entities. You will not be asked to provide additional informed consent for these uses. No results or information collected only for the purposes of this research will be shared with anyone at Youth Villages.

Will you get the results of this research study?

No. The research study we are doing is only a stepping stone in understanding the effects of homebased services on symptoms and thinking skills. Therefore, no information about the results of this research study or the results of your child's individual participation in the research study will be given to you or your child's clinical specialist at Youth Villages. Tests done for the research using your child's samples will not be useful in directing your child's medical or mental health treatment. The results of the tests will not be placed in your child's health record.

What are the risks and possible discomforts from being in this research study?

We believe this study has minimal risks for you and your child. The only rare and minor physical risks associated with participating in this research are: a) You or your child may experience discomfort associated from sitting still in one position for approximately one hour; b) your child may feel burdened by completing the tasks on a computer tablet. Those burdens will be minimized by providing breaks when needed.

Another potential risk involved in participating in this research study is if sensitive information were not kept confidential. If that were to happen, an unauthorized individual could have access to that sensitive information. However, every effort will be made to keep all of your information confidential. For instance, we will stress the importance of confidentiality in training of all project staff, and we will reiterate this point as opportunities arise in handling of such material. Testing outputs and surveys will be labeled only with ID numbers, not with names, and will be stored securely. Every effort will be made to ensure that the identity of participants cannot be

Partners HealthCare System Research Consent Form

Parent Template
Version Date: January 2019

Subject Identification

determined by the use of the data. Results will be presented only when combined with information from others, and there will be no identifying information included.

What are the possible benefits from being in this research study?

There will be no direct benefit to you or your child for participating. However, we hope that information derived from this research leads to greater understanding of treatment effects in a homebased setting. Information from this study may be helpful to other parents and children in the future by contributing to improved mental health services for children and families.

What other treatments or procedures are available for your child's condition?

Your child does not have to take part in this study to receive treatment from Youth Villages. You are free to decline participation and your child will receive the same clinical services offered by Youth Villages.

Can your child still get medical care within Partners if s/he doesn't take part in this research study, or if s/he stops taking part?

Yes. Your decision won't change the medical care your child gets within Partners now or in the future. There will be no penalty, and your child won't lose any benefits your child receives now or has a right to receive.

We will tell you if we learn new information that could make you change your mind about your child taking part in this research study.

What should you do if you want your child to stop taking part in the study?

If your child takes part in this research study, and you want him/her to drop out, you should tell us. We will make sure that your child stops the study safely. We will also talk to you about follow-up care for your child, if needed.

Also, it is possible that we will have to ask your child to drop out of the study before s/he finishes it. If this happens, we will tell you why. We will also help arrange other care for your child, if needed.

Partners HealthCare System Research Consent Form

Parent Template
Version Date: January 2019

Subject Identification

Will you or your child be paid to take part in this research study?

To thank you and your child for participating in this study, you will receive \$10 for each of the two research appointments in your home, for a total of \$20, plus a \$30 bonus for completing both. This means that you can receive a total of \$50 for your participation (a \$25 gift card to each of you). The \$10 from the first appointment will be combined with your payment from the second appointment, so you will receive a single payment. If your child withdraws from the study between the first and second appointment, s/he will still receive \$10 for one completed appointment.

What will you have to pay for if your child takes part in this research study?

There are no costs to participate in this research study. Whether or not you take part in the research study, Youth Villages will bill your health insurance for routine items and services you would receive as part of your usual care at Youth Villages. You will be responsible for payment if there are deductibles or co-payments required by your insurer. There is no difference in what you will pay, whether or not you decide to take part in the research study.

Limits to Confidentiality

While unlikely based on the screening and consenting topics, if during the screening and consenting procedure, you or the youth discloses abuse or reports suicidal/homicidal ideation (past or current), or self-harming behavior (past or current); the study staff must share that information with the YV specialist. In the extremely unlikely case that the study staff member is not able to speak with the YV specialist by phone immediately, the study staff member will immediately contact a licensed Youth Villages clinical consultant. The Principal Investigator of this research study (a licensed clinical psychologist) will also be informed immediately of any disclosures and will ensure appropriate clinical followup.

Youth will not be excluded from the study based on any of these disclosures, however if the youth proceeds to a higher level of care (e.g., inpatient hospitalization), the youth may not be able to schedule data collection sessions in a timely manner, and thus participation may be affected. Participation would resume if and when the youth returns to in-home services.

What happens if your child is injured as a result of taking part in this research study?

Partners HealthCare System Research Consent Form

Parent Template
Version Date: January 2019

Subject Identification

Since participation in this research includes nothing other completing surveys and computer-based measurements, it is extremely unlikely that your child will be injured as a direct result of this research study.

We will offer your child the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care your child gets for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or your child or give you other compensation for an injury, should one occur. However, you or your child are not giving up any of your legal rights by signing this form.

If you think your child has been injured or has experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the beginning of this consent form.

If your child takes part in this research study, how will we protect your child's privacy?

Federal law requires Partners to protect the privacy of health information and related information that identifies you. We refer to this information as "identifiable information."

In this study, we may collect identifiable information about your child from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your child's identifiable information and why they may need to do so:

- Partners researchers and staff involved in this study
- The sponsor(s) of this study, and the people or groups it hires to help perform this research or to audit the research
- Other researchers and medical centers that are part of this study

Partners HealthCare System Research Consent Form

Parent Template

Version Date: January 2019

Subject Identification

- The Partners ethics board or an ethics board outside Partners that oversees the research
- A group that oversees the data (study information) and safety of this study
- Non-research staff within Partners who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to your child or others (such as to make required reports about communicable diseases or about child or elder abuse)
- Other: Youth Villages research staff involved in this study

Some people or groups who get your child's identifiable information might not have to follow the same privacy rules that we follow and might use or share your child's identifiable information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your child's identifiable information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your child's identifiable information only when we must, and we ask anyone who receives it from us to take measures to protect your child's privacy. The sponsor has agreed that it will not contact you or your child without your permission and will not use or share your child's identifiable information for any mailing or marketing list. However, once your child's identifiable information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your child's identifiable information. Your permission to use and share your child's identifiable information does not expire.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your child's name or other identifiable information **will not** be used for these purposes without your specific permission.

Your Child's Privacy Rights

Partners HealthCare System Research Consent Form

Parent Template
Version Date: January 2019

Subject Identification

You have the right **not** to sign this form that allows us to use and share your child's identifiable information for research; however, if you don't sign it, your child can't take part in this research study.

You have the right to withdraw your permission for us to use or share your child's identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, your child cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your child's identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Parent(s)/Guardian for Child:

I give my consent for my child to take part in this research study and agree to allow his/her health information to be used and shared as described above.

Parent(s)/Guardian for Child

Date

Time (optional)

**Partners HealthCare System
Research Consent Form**

Parent Template
Version Date: January 2019

Subject Identification

Assent of Youth ages 14-17

Signature of Child:

I agree to take part in this research study and agree to allow my health information to be used and shared as described above.

Child, Ages 14-17

Date/Time

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the parent(s)/guardian and child.
- I have answered all questions about this research study to the best of my ability.

Study Doctor or Person Obtaining Consent

Date

Time (optional)

Consent Form Version Date: 3/2/2020